Participant Name:	**Date:**
Title of Study: Rage Against the Pain: An Alternative Yoga Program to Address Chronic Low Back Pain Among Veterans	
Principal Investigator: Bella Etingen, PhD	

SUMMARY

This research is being conducted to develop and test an alternative strategy for pain management for Veterans with chronic low back pain.

If you agree to join the study, you will be randomly assigned to one of the two interventions: Rage Against the Pain High Intensity Stretching or Hatha Yoga. Classes for both will be held once per week for about 60 minutes with participation in the study lasting a total of 12 weeks. The overall study will be 1 year long.

You will also be asked to complete the following research procedures:

- Pre-Program Participation Survey, which will be mailed to you within one week prior to the beginning of the class (you also be given the opportunity to complete the survey over the phone or in person with research staff). Once you complete the survey, you will receive $25.00 in appreciation of your time.
- Practice Log, which you will fill out each time you practice in class.
- Post-Program Participation Survey, which will be mailed to you within one week after the 12-week program ends (you also be given the opportunity to complete the survey over the phone or in person with research staff). Once you complete the survey, you will receive $25.00 in appreciation of your time.
- We will also ask a sub-sample of Veterans to participate in a brief (~30 minute) audio-recorded telephone interview. If you complete an interview, you will receive $30 in appreciation of your time.

Participants may directly benefit as a result of this study. The results of this study may provide a Veteran-centered program that the VA can offer to Veterans with chronic pain who may not find other available pain management options to be appealing or effective. The potential benefits of this study should greatly exceed the risk to individual subjects.

Individuals involved in any aspect of this study will be subject to minimal risk through their participation. The most common risks of participation are injuries related to program participation; we have come up with a detailed safety plan that is built-in to the study to minimize the potential for these risks.

Your participation in this study is voluntary. You may refuse to answer questions or withdraw from the study at any time. The alternative to the intervention that we will be studying in this project is usual care.

Please note that there are other factors to consider before agreeing to participate, such as additional procedures, use of your personal information, costs, and other possible risks not included here. If you are interested in participating, a member of the study team will review the full information with you. You are free to not participate or stop participating at any time during or after the consenting process.

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INTRODUCTION

You are being invited to participate in a research study that is being carried out at the Edward Hines Jr. VA Hospital. Your participation is voluntary and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. 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. If you have any questions about your rights as a human research participant at any time before, during, or after participation, please contact the Institutional Review Board (IRB) at (708) 202-2811 for assistance. If you have questions about this study, you may contact the Principal Investigator, Dr. Bella Etingen at (708) 202-4922.

Read the information below closely, and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

BACKGROUND AND PURPOSE

Chronic low back pain is a leading cause of disability among adults. It is also a significant problem within the Veteran population, and is the most commonly reported location for chronic pain for Veterans. Research indicates that chronic low back pain can cause a wide range of negative physical and mental health-related outcomes as well as increased use of healthcare services and healthcare related costs.

Research indicates that non-medication based pain management strategies are effective and recommended for Veterans who experience chronic low back pain, however, the use of these strategies is low. This research project is designed to evaluate and test an alternative pain management program for Veterans who experience chronic low back pain. Approximately 40 participants will be enrolled into the study from Edward Hines VA Hospital.

DURATION OF THE RESEARCH

Your participation in this study is expected to take approximately (but likely just over) 12 weeks. The overall study will be 1 year long.

STUDY PROCEDURES

If you decide to take part in this study, you will be randomized to receive one of two interventions (Rage Against the Pain High Intensity Stretching or Hatha Yoga) using a random number generator. Both programs will consist of meeting weekly on the Hines VA Campus for approximately 60 minutes a week for 12 weeks. The classes will be led by recreation therapists at Hines VA, both of whom have extensive experience working with Veterans who experience chronic pain.

Participating in the interventions will entail following along with the poses and corresponding breath work (e.g., suggestions for when to inhale and exhale with the movement) being cued by the instructor. During

the classes, you will be cued about options for how to modify poses, including options to modify poses using a chair or the wall; if you are unable to do a modified version of any pose you will be instructed to take child's pose or rest in a chair, against the wall or on the floor during that pose. When the set of movements for each class has been run through, the class will engage in a culminating activity wherein you will be instructed to lay on the floor with your eyes closed to relax.

The Hatha Yoga classes will be conducted in the style of the yoga classes currently being offered to Veterans at the Hines VA Hospital, which is a traditional form of yoga practice that offers chair modifications available to all Veterans who choose/need to use them. At the end of each class, you will be guided through a meditation/relaxation exercise.

The Rage Against the Pain High Intensity Stretching program will also involve following cues to a number of stretching movements and poses cued by the instructor (with modifications available), but will be set to rock/heavy metal music and will not incorporate meditation. At the end of each class, you will be guided through a structured 'cool down' exercise.

Each participant enrolled in the study will be asked to complete a pre- and post- program survey, and a practice log.

- You will be mailed the pre-participation survey and will be asked to complete it one week prior to the beginning of class. You will be given the option of completing the post-participation surveys and returning it by mail with the prepaid addressed envelopes supplied or completing surveys over the phone or in person with a member of the study team.
- Approximately one week after the end of the 12-week program you will be mailed the post-participation survey. You will be given the option of completing the post-participation survey and returning it by mail with the prepaid addressed envelopes supplied or completing it over the phone or in person with a member of the study team.
- Surveys will include questions related to your back pain, physical function, sleep quality, mood, stress, and overall health.
- When you return the pre or post survey, you will receive $25.00 in appreciation of your time, so if you return both surveys, you will receive $50.00 total.
- You will also receive a practice log, which you will be asked to fill out each time you practice in class.

We will also invite:

- A sub-set of Veterans to participate in a brief (~30 minute) audio-recorded telephone interview. If you complete an interview, you will receive $30 in appreciation of your time. With your permission, interviews will be audio-recorded so that we can transcribe them word-for-word before doing analyses to make sure we accurately capture everything you say. We will combine your responses with those of other Veterans who complete the interview for reporting purposes without identifying participants.
- Please tell the study principal investigator or research staff if you change your mind about staying in the study at any point.

All procedures are being done solely for research purposes.

POSSIBLE RISKS OR DISCOMFORTS

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed: participating in the Rage Against the Pain High Intensity Stretching or Hatha Yoga classes may cause muscle soreness, pain, fatigue, injury, and/or emotional discomfort; participating surveys/semi-structured interviews may lead to discomfort with answering certain questions (please know that you do not have to answer any question(s) that make you feel uncomfortable). The recreation therapists running the intervention classes are trained and will make sure the class activities can be modified to make sure everyone can participate safely. You will be encouraged to participate at your own ability and not push past your limits. Our instructors are seasoned VA recreation therapists and have experience with working with Veterans who experience pain.

There is also a small risk of breach of confidentiality. We will take every possible step to protect the privacy of the study information you provide, such as using a study ID rather than your name for all data collection (surveys and interviews) and making sure research data are secure and computer files are password protected.

Risks of the usual care you receive are not risks of the research. 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. Participation in research may involve a loss of privacy. Your research records will be kept as confidential as possible.

POTENTIAL BENEFITS

While there is no guarantee of benefits to participation, participants may directly benefit as a result of this study. The results of this study may provide a Veteran-centered program that the VA can offer to Veterans with chronic pain who may not find other available pain management options to be appealing or effective. The potential benefits of this study should greatly exceed the risk to individual subjects. In addition, the information we get from this study might help us treat future patients.

CONFIDENTIALITY

Taking part in this study will involve collecting private information about you. Full measures will be taken to ensure the confidentiality of your identity as well as the confidentiality of all collected data.

Information About You is Protected in the Following Ways. All information about you that is gathered during the research, including audio recordings, will be coded without the use of personally identifiable information. All research information will be kept in locked files at all times. 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. Federal Agencies such as the Office for Human Research Protection (OHRP), Government Accountability Office (GAO) and Food and Drug Administration (FDA) may have access to the records. The Department of Veterans Affairs (VA) requires some information to be recorded in the VA electronic medical record for all 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.

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. Your research records will be kept indefinitely or until the law allows their destruction in with VA Records.

The information collected for this study will be kept confidential. It will not be used or distributed for future research studies or to other research investigators.

This informed consent form does not give the study doctor permission to access, record, and use your private health information. You will be given a separate HIPAA form which provides more information about how your private health information will be used in this study, who will have access to your records, and how you can revoke (take back) your permission in the future. You will not be able to participate in this study if you do not sign the separate HIPAA authorization form.

COSTS TO PARTICIPANTS AND PAYMENT

Costs to Participants*:* A veteran subject will not be required to pay for medical care and services received as a subject in an approved VA research study. Some veterans are required to pay a co-payment for the care they receive. These requirements will continue to apply to medical care and services provided by the VA that are not part of this research study.

Payment Offered for Participation: Payments will be provided through a voucher that can be redeemed for cash at the Agent Cashier or by direct deposit.

- You will receive $25 for each survey that you complete and return for this study (up to $50 total if you return both surveys).
- If you are asked to participate in an interview, you will receive $30 upon completion of that interview.
- If you return both surveys and complete an interview, you may receive up to $80 total throughout your participation in this study. These payments will not be pro-rated if you withdraw from the study or if your participation is terminated before the study is over.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

According to federal regulations (Title 38 CFR17.85), the VA will provide necessary medical treatment to you as a research participant if you are injured by participation in this research project approved by the Research & Development Committee and conducted under the supervision of one or more VA employees. Except in limited circumstances, this care will be provided at this VA facility. If you experience injuries from your participation in this research project, we will either (1) get your permission to contact your Hines primary care provider and suggest that they follow up with you, or (2) escort you to the Hines Emergency Department, contact the Hines rapid response team (if you are within the area of their purview), or call 911.

This does not apply to treatment for injuries that result from non-compliance by you with study procedures.

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:

Dr. Bella Etingen at (708) 202-4922 or Ms. Felicia Bixler at (708) 202-8387 x23377.

AFTER HOURS:

Please call 911 for medical emergencies. Emergency and ongoing medical treatment will be provided as needed. You may also contact the crisis line at 1-800-273-8255 and Press 1 or chat online to receive confidential support 24 hours a day, 7 days a week, 365 days a year.

Emergency and ongoing medical treatment will be provided as needed. This does not apply to treatment for injuries that result from non-compliance by you with study procedures.

PARTICIPATION IS VOLUNTARY

It is up to you to decide whether or not to take part in this study. If you do decide to take part in the study, you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctors or other staff, and it will not affect the usual care that you receive as a patient.

If you withdraw from this study, we ask that you contact the research team so an orderly termination of participation can be conducted. To withdraw, please contact us by phone, tell us at the last Rage Against the Pain High Intensity Stretching or Hatha Yoga class you choose to attend, or write us a letter to let us know. Data already collected prior to your withdrawal can still be reviewed and used by the investigators. We will not be doing follow-up care with individuals who choose to withdraw from the study.

While we do not anticipate any, if there are significant new findings developed during the course of the research which may relate to your willingness to continue participation, they will be provided to you in a timely manner.

RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION

The investigator has the right to terminate your participation, without regard to your wishes, in the research study if:

- You become uncooperative or unwilling to complete study-related tasks
- You are experiencing undue stress from the study procedures
- You are experiencing undue physical strain from the study procedures (e.g., the exertion required is too great for you, participation is causing you excessive pain, etc.)

- You have substance abuse, mental health, and/or medical problems that interfere with completion of the study-related tasks
- You behave inappropriately in a session or while completing a study-related task
- The study is stopped by the sponsor, which is the VA Office of Research Development

ADDITIONAL CONTACT INFORMATION

If at any time before, during or after your participation in this study you have questions or concerns, want to get additional information, lodge a complaint or offer your input with a person who is not part of the study team, you can contact the Hines VA IRB Administrator at 708-202-2811.

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. 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.

_____ / /
Signature of Participant Date Written by Participant