Subject's Name: **Date:**

Principal Investigator: Jesse Dean

Study Title:
Development of sensory augmentation methods to improve post-stroke gait stability

SUMMARY

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this research study is to test a new method of improving sensation during walking among individuals who have experienced a stroke, which may improve balance. You are being asked to participate in this study because you have experienced a stroke.

If you agree to participate, you will be enrolled in the study for a period of up to a year. We will ask you to stand still, walk on a treadmill, and walk overground. We will sometimes use small motors to apply vibration to your hip muscles, which may cause you to feel as though you are slightly swaying to the side. These vibrating motors have not been submitted to the Food and Drug Administration (FDA) as a medical device. Each experimental session will last about 2 hours.

You may experience some muscle soreness if these walking and standing activities are harder than your usual level of activity. You may feel like you are going to lose your balance while standing or walking. A loss of balance could result in a fall, although for this study you will wear a harness attached to an overhead support for all trials to prevent you from falling to the ground. There is also a risk of minor skin irritation due to the vibration of motors next to your skin, or the use of adhesive tape to secure the motors and Light Emitting Diode (LED) markers. There is a risk of loss of confidentiality as a result of your participation in this study. It is possible that participation in this study could improve your balance, although this cannot be guaranteed. Your alternative is to not participate in this study. You do not have to participate in this study to have your condition treated.

If you are interested in learning more about this study, please continue reading below.

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. You are being asked to participate in this study because you have experienced a stroke. The study involves the use of an investigational device that applies weak vibration to your hip muscles, and may help to improve your balance. The study is sponsored by the Department of Veterans Affairs. The investigator in charge of this study at the Ralph H. Johnson VA Medical Center is Jesse Dean, PhD. The study is being done at one site, in the

College of Health Professions Research Building at the Medical University of South Carolina (MUSC). Approximately 120 people will take part in this study.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. You will complete an initial Screening session. In this session:
    - You will perform several clinical tests to measure your balance and how you move. You will also be asked questions about your balance in different situations. All of these tests and questions are commonly used in clinical practice.
    - You will walk on a treadmill at a speed that feels safe for you. While you walk, we will use LED markers and inertial measurement units (devices that measure how you move) placed on your legs and trunk to measure how you are moving.
    - You will walk overground at a speed that feels safe for you. While you walk, we will use LED markers and inertial measurement units placed on your legs and trunk to measure how you are moving.
2. You may be asked to complete a one-session Aim 1 experiment, if you qualify and are interested. In this experiment:
    - Vibrating motors will be placed over your hip muscles. You will be asked whether you can feel the motors vibrating at several strengths. These motors are investigational devices.
    - You will stand on a device able to measure the force through your legs. We will measure these forces while the motors over your hip muscles vibrate.
    - You will walk on a treadmill while vibration is applied to your hip muscles or trunk. While you walk, we will use LED markers and inertial measurement units placed on your legs and trunk to measure how you are moving.
3. You may be asked to complete a two-session Aim 2 experiment, if you qualify and are interested. In this experiment:
    - Three investigational device vibrating motors will be placed over your hip muscles. You will walk on a treadmill while we vary the pattern and location of vibration applied to your

muscles. While you walk, we will use LED markers and inertial measurement units placed on your legs and trunk to measure how you are moving.

4. You may be asked to participate in an Aim 3 clinical trial including 10-11 experimental sessions over the course of 4 weeks, if you qualify and are interested. For this clinical trial:
    - You will be randomly assigned to one of two groups (A or B), like picking letters out of a hat. In Group A, motor vibration from the investigational device will be applied based on the motion of your pelvis as you walk. In Group B, motor vibration will be applied based on the timing of your steps as you walk. The intervention will otherwise be identical for the two groups.
    - In the first and last sessions, you will perform several clinical tests to measure your balance and how you move. You will also be asked questions about your balance in different situations. All of these tests and questions are commonly used in clinical practice. You will also walk on a treadmill and overground at speeds that are comfortable for you, while we use LED markers and inertial measurement units placed on your legs and trunk to measure how you are moving.
    - In the remaining sessions, you will walk on a treadmill at speeds that are comfortable for you. While you walk, vibration will be applied to your hip muscles. We will use LED markers and inertial measurement units placed on your legs and trunk to measure how you are moving. These sessions will be performed twice a week for four weeks.

Each session will last approximately two hours. If you agree to participate in this study, you will be enrolled for a period of up to a year.

While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, extra X-rays, or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

C. RISKS AND DISCOMFORTS

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your healthcare providers if you have any questions about the risks of usual care.

D. MEDICAL RECORDS and/or CERTIFICATE OF CONFIDENTIALITY

If you are a Ralph H. Johnson VA Medical Center patient, you have a VA medical record. If you have never been a Ralph H. Johnson VA Medical Center patient, a VA medical record will be created for the purposes of this study. Results of research tests or procedures will be included in your VA medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law.

E. BENEFITS

There will be no direct benefit to you from participating in the Screening session or Aims 1 and 2 of this study. However, it is hoped that the information gained from the study will help in the treatment of future patients with poor balance after a stroke. If you participate in the 4-week intervention, there is a chance that your walking balance and mobility may be improved. However, this cannot be guaranteed.

F. COSTS

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these copayments for VA care and medications that are not part of this study.

G. PAYMENT TO PARTICIPANTS

In return for your time, effort, and travel expenses, you will be paid $750 for participation in this study. If you do not complete the study, you will receive $50 for each completed visit. The IRS requires a tax form be filed if your compensation exceeds $600.00/year. However, if the payment for participation will be made through Austin Financial Services Center, this will require the use of your Social Security Number and it may generate IRS Form 1099 automatically, regardless of amount. Alternatively, you may be paid using a "ClinCard". ClinCard is managed by a company named Greenphire. If this payment method is used, your personal information, such as your name, date of birth, and social

security number will be shared with Greenphire in order to put study payments onto the ClinCard. While the ClinCard is not a credit card, Greenphire may use your information like a credit card company would. You should review the terms and conditions of ClinCard when deciding whether to take part in the study, which will be made available to you.

H. ALTERNATIVES

If you choose not to participate in this study, you could receive other treatments for your condition. The standard therapy for balance problems after a stroke is physical therapy, involving methods such as practice standing on foam or with your eyes closed. However, no physical therapy treatments have been shown to reduce fall risk after a stroke.

I. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

We would like to include data collected in this study and from other stroke related studies you may participate in with the Registry for Stroke Recovery (RESTORE). RESTORE provides MUSC's stroke recovery research community with a database containing information on research participants including stroke type, disability status, and demographics to assist in recruitment. By including data from this study in RESTORE, MUSC researchers will have access to a more complete database with key elements of physical function characteristics for more targeted recruitment efforts in the future. Additionally, this could reduce the burden placed on subjects by reducing the duplicative efforts of collecting common data and assessments requested by multiple studies and storing them in one centralized and secure location.

Your data from this study, including your personal health information, will be included in the RESTORE registry.

J. DISCLOSURE OF RESULTS

This study will not produce clinically-relevant research results. Research results will not be disclosed to participants.

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K. CLINICAL TRIALS.GOV

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.

CONSENT

Your privacy is very important to us and the researchers will make every effort to protect it. Results of this research will be used for the purposes described in this study. These results may be published, but you will not be identified.

The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. There are times when we may have to show your records to other people from Federal agencies that oversee our research such as the Department of Health and Human Service's Office of Human Research Protections (OHRP), the Food and Drug Administration (for FDA regulated research only), the Government Accountability Office (GAO), the VA Office of the Inspector General (OIG), the VA Office of Research Oversight (ORO), our local VA Research and Development Committee, and other study monitors may look at or copy portions of records that identify you. Also, all records in South Carolina are subject to subpoena by a court of law. Any information shared with these outside groups may no longer be protected under federal law.

The VA will provide necessary medical treatment to a research subject injured by participation in a research project. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. If you sustain an injury as a direct result of your study participation, medical care will be provided by the Ralph H. Johnson VA Medical Center. Financial compensation is not available for such things as lost wages, disability or discomfort due to an injury.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

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The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

VOLUNTEER STATEMENT

A member of the study team has explained the research study to me. 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 have been given the chance to ask questions and obtain answers.

If I have any more questions about my participation in this study or study related injury, or if I have comments, concerns or complaints, I may contact: **Jesse Dean at (843) 792-9566.**

If I have questions about my rights as a study participant, or I want to make sure this is a valid VA study, I may contact the Medical University of South Carolina's Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. I may call the MUSC IRB (843) 792-4148, or the Ralph H. Johnson VA Medical Center's Research Compliance Officer at (843) 789-7399, if I have questions, complaints or concerns about the study or if I would like to obtain information or offer input.

By signing this document below, I voluntarily consent to participate in this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date
_____ Name of person obtaining consent	_____ Signature of person obtaining consent	_____ Date