VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM

Subject Name: _____ Date: _____

Title of Study: Sensory Feedback Tactor Systems for Implementation of Physiologically Relevant Cutaneous Touch and Proprioception with Prosthetic Limbs : Kinesthesia

Principal Investigator: Paul Marasco PhD VAMC: Cleveland (541)

Consent Version Date: September 22, 2017

DESCRIPTION OF RESEARCH BY INVESTIGATOR

NOTE: The consent form must include the following section headings:

I. Purpose of the Study
II. Description of the Study
III. Inconveniences
IV. Discomforts/Risks/Side Effects
V. Benefits
VI. Alternative Procedure(s)/Treatment(s)
VII. Privacy, Confidentiality, and Use of Research Results
VIII. Special Circumstances
IX. Contact Information

TO POTENTIAL PARTICIPANTS: Federal regulations require written informed consent before participation in a research study. This is to be certain that research volunteers know the nature and risks of the study, so they can make an informed decision about participation. You are asked to read the following information and discuss it with the investigator, so that you understand this research study and how it may affect you. Your signature on this form means that you have been fully informed and that you freely give your consent to participate. It is also important that you read and understand these principles that apply to all individuals who agree to participate in the research project below:

1. Taking part in the research is entirely voluntary.

2. You may not personally benefit from taking part in the research but the knowledge obtained may help the health care professionals caring for you to better understand the disease/condition and how to treat it.

3. You may withdraw from the study at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled.

4. If, during your participation in the research project, new information becomes available concerning your condition (disease) or concerning better therapies, which may affect your willingness to continue in the research project, your doctor will discuss the new information with you and will help you make a decision about continuing in the research.

Cleveland VAMC IRB approved
the use of this version on 9/14/17

5. The purpose of the research, how it will be done, and what your part in the research will be, is described below. Also described are the risks, inconveniences, discomforts, and other important information, which you need to make a decision about whether or not you wish to participate. You are urged to discuss any questions, concerns, or complaints you have about this research with the research staff members.

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.

I. PURPOSE OF THE STUDY:

You are being asked to participate in this research study because you have an amputation of part of your upper limb, have undergone an upper limb Targeted Reinnervation surgery in the past and are interested in participating in a research study that investigates touch feedback from an upper limb prosthesis.

The sense of limb movement (kinesthesia) is absent when using a prosthetic limb. This means that accurate use of the prosthesis is completely reliant on vision.
The purpose of this study is to explore new ways to interface back with the nervous system and provide physiologically relevant sensory feedback from prosthetic limbs.

The Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSCDVAMC) is the main site for this study, the University of Alberta and the University of New Brunswick will also be participating. There will be a total of 12 participants in the study, 6 will be seen at the LSCDVAMC.

II. DESCRIPTION OF STUDY:

The study will take place at the LSCDVAMC. Your participation will last up to four years and will involve multiple spaced out visits to the LSCDVAMC.
Because Targeted Reinnervation has only been performed on a small group of people, the study is anticipated to recruit subjects that might not live in the vicinity of the LSCDVAMC. For this

reason , the team has clustered the visits into 3 sets of 2-6 days spanned over four years. The visit schedule is below:

Aim 1:Perceptual Mapping (2 days): we will use gradations of deep pressure and vibration centered around 70-85 Hz to specifically activate the kinesthetic receptors and build a perceptual map of where the limb movement sensations are located within the reinnervated muscle or tissue. The mechanical input will be provided by a computer controlled solenoid actuator (a voice coil stage) to the deeper reinnervated tissues (muscles and tendons). We will use the mechanical input to determine how discrete or separateable the percepts are from each other.

Aim 2: Matching, Internal Models and Tactor Integration (4 days- but can be broken up into two 2 day visits, based on your availability)

We will apply mechanical stimulation to the redirected sensory afferents to activate perceptions of limb movement. We will then match those percepts to the passive movement of a prosthetic limb. For example, if we isolate a percept of the elbow bending we will place the kinesthetic tactor over this area of the reinnervated tissue. With a sensor, such as a potentiometer, mounted at the elbow of a prosthesis we will send a signal to activate the tactor every time the elbow of the prosthesis is bent by the investigator. We would expect that this feedback would allow you determine the direction of movement of the prosthesis without looking at the device. We will assess this by having you mirror with mirror the movement that you feel from the kinesthetic tactor feedback with your intact arm, or by using a diagram of limb movements in the case of bilateral amputees. This will be done with the prosthetic arm physically separate from you, such as in a different room, to prevent any kind of physical feedback from the prosthetic socket, sounds of the prosthesis being moved, or any visual cues about the movement of the prosthesis. The artificial limb will be moved by the investigator and comparisons will be made between the actual movement of the prosthesis and the perception of movement felt by you.

We will also test how sensory feedback is functionally useful. We will ask you to perform standard occupational therapy tasks and with and without sensory feedback.

Aim 3: Socket Design and Visual loading (about 6 days)

The functional experiments will occur concurrently with integration of new socket designs to incorporate control and feedback. We will investigate the use of open frame and alternating compression socket design, with a modified strut and floating arm system. This strut system will allow placement of the additional electrodes and sensory tactors over areas of the skin and/or muscle. You will be mapped as to your muscle electrode sites and their sites of maximal sensory

feedback based on the first part of the protocol. Once this is determined, socket fabrication will be done based on a digitized scan of your arm. The socket modifications will involve incorporation of a new sensory tactor, followed by fitting of the socket and functional testing trials with real time sensory feedback.

After the device has been constructed, the study team will ask you to complete a series of baseline tests while using the prosthetic. These baseline tests will include questionnaires about what you feel, tactile tests in which you will be timed while you complete a set of tasks (such as moving a block from one side of the table to the other), as well as video of you completing the tasks with the tactor function on and off.

III. INCONVENIENCES:

You will be asked to come to the LSCDVAMC for three sets of 2-6 day testing sessions, if you are not local to the Cleveland area this would require you to travel and the time involved could be inconvenient . If you cannot or are unwilling to do this, you should not participate in the study.

IV. DISCOMFORTS / RISKS / SIDE EFFECTS:

Your participation in this study may involve the following risks:

Bruising/Pain: There is a possibility of pain or bruising from the mechanical piston. The study staff can alter the level of force used by the device to minimize any discomfort.

Electrical Hazards: There is a possibility of an electrical shock whenever electricity is used to power instruments. The tactors on the prosthesis carry a battery pack that is similar to the battery pack utilized by your current myoelectric prosthesis. The risk of electrical shock by this device is no greater than that on your current device

V. BENEFITS:

You will not directly benefit from participating in his study. The information gained however, will guide the development of a new type of prosthesis.

VI. ALTERNATIVE PROCEDURE(S) / TREATMENT(S):

Because this study offers no direct benefits to participants, your only alternative is to not participate.

VII. PRIVACY, CONFIDENTIALITY, AND USE OF RESEARCH RESULTS:

Any information obtained about you in this study will be treated as confidential and will be safeguarded in accordance with the Privacy Act of 1974. Participation in this study will involve a loss of privacy, but information about you will be handled as confidentially as possible. Your research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in the research team's office. The research records will be kept in a password-protect computer file that only the study team has access to. Your information will be combined with information from other people taking part in the study. We will write about the combined information we have gathered. Any presentations or publications from this information will not identify you.

VA policy requires us to keep study records indefinitely. However, protections will be put in place to be sure that this information is kept confidential.

In the event of an emergency, details of your participation in this study may be disclosed to your primary care provider.

In order to comply with federal regulations, research records identifying you may be reviewed by the following:

- Authorized representatives of the LSCDVAMC Institutional Review Board and VA
- Federal Agencies such as the Government Accounting Office (GAO) and the Office for Human Research Protections (OHRP)

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VIII. SPECIAL CIRCUMSTANCES:

New Findings:

You will be told by the study doctor of any significant new findings during the course of the study, which may affect your willingness to continue to participate.

Financial Considerations

You will be paid for your time and effort for being in this research project. You will be paid $80.00 via check for each visit day that takes place at the LSCDVAMC that you complete. You will receive the payment at the end of each week. If you withdraw from the study before completing all the sessions, you will be paid for the sessions you complete. If you complete all of the scheduled sessions, you will have received $960.00 total. Any income above $600.00 in a calendar year will be reported to the IRS.

If you do not live in the vicinity of the LSCDVAMC, the study will provide travel and lodging for the sessions that you are required to be at the study site.

Ending Participation

The investigators may stop your participation in this study without your consent, for example, if they think that it will be in your best interest, if you do not follow the study plan, if you experience a study-related injury, or for any other reason.

Compensation for Research-Related Injury

If you sustain injury as a direct result of your study participation, medical care will be provided by the LSCDVAMC at no cost to you. Financial compensation for such things as lost wages, disability, or discomfort due to an injury may not be available.

VIII. CONTACT INFORMATION

To answer questions about the research or if you sustain a research related injury contact the following:

- During the Day: Dr. Clay Kelly (216) 791-3800 ext 4153

- After Hours: Dr. Clay Kelly (216) 791-3800 ext 4153

For answers to questions about rights as a research participant or to voice a concern or complaint contact the following:

- The Research Administrative Officer at (216) 791-3800 ext. 4657
- The LSCDVAMC Patient Representative at (216) 791-3800 ext. 4026

If you wish to speak with someone other than study staff to provide input concerning the research process, check whether a study is being conducted at the LSCDVAMC ,and if study staff are permitted to represent the study contact :

- The LSCDVAMC Institutional Review Board Office at (216) 791-3800 ext. 4658

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RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me all of the preceding information.

Dr./Mr./Ms. _____has explained the study to me and answered all of my questions. 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 I will not be identified in publications by name, photograph, or other identifiers. My records, including my name and results of my participation, may be revealed as required by laws and regulations of state and federal agencies.

I understand my rights as a subject, and I voluntarily consent to participate in this study. I understand what the study is about and how and why it is being done. I will receive a signed consent form or a photocopy of it. I understand that in signing this consent form I do not waive my legal rights nor release the LSCDVAMC from liability for negligence.

Subject's Signature_____ Date __ /__/__

Signature of Subject's Representative _____ Date __ /__/__
(if subject not competent)

Printed name_____

Signature of Person Obtaining Consent_____ Date __ /__/__