Department of Veterans Affairs

VA RESEARCH CONSENT FORM

Subject Name: _____ **Date:**_____

ICF Template version: 3/8/2016

Title of Research Study: Effect of Postoperative Percutaneous Peripheral Nerve Stimulation on Acute and Chronic Amputation Pain
Sponsor: Hunter Holmes Pilot Grant Award,
Protocol No: none
Investigator Name and Address: Dr Denise Lester, 1201 Broad Rock Blvd, Richmond VA, 23249

1. Whom should I contact for questions? (Contacts)
If you have any questions, concerns or complaints regarding this study, unexpected reactions, or you are injured and become ill because of participation in this study please call AM or PM:

	Office	Off Hours
Dr Denise Lester	**(804) 675-5188**	**(pager) 359-9954**
Dr Brooke Trainer	**(804) 675-5000 ext. 2289**	**(pager) 351-2105**
Dr Robert Trainer	**(804) 675-5000 ext. 3244**	**(pager) 351-2726**
Dr Erik Baker	**(804) 675-5234**	**(pager) 351-2126**
Dr Doug Murphy	**(804) 675-5000 ext. 3620**	
Dr Thomas Phan	**(804) 675-5188**	**828-0951 (pager) 1310**

If you are unable to reach any of the study staff listed and need immediate medical assistance, please call the VAMC hospital operator at 800-784-8381 and ask for the Emergency Room physician to obtain advice, or call the **Emergency Room directly at (804)-675-5527**. If you have any questions, concerns or complaints about your rights as a research subject you may contact the **McGuire Institutional Review Board (IRB) at (804) 675-5676.** The IRB is responsible for reviewing research in humans and making sure that their safety and rights are protected.

2. What is this research study about? (Introduction)
You are being asked to take part in this research study because you have had, or are scheduled to have an amputation surgery of your leg. Subjects that undergo leg amputation often develop chronic pain known as phantom limb pain. The purpose of this research study is to evaluate if an electrical nerve stimulator placed below the skin

MIRB APPROVED
6/20/18

for 30 to 60 days will reduce your pain after surgery. The study is expected to last up to 12 months. We aim to enroll 16 subjects.

3. What is expected of me? (Procedures)
Your chart was screened and reviewed by the investigators to ensure that you meet all the necessary criteria for participation in the study. After you agree to participate, you will be randomly (by chance, like flipping a coin) assigned to one of two groups There is an equal chance of being assigned to either group. Your "Group" assignment will determine the treatment(s) you will receive as a part of the study. The difference between the groups are as follows:

Group A) Standard Medical Therapy plus 30 to 60 days of electrical nerve stimulation starting 2 to 7 days after your surgery

Group B) Standard Medical Therapy only

Standard Medical Therapy (SMT) is the same health care given to all patients. This may include but is not limited to:

1) Pain medications
2) Numbing medications given through a tube placed around your nerves
3) Daily visits by the Acute Pain Service (APS) after surgery, and
4) Follow up visits in the Chronic Pain Clinic (CPC)

Group A:
Subjects in Group A will be transported to the Chronic Pain Clinic 2 to 7 days after surgery to undergo placement of the nerve stimulator device. The procedure takes 1 to 2 hours. Before the procedure, a Functional Independence Measure (FIM) evaluation will be done. Meaning a physical therapist will measure your ability to get up from a chair, walk, and use a wheelchair. Once you have been properly positioned on the procedure table (lying on your back or on your side), a physician will locate a major nerve in your upper thigh using an ultrasound machine. Once the nerve is located, your skin is cleaned and numbing medication is given. A thin needle will be inserted into your skin until it is near the target nerve. Electrical stimulation will be delivered through the tip of the needle to confirm the appropriate location. You may experience a tingling sensation but should not experience pain. The medical staff will be asking you questions about these sensations to assist them in finding an acceptable location. Once found, the needle will be removed but a thin wire will be left behind and will remain under the skin during the treatment period (30 to 60 days). The wire is connected to a small device (approximately 2 in. x 1.5 in.) which will be taped to your upper leg. The small device can be removed during the treatment period (for showering or between therapy sessions) but the wire should always remain under the skin. This procedure may be repeated so that you may have up to 2 nerve stimulator devices. You will be given instructions on using and caring for the device(s).

The device will provide electrical stimulation continuously or intermittently (on and off) to help control your pain. You may pause or turn off the device at any time. You may adjust the strength of electrical stimulation as needed for comfort.

Group A will be followed by the APS each day while in the hospital for up to 7 days, or until discharge. After you are home, we will call you each week until week 4. We will ask you questions about your pain, daily activities, medications and side effects. The calls are expected to take 5 to 10 minutes. At week 4, we will see you in the CPC. At this visit, we will ask several questions about your pain, activity, mood, and experience with the device. A FIM will be done. We will decide whether to continue the device or not. All questions and concerns will be answered and addressed. If the device is kept, you will be followed by weekly phone calls. At about 60 days, you will return to the CPC for your final visit. During this visit, we will ask you questions about your pain, daily activities, medications and side effects. The device will be removed, which involves gently pulling the wire from the skin. A FIM will be done. If there is any bleeding, pressure will be applied until it stops and a bandage will be applied. If the device needs to be removed prior to this visit or accidentally comes out while at home, then you may need to be seen sooner in the CPC. If the lead comes out, keep the area clean and call (804) 675-5188 as soon as possible. You will be asked to come to the CPC to be examined and you may undergo another procedure to replace the lead, or electrical stimulation therapy may be stopped. After the second CPC visit, you will be followed by phone evaluation at 3, 6, and 12 months. We will ask you questions about your pain, daily activities, medication use, and overall well-being. The calls are expected to take 5 to 10 minutes

Group B:
Group B will receive Standard Medical Therapy only. A FIM will be done. The APS will follow you each day while an inpatient for up to 7 days, or until discharge, whichever comes first. You will be followed by a phone evaluation each week until week 4. We will ask you questions about your pain, daily activities, medications and side effects. The calls are expected to take 5 to 10 minutes. At week 4, you will be seen in the CPC. During this visit, you will be asked several questions regarding your pain, activity, mood, and overall well-being. A FIM will be done. All questions and concerns will be answered and addressed. At about 60 days, you will return to the CPC for your final visit and we will ask you questions about your pain, activities, medication use, and overall well-being. A FIM will be done. After this visit, you will be followed by phone evaluation at 3, 6, and 12 months. We will ask you questions about your pain, daily activities, medication use, and overall well-being. The calls are expected to take 5 to 10 minutes

Photographs and/or videos may be taken and used for research purposes. They may be used in presentations, publications, future grant applications, or educational purposes. Photos and videos will not include any identifying information such as your face, hair, tattoos, or birthmarks. The videos and photos may help teach proper methods and techniques for placing and using the device.

Please initial one:

_____ YES, I give permission to take photographs and/or videos
(INITIAL)

_____ NO, I do not give permission to take photographs and/or videos
(INITIAL)

4. Will the research benefit me?
There are no known direct benefits to you. However, information obtained from your participation in this study may help others in the future.

5. What are my alternatives to being a research subject?
You do not have to participate in this study to receive treatment for your condition. Your alternative is to not participate.

6. What are my risks? (Risks, Inconveniences, Discomforts)
Participation in this study may involve risks that are unknown at this time. Your condition may stay the same, may improve or may worsen from study participation.

The devices used in this study have been approved by the United States Food and Drug Administration. Risks of this device include but are not limited to:

1) **Infection**: If there is concern for infection related to the device, the device may be removed. You may be treated with antibiotics and monitored as needed. This may require extra clinic visits.
2) **Nerve injury**: You may feel "pins and needles," changes in sensations (feeling), numbness, tingling, or weakness in one or more muscles. Permanent nerve damage is a potential risk; however, this is uncommon.
3) **Damage to blood vessels, organs, and joint spaces**: Damage to these structures may lead to (but is not limited to) bleeding, changes in heart rate or blood pressure, shortness of breath, dizziness, lightheadedness, impaired organ function, pain, or stiffness.
4) **Broken wire, and/or wire movement**: If the wire breaks or moves, the nerve stimulator device may not function properly. If a fragment of the wire remains under the skin, the medical team will determine if the wire fragment needs to be removed. Usually, it does not need to be removed and can remain safely under

the skin. You may or may not have the option of replacing the wire to complete the 30 to 60 days of nerve stimulation therapy. Retained wire fragments have a risk of infection or unwanted tissue reaction. If an infection occurs treatment includes antibiotics and/or removal of the wire fragments by an outpatient surgical procedure under local anesthesia. Unwanted tissue reactions (pain, redness, or swelling) are rare and usually resolve without treatment.

5) **Risks associated with numbing medication (e.g. lidocaine)**: Medication is used to numb the skin before placing the device. Side effects include but are not limited to: flushing or redness of the skin, itching, bruising, bleeding, burning, swelling, pain at the application site, nausea, or vomiting.
6) **Bleeding**
7) **Skin irritation**
8) **Increased pain**
9) **Discomfort on insertion, during use or with withdrawal**
10) **MRI Safety:** Should you require an MRI procedure during the electrical stimulation treatment period, then the wire and all stimulator components must be removed prior to the MRI. In the case of a retained wire fragment, if the wire is completely under the skin, you may safely undergo an MRI under very specific conditions which is further discussed on page 58 of the "Patient Instructions for Use" (given to you after device placement). This page contains an "MRI Safety Card" which you should carry with you. Undergoing an MRI with a retrained wire fragment carries the risk of burning or injury to tissues near the wire fragment.

The adhesive, and/or the numbing medication used during the placement of the device has the potential to cause allergic reactions. Allergic reactions may be mild to severe, and include the following symptoms: chills, fever, skin rash, hives, itching, watery eyes, swelling, headache, difficulty breathing, difficulty swallowing, severely low blood pressure, organ failure, and death. Serious allergic reactions require immediate medical attention.

7. Will I get paid? (Compensation)
Subjects in Group A will be paid a total of $300. Subjects in Group B will be paid a total of $150. There will be three equal payments of $100 for Group A or $50 for Group B.

If you receive payments from the Department of Veterans Affairs they will be reported to the IRS along with your social security number.

8. Will I have to pay? (Cost of Participation)
You will <u>not</u> have to pay for care received as a subject in a VA research project regardless of whether you are a Veteran or a non-Veteran. If you get a bill for research services, contact your study doctor or research nurse. Some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are <u>not</u> part of the study.

There is no guarantee that the treatment you will receive during this study will be continued after the study is completed. If you are a Veteran and are eligible for care you may continue to receive the same treatment after the study only if the treatment is routinely available at McGuire VAMC and your physician decides that it is the most appropriate treatment.

9. Does pregnancy prevent me from participating? (Pregnancy)
Every effort will be made to have females enter this study. Any subject who is pregnant or becomes pregnant during the study will not be allowed to participate.

10. What if I get injured? (Research Related Injury)
In the event of injury resulting from your participation in this research study, McGuire Veterans Affairs Medical Center may or may not provide compensation, depending on applicable federal regulations. A research injury is any injury or illness caused by your participation in the study. In the event of a research injury, necessary medical treatment will be provided to assist your recovery from the injury. For research related injuries, the VA must provide necessary medical treatment regardless of whether you are a Veteran or a non-Veteran.

This agreement to provide medical treatment does not include treatment for injury/illness that is not a result of the study. To help avoid injury, it is very important to follow all study directions. You are not giving up any of your legal rights by signing this form.

11. Who Will See My Information? (Confidentiality)
The confidentiality of your research records will be maintained according to professional standards of confidentiality and VA regulations. Records identifying you may be reviewed by the members of the research team, the Research and Development Committee and its sub-committees, accrediting agencies, officials from the Veterans Health Administration, the Office of Research Oversight, the VA Office of the Inspector General, Richmond VAMC, and other federal oversight agencies such as the Food and Drug Administration, Office for Human Research Protections, or as required by law. Data collected during this study may be sent to a contractor for analysis.

Subjects will be asked to provide name, social security number, and date of birth which will be used to create a "unique identifier." The unique identifier will be used in place of your name for all data collection forms and study databases. A master list linking the subjects to the unique identifier will be maintained by study investigators. The protection of patient confidentiality is of utmost importance. Subject names and personal identifiers will not appear in any publications resulting from this research. Data pertaining to you will be stored in a secure, locked file cabinet in the Chronic Pain Clinic. Only study investigators will have access to any identifying information.

The ways your study doctor will use your study-related health information and the people who may receive it are identified in a separate form entitled, Authorization for Use & Release of Individual Identifiable Health Information for Veterans Health

Administration Research. You will be asked to sign that form to show that you give permission for these uses and sharing of your information. You do not have to sign the authorization form. However, if you do not sign, you will not be able to participate in the study.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

12. Do I have to participate in this study or can I withdraw from the study? (Voluntary Participation and Withdrawal)

Participation in this study is voluntary and you may refuse to participate without penalty or loss of benefits to which you are otherwise entitled. The study staff will answer any questions you may have about the study. You are free to withdraw your consent and stop participation at any time. If you decide to withdraw from this study, you should contact *Dr Denise Lester* to discuss termination of your participation. It is important that you do this so that *Dr Denise Lester* can withdraw you safely. Stopping will in no way change the quality of care you receive now or in the future at this institution or your right to participate in other studies.

Any significant new findings that develop during the research study that may affect your decision to continue participating will be provided to you as soon as possible.

Your participation in this research study may be ended without your consent for the following reasons:

- If the study doctor believes, for any reason, that it is within your best interest.
- If you refuse to allow placement of the study device if you are in the treatment group or fail to return for follow-up as recommended by your study doctor or fail to follow the study doctor's instructions.
- If you refuse to participate in tests or complete surveys that are needed to determine whether **study device** is safe and effective.
- If you require treatment with drugs that are not allowed in this study.
- If you become pregnant.
- If other causes prevent continuation of the clinical research study.
- Hunter Holmes Pilot Grant Award, SPR Therapeutics, FDA, McGuire IRB may also end the study at any time.

13. Date of Consent Form Revision: 10/3/17, 11/7/17 and 6/11/18

MIRB APPROVED
6/20/18

Subject Name:_____ Date:_____

Research Study Title: Effect of Postoperative Percutaneous Peripheral Nerve Stimulation on Acute and Chronic Amputation Pain

Principal Investigator: Dr. Denise Lester VAMC: Richmond

RESEARCH SUBJECTS' RIGHTS:

I have read the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. 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 understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled. The results of this study may be published, but my records will not be revealed unless required by law. By signing below, I am agreeing to participate in this research study. I will receive a signed copy of this consent form.

_____ _____

Signature of Participant Date

_____ _____

Signature of Person Obtaining Informed Consent Date

MIRB APPROVED
6/20/18