Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Optimization of Closed-loop Transcutaneous Auricular Vagus Nerve Stimulation (taVNS) as a Neurorehabilitation Tool (PART 1)

SUMMARY

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who are willing to take part in them. You are being asked to participate because you had a stroke at least 6 months ago and have arm weakness.

This study will explore the use of sticker like devices that stick to your arms to measure when your arm moves. This study has two parts. You are being asked to only participate in Part 1.

The purpose of Part 1 of the study is to determine if it's possible for these sticker-like devices to record your arm movement onto a computer. This part of the study will also test the comfort of having a clip electrode placed on your ear, similar to a clip-on earring.

If you choose to participate, stickers will be placed on your arm, and you will be asked to perform specific arm movements. While your arm is moving the sticker will be sending information about your arm movement to a computer.

We also will be testing the comfort of ear stimulation using clips attached to your left ear. This involves attaching a clip electrode to your ear and measuring how much intensity is required for you to sense a tickle or tingle feeling on your ear.

Your participation is voluntary, and the purpose is to make a new tool for stroke rehabilitation. This study is a single visit and will require about 1.5 hours of your time.

There are minimal risks involved in this study. You may experience a warm, tingling sensation on your ear. You may also feel fatigued after 1 hour of rehabilitation training that the therapist will conduct with you. The rest of the study details are described below.

A. PURPOSE OF THE RESEARCH

There are 2 purposes of this research. The first is to test a new system for upper limb movement. This system uses stickers that attach to your arm. These stickers record when you move and send this information to a computer. The second purpose is to test the comfort of an ear stimulation device.

These research procedures are not treatments for stroke but only used to learn more about upper limb function post-stroke.

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 are/have had a stroke and have upper limb motor problems within at least the past 6 months. The study is sponsored by the medical university of South Carolina. The investigator in charge of this study at MUSC is Dr. Bashar W. Badran. The study is being done at the medical university of South Carolina and is the only sites. Approximately 5 people will take part in this part of the study.

B. PROCEDURES

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

1. Urine pregnancy test: You will be given a cup for you to give a urine sample. The study team will use a urine pregnancy test to confirm you are not pregnant.

2. Attach stickers to your arm: Stickers will be placed on your shoulder, bicep, forearm, and ankle. These stickers will sense when you move and send the information to a computer.

3. Motor Assessment: A trained study team member will walk you through performing several tasks to document how well you are able to move your arm after stroke. It will take about 45 minutes to complete the tasks. During this assesment, the stickers will send information about your movement to a computer.
4. Ear Clip Stimulation: The study team will attach one small clip electrode to your ear and deliver a small electrical pulse to your ear. It will feel like a tingling warm sensation. The team will do this in bursts for 5-10 seconds at a time in order know when you feel stimulation and how comfortable it is by asking you to rate it on a scale of 0-10. This should take about 10 minutes.

C. DURATION

Participation in the study will take about 1 visit over a period of 1 day. This visit should last about 1.5 hours.

D. RISKS AND DISCOMFORTS

There are no associated risks with using stickers on your arm, however you may experience temporary discomfort (pulling on the skin/skin hair) during removal of the patches.

There may be risks associated with ear clip stimulation. These risks are listed below:

Potential skin discomfort: You may feel local discomfort on your ear. This is temporary. In extreme cases burns may occur. Prevention of discomfort or burns requires you to notify the study team immediately, and they will stop stimulation and apply vitamin E cream. Tissue surrounding the ear may be sensitive, sore or feel slight numbness, and this is temporary and will go away after stimulation is turned off.

Potential headache, dizziness, and facial pain: Ear stimulation may cause headaches or face pain, which should resolve shortly after treatment.

Safety in case of pregnancy: This protocol will exclude pregnant women. The risks of using taVNS with pregnant women are currently unknown. Please inform the research team if you are pregnant or think that you might have become pregnant during the study. A urine pregnancy test will be performed before the experiment begins.

Potential decrease in heart rate: Ear stimulation may slow your heart rate. In rare cases (less than 1%) decreased blood pressure or fainting may occur. We expect no significant changes in heart rate or blood pressure, but if this occurs, the study team will immediately stop stimulation. If fainting occurs, you will be slowly placed into a position which has you laying flat on your back and your legs lifted.

Unknown Risks: Although taVNS considered very safe, taVNS is still an experimental procedure that has not been approved by the FDA. The Principal Investigator will let you know if they learn anything that might make you change your mind about participating in the study.

There is also a risk of a loss of confidentiality of your personal information as a result of participation in this study. However, this risk will be minimized by following health information guidelines and keeping the study data in a secured location that is only accessible by authorized personnel.

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

Information about your study participation will not be in your medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record.

F. BENEFITS

There will be no direct benefit to you from participating in this study. However, it is hoped that the information gained from the study will help in the treatment of future patients with conditions like yours/will help the researcher learn more about chronic stroke.

G. COSTS

There will be no cost to you as a result of participation in this study.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid $50.00 for participation in this study. Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

Payment for study visits will be made using a pre-paid debit card, called a ClinCard. It works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be given a ClinCard at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule above. Details of the debit card system are explained on an additional sheet.

If you park at the E Lot parking garage located at 91 President Street, we will validate your parking up to $5. We ask that you bring you parking ticket to your appointment so that we can stamp you ticket to validate it.

I. ALTERNATIVES

Your alternative is to not participate in this study.

J. 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-Pro00037803). 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.

If you consent to participate in RESTORE your data from this study, including your personal health information, will be included in the registry. You will be asked to sign a Release of Study Records Form to share data from other stroke related studies in which you have participated. If you authorize this release your information from those studies will become part of the RESTORE registry study

K. DISCLOSURE OF RESULTS

Results will not be disclosed to participants in the study, however will be released for public dissemination in published manuscripts and conference presentations.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your

permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

L. **SIGNIFICANT NEW FINDINGS**

If there are significant new findings during the course of the study, you will be notified by the manner you prefer.

M.__**STUDENT PARTICIPATION**

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

N.___EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

O.___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.

P.___FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. 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. The sponsor and the Food and Drug Administration (FDA) will receive copies of the research records. The investigators associated with this study, employees of the sponsor, the FDA, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event of a study related injury, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

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. The data collected on you to this point remains part of the study database and may not be removed. 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.

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.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact ***Dr. Bashar W. Badran at 843-792-6106***. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

_____ _____

Signature of Person Obtaining Consent Date *Name of Participant

_____

Signature of Participant Date

NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESSS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, and MUSC Physicians Primary Care) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." W**e collect or receive this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.**

HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI)

A. The following uses do NOT require your authorization, except where required by SC law:

1. For treatment. Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.

2. To obtain payment. We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.

3. For health care operations. We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.

4. For public health activities. We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.

5. Victims of abuse, neglect, domestic violence. Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.

6. Health oversight activities. We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.

7. Judicial and administrative proceedings. Your PHI may be released in response to a subpoena or court order.

8. Law enforcement or national security purposes. Your PHI may be released as part of an investigation by law enforcement.

9. Uses and disclosures about patients who have died. We provide coroners, medical examiners and funeral directors necessary information related to an individual's death.

10. For purposes of organ donation. As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.

11. Research. We may use your PHI if the Institutional Review Board (IRB) for research reviews, approves and establishes safeguards to ensure privacy.

12. To avoid harm. In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.

13. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.

14. Marketing. We may send you information on the latest treatment, support groups and other resources affecting your health.

15. Fundraising activities. We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.

16. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.

B. You may object to the following uses of PHI:

1. Hospital directories. Unless you object, we may include your name, location, general condition and religious affiliation in our patient directory for use by clergy and visitors who ask for you by name.

2. Information shared with family, friends or others. Unless you object, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.

3. **Health plan.** You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:

You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation

1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.

2. Psychotherapy notes.

3. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:

A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date**.**

B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.

C. The Right to See and Get Copies of Your PHI. You have the right to inspect and receive a copy of your PHI (including an electronic copy), which is contained in a designated record set that may be used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a fee for

copying, mailing or other costs associated with your request. We may deny your request to inspect and receive a copy in certain very limited circumstances. If you are denied access to PHI, you may request that the denial be reviewed.

D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.

E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record.

F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 369 / Charleston, SC 29425. The phone number is (843) 792-3881.

G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.

H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

HEALTH INFORMATION EXCHANGES
MUSC, along with other health care providers belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of patients. As a member of these exchanges, MUSC shares certain patient health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES
If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. **Please be assured that you will not be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.**

PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES
If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue / MSC 332 / Charleston SC 29425. You also may send a written complaint to the Office of Civil Rights. The address will be provided at your request.

CHANGES TO THIS NOTCE
We reserve the right to change the terms of this Notice at any time. We also reserve the right to make the revised or changed Notice effective for existing as well as future PHI. This Notice will always contain the effective date. You may view this notice and any revisions to it at: http://www.musc.edu/privacy.

EFFECTIVE DATE OF THIS NOTICE
This Notice went into effect on April 14, 2003.
Revised September 2013.

Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Optimization of Closed-loop Transcutaneous Auricular Vagus Nerve Stimulation (taVNS) as a Neurorehabilitation Tool (PART 2)

SUMMARY

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who are willing to take part in them. You are being asked to participate because you had a stroke at least 6 months ago and have arm weakness.

This study will test the use of 4 weeks of arm training to improve function in your affected arm. Your participation is voluntary, and the purpose is to test a new tool for stroke rehabilitation. This study will have 15 visits spread over 12 weeks. You will attend a baseline visit, followed by 4 weeks of arm rehabilitation training and then 2- and 8-week follow-up sessions.

At your first and last visits, we will measure how severely your arm is impaired with a brain scan, surveys, a watch that measures movement, and cameras that will record your movement and will be rated at a later time. These measures will all be repeated at the end of this study and at the follow-up visits.

The rehabilitation training is provided to you at no cost and consists of 12 training sessions spread over 4 weeks with an occupational therapist. During this rehabilitation, you will receive ear stimulation at the same time. Training sessions last about 1 hour.

There are minimal risks involved in this study. You may experience a warm, tingling sensation on your ear. You may also feel fatigued after 1 hour of rehabilitation training that the therapist will conduct with you. The rest of the study details are described below.

The rehabilitation training and stimulation you receive as part of this study may provide benefits like improved function in your affected arm. Also, the knowledge gained will help future stroke patients with their rehabilitation. You may choose to not participate in this study as an alternative and even if you choose to participate you may stop at any time. You may also choose other standard of care rehabilitation options that your providing physician may review with you.

A. PURPOSE OF THE RESEARCH

The purpose of this research is to test if a new form of ear stimulation can help improve your arm movement. The ear stimulation is very safe and this study tests whether stimulating your ear while you are training your arm will make your arm training more effective

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 are/have had a stroke and have upper limb motor problems within at least the past 6 months. The study is sponsored by the medical university of South Carolina. The investigator in charge of this study at MUSC is Dr. Bashar W. Badran. The study is being done at the medical university of South Carolina and is the only sites. Approximately 20 people will take part in this study.

B. PROCEDURES

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

Before starting the study, the study team will review your medical chart to make sure you are meet the requirements to participate in the study. If you are a female, you will also be asked to give a urine sample to test for pregnancy.

Visit 1 (4 hours)

Your first visit will last 4 hours and will consist of performing tests to see how well you are able to move your arm. Movement assessments will be video recorded and rated by the study's Treatment Occupational Therapist. .

1. Arm Motor tests - The study team will perform tests to see how well you are able to move your arm after stroke. It will take about 60 minutes to complete the assessments and the study team member assisting you is trained and/or certified to do the tests. These tests include moving, grasping, and reaching with your arm.
2. Arm Motor Tracking - The study team will place red lights on your arms. These lights will be tracked by a camera and we will measure the range of your arm movements.
3. Overground Walking- You will walk indoors on and off a pressure-sensitive walkway at multiple speeds, but we will not ask you to run or go faster than you feel comfortable and safe. The walkway measures the speed of walking and the size of steps. A physical therapist or trained assistant will walk beside you across the walkway, and when possible, you will be attached to a mobile, ceiling-mounted safety support. You will be asked to walk several times across the walkway.
4. Treadmill Walking- We will test walking adaptability with a series of tasks. You will be asked to walk on a split-belt treadmill at varying speeds, but we will not ask you to run or go faster than you feel comfortable and safe. During all treadmill walking, you will wear a harness attached to a device attached to the ceiling. This device can move with you and will catch you and prevent a fall in case of a stumble or misstep. A therapist or trained assistant will stay along to provide any physical assistance you may need.Training on Movement Tracking Watch - The study team will train you on how to use the watch like devices which you will take home and use daily.

5. Brain Scan - The study team will take pictures of your brain to measure how your brain responds to ear stimulation. This will be done at the MUSC center for biomedical imaging. You will lie down on a narrow bed, which will then be placed in a tube that is about 6 feet long and open at each end. You will lay there quietly for about 1 hour during which you will hear a loud noise. The study team will connect ear clips to your ear during the brain scan which will tickle your ear and feel warm during the 1 hour scan.

Visits 2-13 (1 hour each)

1. Arm Motor Training - you will be assigned randomly to either: group 1- high dose ear stimulation and training; or group 2- low dose ear stimulation and training. You have a 50% chance (like flipping a coin) of being assigned to either the high dose or low dose group. Both groups receive identical arm training, however the only difference is the amount of ear stimulation received.
    a. For each training you will have to come to MUSC and work with the occupational therapist for 1 hour.
    b. All participants will receive ear stimulation during training. This will feel like a warm, tingle sensation and fits on your ear like a clip-on earring.
    c. Participants receiving low-dose ear stimulation will have stickers placed on their arm and ankle to track movement and start ear stimulation.
2. Brain Scan 2 (Visit 13 only) - The study team will take pictures of your brain to measure how your brain responds to ear stimulation. The study team will connect ear clips to your ear during the brain scan which will tickle your ear and feel warm.

Visit 14 (2 hours)

This visit will be identical to Visit 1 (Above), however we will not be doing a brain scan.

Visit 15 (2 hours)

This visit will be identical to Visit 14 (Above).

C. DURATION

Participation in the study will take about 15-16 visits over a period of 1.5 months. Each visit should last about 1-2 hours with the exception of the initial visit will take about 4 hours.

D. RISKS AND DISCOMFORTS

Risks are associated with the following procedures conducted in this trial

1. Ear Stimulation:
Ear stimulation is a safe, however there are some risks associated with stimulating your ear:

Potential skin discomfort: You may feel local discomfort on your ear. This is temporary. In extreme cases burns may occur. Prevention of discomfort or burns requires you to notify the study team immediately, and they will stop stimulation and apply vitamin E cream. Tissue surrounding the ear may be sensitive, sore or feel slight numbness, and this is temporary and will go away after stimulation is turned off.

Potential headache, dizziness, and facial pain: Ear stimulation may cause headaches or face pain, which should resolve shortly after treatment.

Safety in case of pregnancy: This protocol will exclude pregnant women. The risks of using taVNS with pregnant women are currently unknown. Please inform the research team if you are pregnant or think that you might have become pregnant during the study. A urine pregnancy test will be performed before the experiment begins.

Potential decrease in heart rate: Ear stimulation may slow your heart rate. In rare cases (less than 1%) decreased blood pressure or fainting may occur. We expect no significant changes in heart rate or blood pressure, but if this occurs, the study team will immediately stop stimulation. If fainting occurs, you will be slowly placed into a position which has you laying flat on your back and your legs lifted.

Unknown Risks: Although taVNS considered very safe, taVNS is still an experimental procedure that has not been approved by the FDA. The Principal Investigator will let you know if they learn anything that might make you change your mind about participating in the study.

2. MRI Brain Scan:
MRI tests are non-invasive and painless. There are no known risks or side effects associated with conventional MRI procedures except to those people who have electrically, magnetically or mechanically activated implants (such as cardiac pacemakers) or to those who have clips on blood vessels in their brain. There are no known additional risks for using ear stimulation in the MRI scanner. However, an MRI may cause you to feel claustrophobic (uncomfortable in a small space) or anxious from the noises made by the machine.

This MRI scan will be used to answer research questions, not to examine your brain medically. This MRI scan is not a substitute for one a doctor would order. It may not show problems that would be picked up by a medical MRI scan. Nevertheless, a clinical neurologist or neuroradiologist will read your scan. If we find an abnormality, we will let you know, and will advise you to follow this up with your doctors. If you wish a copy of your MRI scan, we can provide it to you on a CD. The MRI scans will be stored on research computers for 7 years and then they will be destroyed. It is not possible to access them after you complete the study so please get a copy of your MRI on a CD if you think you might want it in the future.

3. Task-Specific Training (TST):
This motor training may cause muscle fatigue or mild soreness as a result of exercise, and usually resolves within 12-24 hours.

5. Motor assessments:
These assessments conducted by a therapist may cause fatigue but you have the option to adjust your pace to complete the test or to discontinue.

6. Overground and Treadmill Walking: The physical activity involved with this study may contribute to temporary muscle soreness or fatigue. These are normal responses to exercise and generally disappear within 1-2 days. Rest periods will be incorporated into the testing and training procedures, but participants will also be allowed additional rest at any time they wish during testing. Assistance will be provided during activities of walking or transferring from one surface to another, including the use of a support harness during treadmill walking. Despite these safety measures, as with any walking activity, there is a risk that participants may lose balance, stumble, fall, and experience an injury. Heart rate and blood pressure will be monitored during testing. Vital signs will be monitored routinely (at least every five minutes of activity) to make sure participants do not have a poor response to activity.

There is a risk of a loss of confidentiality of your personal information as a result of participation in this study. However, this risk will be minimized by following health information guidelines and keeping the study data in a secured location that is only accessible by authorized personnel.

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

Information about your study participation will not be in your medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record.

F. BENEFITS

All participants will receive 12 sessions of upper limb rehabilitation by an occupational therapist. However, it is hoped that the information gained from the addition of stimulation will help in the treatment of future patients with conditions like yours/will help the researcher learn more about chronic stroke. There is also a chance you do not benefit from the motor rehabilitation training or the stimulation.

G. COSTS

There will be no cost to you as a result of participation in this study.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid $20.00 for each training and follow-up visit for a total of $280.00. Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

If you park at the E Lot parking garage located at 91 President Street, we will validate your parking up to $5. We ask that you bring you parking ticket to your appointment so that we can stamp you ticket to validate it.

I. ALTERNATIVE

You may choose to not participate in this study as an alternative and you may stop at any time. You may also choose other standard of care rehabilitation options that your providing physician may review with you.

J. DATA SHARING

1. 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-Pro00037803). 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.

   If you consent to participate in RESTORE your data from this study, including your personal health information, will be included in the registry. You will be asked to sign a Release of Study Records Form to share data from other stroke related studies in which you have participated. If you authorize this release your information from those studies will become part of the RESTORE registry study.

2. Any data collected from this study will be released to the RESTORE registry once the study has completed.We may share your brain scans or behavioral outcomes in databases for advancement of research. If your data is shared in these databases, all of your identifiable information will be removed from the data and only deidentified results will be shared.

K. DISCLOSURE OF RESULTS

Data collected and results will not be disclosed to participants in the study, however will be released for public dissemination in published manuscripts and conference presentations.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you

choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

L. **SIGNIFICANT NEW FINDINGS**

If there are significant new findings during the course of the study, you will be notified by any manner you prfer (phone or email).

M.__**STUDENT PARTICIPATION**

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

N.___EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

O.___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.

P.___FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. 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. The sponsor and the Food and Drug Administration (FDA) will receive copies of the research records. The investigators associated with this study, employees of the sponsor, the FDA, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event of a study related injury, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

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. The data collected on you to this point remains part of the study database and may not be removed. 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.

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.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact ***Dr. Bashar W. Badran at 843-792-6076***. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

_____
Signature of Person Obtaining Consent Date

_____
* Printed Name of Participant

_____
Signature of Participant Date

NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESSS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, and MUSC Physicians Primary Care) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." W**e collect or receive this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.**

HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI)

A. The following uses do NOT require your authorization, except where required by SC law:

1. For treatment. Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.

2. To obtain payment. We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.

3. For health care operations. We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.

4. For public health activities. We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.

5. Victims of abuse, neglect, domestic violence. Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.

6. Health oversight activities. We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.

7. Judicial and administrative proceedings. Your PHI may be released in response to a subpoena or court order.

8. Law enforcement or national security purposes. Your PHI may be released as part of an investigation by law enforcement.

9. Uses and disclosures about patients who have died. We provide coroners, medical examiners and funeral directors necessary information related to an individual's death.

10. For purposes of organ donation. As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.

11. Research. We may use your PHI if the Institutional Review Board (IRB) for research reviews, approves and establishes safeguards to ensure privacy.

12. To avoid harm. In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.

13. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.

14. Marketing. We may send you information on the latest treatment, support groups and other resources affecting your health.

15. Fundraising activities. We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.

16. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.

B. You may object to the following uses of PHI:

1. Hospital directories. Unless you object, we may include your name, location, general condition and religious affiliation in our patient directory for use by clergy and visitors who ask for you by name.

2. Information shared with family, friends or others. Unless you object, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.

3. **Health plan.** You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:

You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation

1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.

2. Psychotherapy notes.

3. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:

A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date.

B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.

C. The Right to See and Get Copies of Your PHI. You have the right to inspect and receive a copy of your PHI (including an electronic copy), which is contained in a designated record set that may be used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a fee for copying, mailing or other costs associated with your request. We may deny your request to inspect and receive a copy in certain very limited circumstances. If you are denied access to PHI, you may request that the denial be reviewed.

D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.

E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record.

F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 369 / Charleston, SC 29425. The phone number is (843) 792-3881.

G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.

H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

HEALTH INFORMATION EXCHANGES

MUSC, along with other health care providers belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of patients. As a member of these exchanges, MUSC shares certain patient health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. **Please be assured that you will not be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.**

PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue / MSC 332 / Charleston SC 29425. You also may send a written complaint to the Office of Civil Rights. The address will be provided at your request.

CHANGES TO THIS NOTCE

We reserve the right to change the terms of this Notice at any time. We also reserve the right to make the revised or changed Notice effective for existing as well as future PHI. This Notice will always contain the effective date. You may view this notice and any revisions to it at: http://www.musc.edu/privacy.

EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003.
Revised September 2013