ATRIUM HEALTH
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Transcutaneous Electrical Nerve Stimulation (TENS) for Pain Alleviation in Perioperative Fracture Patients

INTRODUCTION

Dr. Hsu and his colleagues are asking you to participate in this research study of transcutaneous electrical nerve stimulation (TENS) at the Atrium Health Musculoskeletal Institute. TENS is non-invasive device that uses electric current to stimulate the nerves to relieve pain sensations. The TENS unit utilizes electrodes placed on the skin and which connect to the unit via wires to block pain transmission. You are being invited to participate in this research study because you are 18 years or older and have an injury to your lower extremity. The purpose of this study is to determine the effectiveness of TENS as part of the after-surgery pain management care. You will be one of fifty participants in this study and your participation will last for three months from your surgery.

SUBJECT RESPONSIBILITIES/EXPECTATIONS

If you agree to be in this study, you will be followed for 3 months from the date of your surgery. The following activities will occur during this period:

Before surgery:

1. We will conduct an interview with you. The interview will include questions about your health-related quality of life, pain level and pain interference. The interview will take about 15 minutes to complete.
2. We will also collect information about your injury, fracture treatment, pain, and pain management treatment. This information will be entered into a secure research database

End of surgery:

1. Prior to leaving the operating room, your surgeon will place the TENS pads to your skin. The TENS unit will be connected to the pads and turned on in the recovery room. You will be given instructions for suggested use of the device. You will be allowed to change the frequency/amplitude of the current to your desired needs.

Follow-up visits (2, 6 & 12 weeks):

1. When you leave the hospital, you will complete study visits at 2, 6, and 12 weeks after surgery. These visits may be complete completed via phone calls, test messages, or emails. They may overlap with regularly scheduled stand of care clinic visits. During these visits you will be asked to complete the following tasks:
    a. The interview will include questions about your health-related quality of life, pain level, pain interference and any pain management modalities since last study visit. The interview will take about 15 minutes to complete.

Affix Participant Barcode Label Here

RISKS

In very rare cases patients using the TENS device have experienced allergic reaction such as skin redness and irritation. Some people have complained about feeling the buzzing, tingling or prickly sensation, which may be uncomfortable.

Any time information is collected for a study; there is a small risk of breach of confidentiality. As described below, your research data will be identified by a unique study number rather than your name and all measures allowed by law to protect your confidentiality will be taken by the research staff.

Some of the questions asked as part of this study may make you feel uncomfortable, like questions asking about your mood or your level of anxiety. You may refuse to answer any of the questions, take a break or stop participation in the study at any time.

EXCLUSION CRITERIA

- You are pregnant

ADDITIONAL COST

There are no additional costs for taking part in this research study above the reasonable and customary costs of caring for patients with injuries like yours who are not in the study. The cost of the TENS unit will be provided to you at no cost.

COMPENSATION

In the event that you are harmed as a result of your participation in this study, we will provide or arrange for treatment as necessary. This treatment, as well as other medical expenses, will be billed to you or your insurance company in the usual manner.

WITHDRAWAL

Your participation in this study is completely voluntary. You should feel not feel pressured to be a part of this study. If you decide not to be in the study, this will not harm your relations with your doctors or with Atrium Health. You are free to stop being in the study if you change your mind after entering it. This would not harm your relations with your doctors or Atrium Health.

We will tell you about new medical findings that may affect your willingness to continue in the study.

CONFIDENTIALITY

The records of this study will be kept private. If any report about this research is published, we will not include any information that will make it possible to identify you. However, there is some risk that de-identified data might be re-identified. Also, your record for this study may be reviewed and/or

Affix Participant Barcode Label Here

photocopied by Atrium Health, or by representatives of the Food and Drug Administration or other government agencies.

I authorize Atrium Health and its representatives (including third-party agents if applicable) to contact me by text at the number I provided. I understand that I am responsible for the standard text message rate of my carrier. Texting is not to be used for emergency situations.

By providing my email address, I give permission for Atrium Health and its representative (including third-party agents if applicable) to send me information, reminders, and messages using this means of communication. I authorize Atrium Health to send me unencrypted messages using this means of communication, and I understand and accept the risks associated with doing so. Email is not to be used for emergency situations.

AUTHORIZATION TO USE AND DISCLOSE YOUR PROTECTED HEALTH INFORMATION

If you wish to participate in this research study, you must sign this Authorization. By signing this Authorization, you _____ **(Print name)** give all healthcare providers, including Atrium Health, permission to use or disclose (release) your protected health information, both past and present, for the research study described here:

Transcutaneous Electrical Nerve Stimulation (TENS) for Pain Alleviation in Perioperative Fracture Patients

The protected health information that we may use or disclose (release) for this research may include all information in your medical record, such as results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition.

The health information listed above may be used by and/or disclosed (released) to:

- Study investigator and research staff
- Regulatory or other governmental authorities of the United States or other countries based on this study
- Atrium Health employees
- Other persons or agencies as required by law or allowed by federal regulations
- Institutional Review Boards or Data Safety and Monitoring Boards.

Atrium Health is required by law to protect your protected health information. By signing this Authorization, you authorize Atrium Health to use and/or disclose (release) your protected health

information for this research study. Those persons who receive your protected health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your protected health information with others without your permission, if permitted by laws governing them. Your protected health information may then no longer be protected by the Privacy Rule.

Please note that you do not have to sign this Authorization, but if you do not, you may not receive research-related treatment through this study. However, Atrium Health may not condition (withhold or refuse) your other Atrium Health providers treating you on whether you sign this Authorization. You may change your mind and withdraw (take back) this Authorization at any time, except to the extent that Atrium Health or the Sponsor has already used or disclosed your protected health information based on this Authorization. To withdraw this Authorization, you must write to: [Joseph Hsu, MD, 1025 Morehead Medical Plaza, Drive, Charlotte, NC 28204, 704-355-2000, 704-355-8708.

No publication or public presentation about the research described above will reveal your identity without another Authorization from you. If all protected health information that does or can identify you is removed, the remaining information will no longer be subject to this Authorization or federal rules (such as the Privacy Rule) and may be used or disclosed for other purposes.

When the research for which the use or disclosure is made involves treatment and is conducted by Atrium Health: To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete.

At the conclusion of the research study and at your request, you generally will have access to your protected health information. Access to your protected health information in a medical record is described in the Notice of Privacy Practices provided to you by Atrium Health.

When conducting research, the data and results may be used or disclosed for further treatment outcomes research or to research a secondary result. This Authorization will remain in effect after the end of the current study, and any future related secondary study unless it is revoked by the you in writing as described above.

_____
Signature of participant

_____
Printed name of participant

_____
Date

* 9 3 3 *

Affix Participant Barcode Label Here

FINANCIAL INTEREST OF INVESTIGATOR

The study doctors will receive no financial benefit in any form by asking you to participate in this study.

QUESTIONS

The researchers doing the study at Atrium Health are Drs. Hsu, Seymour, Odum, Ransone, Shing, Meghan Wally and Christine Churchill. You may ask them any questions you have now. If you have questions later, you may contact Dr. Joseph Hsu at:

Department of Orthopaedic Surgery
Atrium Health
1000 Blythe Boulevard
Charlotte, NC 28203
Telephone (704)355-2000

The Institutional Review Board is a group of people who review the research to protect your rights. If you have questions about the conduct of this study or about your rights as a research subject, you may call the chairperson of the Institutional Review Board of Atrium Health for information regarding patients' rights in a research study. You can obtain the name and number of this person by calling (704) 355-3158 or by email at: IRBInfo@atriumhealth.org

(This space intentionally left blank.)

Affix Participant Barcode Label Here

CONSENT

I have read the above information. I have asked any questions I had, and those questions have been answered. I agree to be in this study and authorize the use of my personal health information. I will receive a signed copy of this form.

_____
Print Name

_____ _____
Patient Signature Date

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

Affix Participant Barcode Label Here