Study Title: Mind-Body Interventions for Chronic Pain in Veterans with PTSD

Principal Investigator: Erik Groessl, PhD

VA Facility: VA San Diego Healthcare System

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 is designed to learn more about the effectiveness of mind-body interventions including aspects of yoga and relaxation for VA patients with chronic pain and post-traumatic stress disorder (PTSD). The study will examine the feasibility of conducting a larger study of the same type and whether two different mind-body interventions reduce disability, pain, and PTSD symptoms. It is being funded by the Department of Veterans Affairs.

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

You will be asked to attend a screening appointment, and if enrolled, you will be asked to complete questionnaires about your health and attend one of two different mind-body interventions.
Your participation in this research will last about 6 to 9 months.

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. The investigator, however, may learn more about the possible benefits of mind-body interventions for Veterans with chronic pain and PTSD.

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

a. Possible loss of confidentiality when providing personal health information to researchers in the format of questionnaires.
b. There may be a slight risk of being injured or experiencing psychological discomfort while participating in the mind-body classes or when practicing these techniques at home as recommended.

A complete description of risks is included in the Research Details Study Risks section.
Participation is voluntary and the only alternative is to not participate. A complete description of alternate treatment/procedures is provided in the Research Details Alternatives section.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Erik Groessl 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 his contact information is: 858-642-6347 or erik.groessl@va.gov.

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RESEARCH DETAILS

WHO IS CONDUCTING THIS RESEARCH AND WHY?

Erik Groessl, PhD is asking for your consent to participate in this research. This study is being sponsored by VA Rehabilitation Research and Development.

The purpose of the research is research study to find out more about the effectiveness of mind-body interventions including aspects of yoga and relaxation for VA patients with chronic pain and post-traumatic stress disorder (PTSD). The study will examine the feasibility of conducting a larger study of the same type and whether two different mind-body interventions reduce disability, pain, and PTSD symptoms. You have been asked to participate because you are eligible for care as a VA patient, you have a diagnosis of chronic low back pain (cLBP) and/or chronic neck pain (cNP), and you have PTSD symptoms. There will be approximately 32 participants at this VA site.

FOR HOW LONG WILL I BE IN THE STUDY?

Your individual participation will take approximately 45 to 75 minutes each time you come to the VA San Diego Medical Center, and you will be expected to come to the hospital 3 times over a 6-month period to complete questionnaire packets and, to attend weekly mind-body intervention classes for 12 weeks. The classes will meet once per week for approximately 75 minutes. The entire study will take about 2 years.

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

If you agree to be in the study, the following will happen to you:

a. You will first be scheduled for a screening with research staff to determine study eligibility where you will be asked to provide informed consent and complete HIPAA authorization forms.
b. Once informed consent and HIPAA authorization are provided, the research staff will review information from your medical record to verify eligibility including PTSD diagnosis, other medical diagnoses including mental health, and alcohol and drug use history. Research staff will also conduct a medical history interview, and assess suicidality, presence of traumatic brain injury, and PTSD via the Clinician Administered PTSD Scale. The screening assessment can take 45-60 minutes to complete.
c. Once 16-18 VA patients express interest and meet inclusion criteria, you will be scheduled to complete the baseline assessment in a group setting at the VA San Diego Medical Center. The baseline assessment will consist of 7-8 questionnaires that take about 30-40 minutes to complete. The questionnaires ask about medical history, lifestyle behaviors, and various aspects of your physical and mental health.
d. You will be asked to complete questionnaires at two other time-points, occurring 12 weeks and again 18 weeks after the baseline assessment.

e. You will be randomly assigned to one of two arms of the study. The random assignment is generated by a computer program. You will be assigned a three-digit number (not associated with your personal health information) and the number will then be entered into a computer-generated randomization system which will assign you to either Arm 1 or 2 of the study. You will be informed after completion of your first questionnaire packet which arm of the study you have been randomized to. Arm 1 will include weekly classes on relaxation skills, techniques, and practice for 12 weeks. Arm 2 participants will attend a similar length program focused on mantram repetition with some yoga-based postures.
f. You may also be invited to participate in a qualitative interview at the end of the intervention period. The interview is designed to collect personal descriptions of barriers to attendance, aspects of the intervention or research project that you liked or disliked, and descriptive data on any benefits experienced. The interview will be audio-recorded and will last 30-45 minutes. The tape will be transcribed and deidentified to maintain confidentiality.
g. You will be encouraged, but not required, to work with your health care providers to reduce or avoid opioid pain medications when medically possible during the study.
h. All participants will continue to receive care as usual for other medical issues at VA.
i. We ask that you keep all treatments stable during the 12-week intervention period unless medically necessary to change.
j. Your data will be shared with University of California Health Services Research Center (UCSD-HSRC) for data processing services only. The data will be coded with a study ID number and no other identifying information. The data will be securely transported and protected.
k. If you participate in a qualitative interview, your data may be securely viewed and transcribed by a research service at VA Salt Lake City. Once transcribed, the data is coded with an ID number and has no other identifying information.

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

Although some mind-body interventions have been used elsewhere or in the VA in the past to treat persons with pain and/or PTSD, this research project is experimental. **All** activities pertaining to your participation in this study, such as consenting to participate, completing questionnaires, performing physical assessments, being videotaped, and participating in the yoga-based classes are research related.

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

Any procedure has possible risks and discomforts. The procedures used include the following risks:

a. Possible loss of confidentiality when providing personal health information to researchers in the format of questionnaires. The investigators believe that it is unlikely that confidentiality concerning personal medical information will be breached given the security plan.
b. There may be a slight risk of being injured or experiencing psychological discomfort while participating in the mind-body classes or practicing these techniques at home as recommended. Preventive measures will be taken to ensure your safety, such as the use of knowledgeable instructors, instruction manuals for home practice, and/or props for yoga poses.

c. Questionnaires: Some people become uncomfortable at being asked questions about their personal 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.

Photographs, audiotaping, or videotaping: The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize pictures and/or voice recording(s) to be made of you while you are participating in this study. The said picture, video, and/or voice recording is only intended for the evaluation of the intervention instructor and intervention content. Efforts are made to only capture the intervention instructor but it is possible that you may inadvertently move into the camera range or your voice could be recorded. The video and audio recording will only be used by research staff.

The study team has also explained that you will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being filmed, photographed or recorded, and may rescind your consent for up to a reasonable time before the picture, video or voice recording is used.

Inclusion of Women of Childbearing Potential:
The safe use of mind-body interventions in pregnant women and nursing mothers has not been established. Consequently, there may be risks to you (or to your embryo or fetus) if you are or may become pregnant that are unknown. Yoga could propose a potential risk to pregnant women. If you are currently pregnant, the study requires you obtain written permission from a physician in order to participate. The yoga being studied is of mild to moderate intensity and is designed to be safe for a wide range of conditions but is not specifically designed to be safe for pregnant women. The yoga will be conducted in the VASD Medical Center and yoga instructors and research staff will call emergency medical staff if ever needed.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There may or may not be a direct benefit to you from these procedures. The investigator, however, may learn more about the possible benefits of mind-body interventions for Veterans with chronic pain and PTSD.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

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

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

If you are injured while participating, the instructor will provide assistance and/or call other VA care services as required. You will receive care free of charge for any injuries resulting from practices related to this study. Home practice is encouraged in a very gradual and cautious manner and safety is always stressed. You will be asked to

use safety strategies when possible while practicing at home such as a) have a cell phone within reach during practice; b) reminding oneself that home practice should be more cautious than practice at instructor-led sessions; c) use props such as towels or blocks that can assist with safely performing poses.

If you are injured as a result of your participation in this research, please contact Dr. Erik Groessl at 858-642-6347 during the day or contact the VA directly at (858) 552-8585 after 5:00 PM.

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 are a VA employee or a student or in training at the VA, your refusal to participate will in no way influence your status or evaluations as a student or an employee. You are free to refuse participation or to end participation at any time with no consequences.

There are no consequences for withdrawing from the research. Data collected prior to withdrawal may be used for research purposes but no further information can be collected, except from public records, such as survival data.

If you decide that you no longer wish to participate in this study please call Dr. Erik Groessl the primary study investigator at 858-642-6347, or Rahil Hernandez, the study coordinator at 858-552-8585 ext. 6519.

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.

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

Your participation in this study may be stopped if the investigator decides that stopping is in your best interest.

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 the Principal Investigator.

Medical care and services provided by the VA that are not part of this study (e.g., normal hospital and prescription expenses which are not part of the research study) may require co-payments if your VA-eligibility category requires co-payment for VA services.

You or your insurance company will be charged for any procedure or test that is medically necessary for the treatment of your illness. You will be responsible for all insurance co-payments and deductibles.
You must pay for your own transportation to study assessments or intervention sessions.

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

You will receive compensation for your time completing the research questionnaires and for yoga class attendance. You will receive a cash incentive of $40 for completing the baseline assessment, and $40 for completing each of the 12-week and 18-week follow up assessments. You can receive an additional $40 if you participate in an additional interview after the intervention. You will be paid after each assessment is completed. Payments typically take 2-4 weeks.

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 Dr. Erik Groessl at (858) 642-6347 or Rahil Hernandez at 858-552-8585 x 6519.

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.

FUTURE USE OF DATA AND RE-CONTACT

Dr. Groessl or his research team may wish to re-contact you for future research in this area.
Do we have permission to contact you by phone and or mail in the future for research purposes?

☐ **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 INFORMATION BE PROTECTED?

Participation in this study may involve a loss of privacy, but information about you will be handled as confidentially as possible. Any presentations or publications from this information will not identify you.

We will collect your SSN for CPRS notes and medical record review, payment for study participation and participant tracking purposes (phone calls and assessment appointment setting). Your research records will be

labeled with a code number. The list that matches your name with the code number will be stored electronically behind the VA secure network. Any research records that identify you will be kept only as paper records in a secure VASDHS location, or as electronic files behind the secure VASDHS computer firewall.

We will keep confidential all research and medical records that identify you to the extent allowed by law. The research team may share health information collected for this study with UCSD or another VA research service only for the purposes of data processing. They will not retain or use the data in any other way. 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 VASDHS R&D Committee, the VASDHS Institutional Review Board, the Office of Human Research Protections (OHRP), and the Government Accountability Office (GAO), and federal compliance officers may look at or copy portions of records that identify you.

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.

While this study is being conducted, you will not 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.

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.

Rahil Hernandez or other study staff have 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.
I agree to participate in this research study as has been explained in this document.

_____ _____

Participant's Signature Date

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_____	_____	_____
Signature of Researcher obtaining consent	Name (print)	Date

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

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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 medical history, allergies, lab results, drug abuse, alcoholism or alcohol abuse, mental health treatment, etc.

We will keep confidential all research and medical records that identify you to the extent allowed by law. The research team may share your health information collected for this study with UCSD or another VA research service only for the purposes of data processing. They will not retain or use the data in any other way. 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 VASDHS R&D Committee, the VASDHS Institutional Review Board, the Office of Human Research Protections (OHRP), and the Government Accountability Office (GAO), and federal compliance officers may look at or copy portions of records that identify you.

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. Erik Groessl, 3350 La Jolla Village Dr. San Diego, CA 92161.

If you revoke this authorization, Dr. Groessl 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.

While this study is being conducted you will not 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 *Select as applicable:* Expire at the end of this research study.

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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.

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

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

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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.