CEDARS-SINAI MEDICAL CENTER

CONSENT FORM FOR RESEARCH

TITLE: Development and Validation of a Digital Pain Reduction Kit for Musculoskeletal Injuries

SPONSOR: TRAVELERS INSURANCE

BRENNAN SPIEGEL, MD **PRINCIPAL INVESTIGATOR**

STUDY CONTACT PHONE NUMBER AT CSMC: (310) 423-5434

AFTER HOURS CONTACT (24 HOURS): (248) 383-5346

This research study is sponsored by Travelers Insurance. Travelers Insurance only reimburses Cedars-Sinai Medical Center for the costs associated with running the study; Travelers Insurance is not providing additional compensation to Cedars-Sinai Medical Center or the Principal Investigator for their participation in the study.

1. WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

We are doing this study to test a set of tools, including audiovisual experiences, an over-the-counter pain relief device, and remote clinical monitoring on patients with pain from musculoskeletal injuries. We want to know if the use of these combined tools can improve a participant's ability to perform everyday tasks, reduce the amount of time missed from work, limit the extent to which pain interferes with a participant's life, and improve their overall health.

You are being asked to take part in this research study because you meet our inclusion criteria of being an outpatient at Cedars-Sinai Medical Center (CSMC) or Medical College of Wisconsin (MCW) with pain from a musculoskeletal injury. Additionally, you own an Android or iOS smartphone device.

In this study, there are two different study groups. If you are assigned to the "normal control group", it means that you have the condition that is being studied, but will be randomly assigned to receive standard of care treatment for patients with your condition, an ALEVE Direct Therapy TENS device. The study needs a control group that will be compared to people who are receiving the intervention. See Section 2 below for more information.

The study will enroll up to 245 people in total.

This research study is designed to test the investigational use of the ALEVE Direct Therapy TENS device. This device has been cleared for marketing, sale and use by the U.S. Food and Drug Administration (FDA) for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities, based on its similarity in structure and function to previously used devices. If you have lower back pain, you will be asked to use the TENS device as needed.

Additionally, this research study is designed to use the Oculus Go and PICO G2 Headsets. The VR headsets can be purchased in stores, are not currently regulated by the FDA, and pose minimal to no risks to individuals.

2. WHAT WILL HAPPEN DURING THE STUDY?

This section provides a general overview of what will happen during your participation in this study.

At the start of the study, a startup survey email will be sent or the applicable mobile applications will be installed on your phone in order to monitor your activity and assign you questionnaires. You will be trained on how to use these apps, along with training on how to use the TENS unit (if necessary) and the VR device.

Overview of study:
This is a randomized research study.

- "**Randomized**" means that you will be assigned to a study group by chance, like flipping a coin. You will be randomized into one of two study groups, and will have an equal chance of being placed in one of the two groups described below.

If you are assigned to the control group, you will be followed as you receive the care generally followed for individuals with your condition, a transcutaneous nerve stimulation unit (TENS) for pain relief. You will be asked to answer questions periodically on your email, Android, or iOS smartphone device about your pain. Standard (routine) care will involve treatment as prescribed by your provider for your pain condition.

If you are assigned to the study group, you will be provided with a digital pain reduction kit, consisting of a virtual reality headset and a transcutaneous nerve stimulation unit (TENS) for pain relief You will be asked to use the VR unit for no more than 15 minutes at least three times a day and as needed during moments of pain, use the TENS unit as directed, and answer questions periodically on your email, Android, or iOS smartphone device about your pain and use of devices.

The VR unit survey emails, and the app we install on your smartphone will collect data and periodically upload data to secure, encrypted servers at Cedars-Sinai.

You will be asked to keep your smartphone on your person and answer surveys as they are prompted. We will also ask you to keep VR and TENS units with you whenever possible. In the event that any of the study devices are lost or damaged, you will not be held responsible for the lost or damaged study devices.

If you encounter issues using the smartphone app, the study team will be able to issue questionnaires and other materials through different means, including an online survey instrument. Make sure to tell someone on the study team if you are having trouble with any of the devices.

Optional Sub-study
Details of an optional sub-study for subjects assigned to the study group are described in a separate consent form. You are not required to participate in the sub-study in order to take part in this research study.

How long will you be in the study?
We think you will be in this study for about 60 days. After that, we would like you to visit the office/clinic for a single follow-up exit survey and to return equipment.

3. WHAT ARE THE POSSIBLE RISKS?

This section describes the possible risks and/or discomforts we anticipate you could experience that are related to the study procedures:

ALEVE Direct Therapy TENS:
While ALEVE Direct Therapy is safe when used as directed, it is possible that you may react to the TENS gel or the electrical current with skin irritation, muscle twitching, or muscle soreness.

VR Intervention:
While using the VR unit, you may experience discomfort with the virtual environment, including temporary headache, vertigo, or nausea.

Questionnaires:
It is possible that some of the items in the questionnaires may make you feel uncomfortable or embarrassed. You are not required to respond to any item that you do not wish to answer. The questionnaires will be labeled with a unique study number that will link your identity so that only the research team can recognize you.

There are no anticipated long-term risks from participating in this study.

Follow-up Visit for Discontinuing Participants
While you are free to discontinue your participation at any time, we encourage you to complete a Final Study Visit. During this visit, we will conduct tests to collect safety data, and discuss any information that may be important to share with your treating physician.

4. ARE THERE BENEFITS IN TAKING PART IN THE STUDY?

If you agree to take part in this research study, there may or may not be direct medical benefit to you if you are assigned to the study group. The possible benefits of taking part in the research study are pain-relief, improved functionality, greater satisfaction with care, reduced absenteeism at work, and overall improvements in physical and mental health. However, no benefit is guaranteed. It is possible that your condition may remain unchanged or even get worse.

If you are assigned to the control group, you will continue to receive standard of care treatment from your physician and may receive some pain-relief benefit from participation in the study. However, no benefit is guaranteed and your participation will advance scientific knowledge by providing a comparison group to determine if the intervention is effective.

We hope the information learned from this research study will benefit other individuals with pain in the future by helping us to learn how we can reduce pain and improve functionality, while minimizing the use of opioids.

5. WHY WOULD MY PARTICIPATION BE STOPPED?

Your participation in this study may be stopped at any time by the researcher or the sponsor without your consent for any reason, including:

- The study is stopped or suspended;
- Funding for the study is reduced, stopped or withdrawn;
- If it is in your best interest;
- You do not consent to continue in the study after being told of changes in the research that may affect you;
- You do not follow the study procedures.

You may choose (or you may be required) to withdraw from certain parts of the study, but invited to continue with other parts. For example, you might stop using the audiovisual experience, but continue using the pain-relief unit or allowing us to monitor your biometric data. Separate written consent will be requested if your continued participation will involve procedures not described in this consent form.

6. ARE THERE ANY OTHER OPTIONS?

Your participation is voluntary so you have the right to decline to participate or to withdraw from this research study at any time without any penalty or loss of benefits to which you would be entitled outside of the study. Choosing not to participate will not affect the care you receive at Cedars-Sinai Health System or MCW.

7. WILL MY INFORMATION BE KEPT CONFIDENTIAL?

We will do our best to make sure that the personal information collected as part of this study is kept private. However, we cannot guarantee total privacy. A copy of your research consent and authorization forms may be filed in your electronic medical record at CSMC or MCW. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other identifiable personal information will not be used. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include: accrediting agencies, government and regulatory groups (such as Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), etc.), safety monitors, companies that sponsor the study, and authorized representatives of the sponsor.

You may, depending on the circumstances of the study and applicable law, be asked to sign a separate "Authorization Form" that outlines with whom your information may be shared for the purposes of this research and under what circumstances.

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.

8. WHAT IF I BECOME ILL OR INJURED BECAUSE OF TAKING PART IN THIS STUDY?

You will not be in danger of any illness or injury from this research study. However, should you believe that you are ill or have been injured as a result of your participation, please contact the study team at the phone number listed on page 1 of this consent form.

9. FINANCIAL CONSIDERATIONS

Costs of Participation
You and your insurance company will not be charged for your participation in this research study. The Sponsor will cover the cost of all items, drugs and services required by this study, including any procedures required by the study that may be standard of care.

Compensation for Participating
You will not be paid for taking part in this research study; however, you will get to keep your Bayer Aleve TENS unit and associated accessories (e.g., gel pads).

Financial Interest in the Research
The PI and institution have no potential financial conflict of interest with respect to this study.

10. WHAT IF I HAVE QUESTIONS OR PROBLEMS?

Please contact one of the investigators listed on the first page of this form for questions or concerns about the research.

If you have questions, problems, or concerns that you want to discuss with someone who is not associated with this study, or want to offer suggestions or feedback, please contact:

Cedars-Sinai Human Research Protection Program (HRPP)
Phone: (310) 423-3783
Email: ResearchConcerns@cshs.org

The Cedars-Sinai HRPP has been established to protect the rights and welfare of research participants. You may also contact the Cedars-Sinai HRPP if you want to offer input or obtain information regarding the study.

11. CONSENT PROVISIONS

If you sign this form below, it means that:

(1) You have taken the time to carefully read and understand the information presented in this informed consent form; you should discuss it with others, and if appropriate seek a second opinion to make an informed decision;
(2) The information concerning the research study and its involved procedures has been fully explained to you and your questions have been answered to your satisfaction;
(3) You have received and understand all of the information you desire regarding your participation in the research study;
(4) You have considered the potential risks, any anticipated benefits and alternatives (and their relative risks and benefits) of participation;
(5) You are voluntarily agreeing to participate in this research study;
(6) You understand that by consenting to participate in the research, you are not giving up any of your legal rights;
(7) You understand that you have the right to be informed of significant new findings related to this research study which may affect your willingness to continue participating in this study; and

(8) You have been provided with a copy of the "Experimental Subject's Bill of Rights", if applicable to this research study, and have been provided with an opportunity to ask questions regarding the Bill of Rights.

We will give you a copy of this signed and dated consent form and a copy of the Experimental Subject's Bill of Rights.

SIGNATURE BY THE PARTICIPANT:

_____	_____	_____
Name of Participant (Print)	Signature of Participant	Date of Signature

SIGNATURE BY THE INVESTIGATOR:

I have personally explained the research to the participant in non-technical terms, answered all questions, and attest that he/she freely consents to participate. The participant has been provided with the Experimental Subject's Bill of Rights.

_____	_____
Signature of the Investigator Who Obtained Consent	Date of Signature

CEDARS-SINAI MEDICAL CENTER

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

In accordance with California Health and Safety Code 24172, any person who is required to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks to the subject reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.