Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Neuromodulation and plasticity in cognitive control neurocircuitry in chronic stroke

NCT04655963

Concise 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 study is to determine whether non-invasive brain stimulation is a promising and safe treatment for stroke-related cognitive difficulties.

Participants will undergo an eligibility screening that assesses cognitive function including memory and attention. Once screening is complete, participants will complete an interview that assesses physical and mental health, medical, and anxiety and depression history (3 – 3.5 hours) and cognitive assessments (2 – 2.5 hours) along with a MRI scan (1 hour). In the event that you are not able to physically come to the MUSC campus such as due to COVID19 precautions, a portion of the interview can be completed remotely over the phone and video conferencing. For video conferencing, the research coordinator will send an email with a link to an approved platform, the participant will click on the link and be brought to a video call with the research coordinator where they will be able to see and hear the coordinator.

These tasks can be scheduled for different days. If you have completed the Neuromodulation of Cognitive Control Neurocircuits for Stroke Rehabilitation study, and consent to participate in this study, then your initial intake assessment data will be used as the intake assessments for both studies, as they are identical. So you would not need to complete the first two sessions again. However, some of these assessments, specified in the procedures section may need to be repeated due to timing adherences before treatment.

After completing the forms and MRI scan, participants will be able to begin their Transcranial Magnetic Stimulation (TMS) treatment visits. All participants would then receive treatment on three different days. To allow some flexibility in scheduling, the three days of treatment can be completed within eight days. On each treatment day, you would receive repetitive TMS (rTMS) in three-minute sessions, each separated by 10-15 minutes.

After treatment sessions, during the breaks, you will be asked to complete computerized

cognitive training exercises. These cognitive training exercises have been used in an array of studies, most focusing on cognitive improvement and brain plasticity. The exercises fall under one of six categories: brain speed, memory, attention, people skills, intelligence and navigation. Each exercise takes less than 10 minutes to complete. All together you will be completing 20 minutes per day of treatment, over the three days of treatment, as well as during any days between treatment visits. We will also ask that you complete 20 minutes per day of these exercises during the one-month post-treatment completion until your one-month follow-up call. We will provide you with your own username and password and show you step by step how to access these exercises from home. We ask that you try to complete as many exercises as you can on intervening treatment days and for 4 weeks following treatment completion. We will be contacting you once a week for 4 weeks after treatment completion to check in on your progress.

After the final treatment session participants will meet for an in-person appointment to repeat the initial assessment (cognitive assessments and questionnaires) as well as the MRI scan. The participants will receive a phone call approximately one month after the final TMS treatment visit to complete brief forms about difficulties related to the stroke, cognitive function, and thoughts about the treatment. For 4 weeks after the end of treatment, participants will be emailed questionnaires and asked about their use of the computerized brain games. Total study duration is about one and half months.

There are risks to the study treatment that are described in this document. Some of the risks include potential risk of seizure, worsening of neuropsychiatric symptoms, effects on brain tissue, changes in cognitive function, hearing loss, facial twitching or skin irritation, risk of a first-degree burn, delay of other psychotropic treatments, and MRI risks. Participation in this study may improve your physical and mental wellbeing, but that cannot be guaranteed. You do not have to participate in this study. If you are interested in learning more about this study, please continue to read below.

A. PURPOSE OF THE RESEARCH

The goal of this pilot study is to determine whether non-invasive brain stimulation is a promising and safe treatment for stroke-related cognitive difficulties, particularly when delivered over a shorter time period than is typical in treating difficulties like depression. If you are interested in learning more about this study, please read this consent form closely and ask any questions you may have.

Repetitive transcranial magnetic stimulation (rTMS) is an FDA approved treatment for depression. In studies of rTMS for depression and other disorders, individuals have experienced improved cognitive function. Thus, we are testing here whether cognitive function in individuals with chronic stroke could be improved.

Repetitive transcranial magnetic stimulation (rTMS) works by rapidly turning a focused magnetic field on-and-off repeatedly over your head, which passes directly through your hair, scalp, and skull and onto your brain, and can temporarily increase brain activity under the magnetic field. Previous studies using rTMS have shown that it is an effective antidepressant treatment. The treatment used in this study is different from the FDA approved treatment because you will receive 24 treatments over three days instead of 24 treatments over 24 days. This sort of accelerated or high dose protocol has been shown to be safe and effective in reducing depressive symptoms in psychiatric patients. We are hoping to find out if this treatment is acceptable to individuals who have experienced cognitive difficulties related to a stroke and to evaluate the safety of this in terms of cognitive function as well as brain structure and function.

You are being asked to participate in this study because you experienced a stroke at least 6 months ago and you have experienced difficulties on cognitive function as a result. Your total participation would include an initial assessment and MRI scan. Treatment would then consist of three half-day sessions followed by another assessment and scan. To allow some flexibility in your schedule, three days of treatment would be completed within eight days. For 4 weeks after the end of treatment, participants will be emailed questionnaires and asked about their use of the computerized brain games. You would then receive a telephone call follow-up approximately one month after treatment completion.

Participation is entirely voluntary. Your participation may help us develop a treatment for cognitive impairment in stroke. At present, there is no FDA-approved treatment for cognitive impairment in stroke. If you consent and then change your mind at any time you are free to discontinue. Some participants receiving rTMS experience headaches and thus choose to stop.

The investigator in charge of this study is Lisa M. McTeague, Ph.D. This study is being done at one site and will involve approximately 40 volunteers.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of the Dr. McTeague's and her research team's salaries will be paid by this grant.

B. PROCEDURES

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

You will meet with research staff once to sign up for the study and learn about your stroke and related cognitive difficulties as well anxiety and depression. You will then complete an MRI scan of your brain. With study personnel, you will choose a 3-day treatment schedule that best suits your other demands such as your work, family, and healthcare. On each of three days, you will receive eight, three-minute treatments of rTMS. These will be separated by 10-15 minutes or more if you would prefer. Once for a follow up after treatment you will complete the same tests to see if the TMS helped your cognitive function as well as anxiety and depression. You will receive a phone call each week for 4 weeks after treatment to remind you to complete the PROMIS measures each week. On the 4th week after treatment completion, we will also administer a short test of cognition over the phone.

At your first session: Motor/Emotion Measures (3 – 3.5 hours)

1) If you are female of childbearing age, you will be asked to complete a urine pregnancy test as the first step. You cannot participate in this study if you are pregnant.

2) Research coordinators will use TMS to find your motor threshold.

3) You will be asked to complete several questionnaires and assessments of your motor capabilities and emotional functioning. These questions will ask about your physical and mental health, medical, anxiety and depression history often associated with stroke. During some of these assessments your audio will be recorded for quality control purposes. Some of these assessments and questionnaires can be completed remotely, due to participation restrictions and COVID19 precautions.

At your second session: Cognitive Assessments (2 – 2.5 hours)

1) You will be asked to complete several cognitive assessments, some paper and pen while others are computerized. You will also be given a questionnaire about these cognitive assessments. During some of these assessments your

audio will be recorded for quality control purposes.

*Although this session may be skipped due to previous completion in the Neuromodulation of Cognitive Control Neurocircuits for Stroke Rehabilitation study, it may need to be repeated if the time before treatment extends too long. This will be determined by the investigator.

** This session may be completed on the same day as the first session.

At your third session (1 – 1.5 hours)

1) You will complete an MRI scan. MRI machines use a strong magnet and radiofrequency magnetic fields to make images your body. You will be asked to lie on a long narrow couch while the machine gathers data. During this time, you will not be exposed to x-rays, but rather a strong magnetic field and radiofrequency magnetic fields, which you will not feel. You will, however, hear repetitive tapping noises that arise from the Magnetic Resonance scanner. We will provide earplugs or headphones that you will be required to wear. There will be a device that looks like a birdcage around your head, which helps to make the images of your brain. The space within the large magnet in which you lie is somewhat small, although we have taken steps to relieve the "claustrophobic" feeling. If you feel uncomfortable in the scanner, you are free to discontinue at any time. During this we will collect a picture of the structure or your brain (structural MRI) as well as a scan of how different brain areas communicate (functional MRI) while you are at rest and while you receive short pulses of TMS.
2) This session could be scheduled on the same day as your first session, if that works best for your schedule. We typically try to separate these to give you a bit of a rest, but you should let us know what would be most convenient for you.
3) *Although this session may be skipped due to previous completion in the Neuromodulation of Cognitive Control Neurocircuits for Stroke Rehabilitation study, it may need to be repeated if the time before treatment extends too long. This will be determined by the investigator.

How your amount of TMS will be determined.

All participants will receive active rTMS shown to be effective in treating depression.

On your treatment visits:

Again, repetitive transcranial magnetic stimulation (rTMS) works by rapidly and repeatedly turning a focused magnetic field on-and-off over your head, which passes

directly through your hair, scalp, and skull and onto your brain, and can temporarily increase brain activity under the magnetic field.

1) You will join us for a total of 3 treatment days. During these days, you will receive spaced treatment sessions, each of which takes approximately three minutes delivered over approximately four hours.
2) Prior to your first treatment, we will determine the intensity of TMS for you. In order to do that we will put the TMS coil over the part of your brain that moves your hand, and find the lowest amount of magnetic stimulation needed to move your hand.
3) You will then receive 8 treatments each day. Each treatment takes about 3 minutes. You will wait at least 10-15 minutes between treatments. You can wait longer between same-day sessions if you prefer. Just let us know.
4) After some treatments, during the 10-15 minute break, you will complete some of the cognitive training exercises. By the end of the treatment day you will have completed a total of 20 minutes of the exercises.
5) You will complete a short-computerized form each day.

After your final TMS treatment visit:

1) We will meet with you in person for an appointment immediately after finishing your three days of treatment to repeat the initial assessment (cognitive assessments and questionnaires) as well as the MRI scan.
2) For 4 weeks after the end of treatment, you will be emailed questionnaires and asked to continue your practice of computerized brain games.
3) You will also receive a video conference call approximately one month after your final TMS treatment visit. During that time, you will complete brief forms about difficulties related to your stroke as well as brief questions about your cognitive function and your thoughts about the treatment.

Birth control precautions.

If you are a woman of childbearing potential and /or a man capable of fathering a child before, during, and/or after participation precaution should be taken. Examples of acceptable methods of birth control for participants involved in the study includes: birth control pills, patch, IUD, condom, sponge, diaphragm with spermicide, or avoiding sexual activity that could cause you to become pregnant.

If a participant (is or) becomes pregnant, the rTMS might involve risks to the embryo or fetus, which are currently unforeseeable.

Early withdrawal from study.

You have the right to withdraw from the clinical investigation at any time. The Investigator for any of the following reasons may discontinue your participation.

- You are found to have entered the study in violation of the protocol.
- You withdraw consent to participate in the study.
- You are noncompliant with procedures set forth in the protocol.
- You experience an Adverse Event that warrants withdrawal from the study.
- It is in the Investigator's opinion that it is not in your best interest to continue.
- You display abnormal laboratory, medical or clinical findings for which clinical intervention should take precedence over study participation including:
- a) Development of mania/hypomania
- b) Generalized seizure
- c) Inpatient hospitalization

The Investigator reserves the right to discontinue study participation for any individual who is determined to be a threat to self, staff or other study participants or who is unable to complete the study assessments, sessions or provide informed consent.

C. DURATION

Participation in the study will take about 6 visits over a period of 1-2 weeks, followed by one phone call at one month after treatment is completed.

APPROXIMATE PARTICIPATION TIMELINE

Session Number	Task Description	Location at Medical University of South Carolina	Approximate Time Commitment
1	**Session 1:** Consent* Motor/Emotion Measures*	Brain Stimulation Laboratory in the Institute of Psychiatry	3 – 3.5 hours
2	**Session 2:** Cognitive Assessments	Brain Stimulation Laboratory in the Institute of Psychiatry	2 – 2.5 hours
3	**Session 3: MRI scanning** Safety Screen	Center for Biomedical Imaging	 5 minutes

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	MRI Scans		1 - 2 hours
4 - 6	**Session 4 - 6: Treatment** Safety Screen 8 x 3min treatment sessions Computerized Cognitive Training Questionnaires	Center for Biomedical Imaging	 5 minutes 2 – 3 hours
7	**Treatment Completion Assessments** Cognitive Assessments Questionnaires	Brain Stimulation Laboratory in the Institute of Psychiatry	2.5 – 3 hours
8	**Treatment Completion Scans** Safety Screen TMS-fMRI scans Resting Scan	Center for Biomedical Imaging	1.5 – 2 hours
9	**1 – 4 weeks post treatment completion** Computerized Cognitive Training Questionnaires	Online	15 – 30 minutes
10	**4 weeks post-treatment completion** Phone assessment	Phone and Online	15 – 30 minutes

*Option to complete remotely due to COVID-19 precautions

D. RISKS AND DISCOMFORTS

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with Dr. McTeague if you have any questions.

Common adverse events occurring in approximately 15% of subjects:

Risks of Emotional Distress. You will be asked at some of these appointments to think and talk about emotional experiences including difficulties related to anxiety and depression. This may cause you to become upset, especially if you have been trying to avoid these thoughts. If you want to discontinue at any time, let Dr. McTeague and her staff know. Dr. McTeague will immediately meet with you privately to discuss how you are feeling, how to manage your distress, and to plan follow-up care if necessary.

Common adverse events occurring in approximately 5% of subjects:

TMS & Pain. Some people report some mild discomfort when the magnetic pulses are applied over the scalp, and a small number of people (approximately 5%) report headache or toothache following TMS. However, these side effects are temporary and manageable with common over-the-counter pain remedies, such as Acetaminophen or Ibuprofen. You will be monitored closely for any potential side effects including any discomfort and headaches. We will discuss with you how to manage the side effects if they occur. As concerning TMS and more severe and chronic pain conditions, accumulating evidence suggests TMS provides temporary relief from pain, a temporary decrease in sensitivity to pain, or no effect at all.

MRI & Pain. Some people report some mild back and/or neck discomfort due to remaining still in the scanner for up to an hour at a time.

MRI & Claustrophobia. Having a MRI may mean you may be bothered by feelings of claustrophobia and by the loud banging noise during the study.

MRI & Metal. Because the MRI machine acts like a large magnet, it could move iron-containing objects in the MRI room during your examination, which could in the process possibly harm you. Precautions have been taken to prevent such an event from happening; loose metal objects, like pocketknives or key chains, are not allowed in the MRI room. If you have a piece of metal in your body, such as a fragment in your eye, aneurysm clips, ear implants, spinal nerve stimulators, or a pacemaker, you will not be allowed into the MRI room and cannot have a MRI. It is important that you consider whether you have ever been in a situation where metal fragments may have ended up in your body and you inform us of any such possibilities.

Less common adverse events occurring in 0.5% of subjects:

TMS & Seizure. TMS stimulates neurons at a level below what triggers seizures. Although TMS is generally safe and well tolerated without enduring side effects, with a sample size of several thousand patients and healthy volunteers a total 20 cases of

seizures induced with TMS were reported. The risk is estimated to be probably less than 0.5% across individuals. There has been one report of seizure in a patient recovering from chronic stroke. This individual was receiving rTMS over the motor cortex, a region more sensitive to the possibility of seizure. In this study you will receive rTMS to the frontal cortex. This part of your brain is involved in problem solving and attention and is less prone to seizure. Nonetheless, we will watch you closely for any signs of seizure throughout all procedures.

The research team has a plan for dealing with fainting and seizures, and every TMS researcher is familiar with it. If you have a seizure, you will be made to lie down with your legs elevated. An emergency response team will be called. Most seizures, including those caused by TMS, last less than 60 seconds and do not require any medication. Once you recover from the seizure, you will be seen by a neurologist. Any participant who has a seizure cannot continue with the study.

Hearing Sensitivity. The discharge of the TMS coil and the MRI scanner generate loud, sustained noises that may cause damage to the inner ear. Humans exposed to TMS have shown temporary increases in auditory threshold (especially at high frequencies) lasting at least 5 minutes and less than 4 hours. Although uncommon, tinnitus has been reported after TMS exposure. Foam earplugs can protect against these changes and you will be required to wear these during TMS sessions.

TMS & Cognitive function. There have been no reports of long-term impairment (more than a minute) in cognitive function (memory, attention, etc.) in TMS studies. Rather, modestly improved cognitive function has been observed.

Confidentiality Risks. All study records and audio recordings will be placed in a locked, secure, limited access location. Your participation in the study and the information you provide will be treated as confidential. The information we collect will contain a code number and not your name to protect your confidentiality. Codes linking numbers and names will be kept in a locked secure location and will not be accessible to anyone outside the research team. Despite these efforts to maintain subjects' anonymity and confidentiality, there is always some minimal risk of people other than the study investigators gaining access to your health information. Every effort will be made to ensure that your health information will be collected and stored in a manner that ensures the highest level of protection of confidentiality.

You should also know that if you threaten to harm yourself or others or give information about child or elder abuse, this information will be reported to appropriate clinical staff and other persons outside the research program as necessary to protect yourself and others and as mandated by law.

If you test positive for both pregnancy and illicit substances, South Carolina state law requires that the South Carolina Department of Social Services (DSS) be notified and you

will be at risk of legal action.

Incidental Findings & MRI. The scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities. The investigators for this project may not be trained to perform medical diagnosis. The investigators and MUSC are not responsible for failure to find existing abnormalities with these MRI scans. However, on occasion the investigator may notice a finding on an MRI scan that seems abnormal. When this occurs, a physician will be consulted as to whether the findings merit further investigation, in which case the investigator will contact you and your primary care physician and inform you of the finding. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The investigators, the consulting physician, and MUSC are not responsible for any examination or treatment that you undertake based on these findings. Because the images collected in this study may not comprise a proper clinical MRI scan, these images will not be made available for diagnostic purposes.

Other risks relate to finding out that you may have a medical abnormality that you had not been aware of before. This knowledge could cause psychological stress to you or your family and possibly affect your health insurance coverage in the future.

Unknown Risks. The experimental treatments may have unknown side effects. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

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.

This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless you have consented to the disclosure. More specifically, identifiable information or biospecimens will not be shared with your medical providers who are not involved in this research unless you authorize the study to disclose information to them, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must authorize the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include: child abuse and neglect, or harm to self and others, but there could be others.

Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

F. BENEFITS

You will receive a number of rTMS treatments that has been used to treat depression and improve cognitive function but over fewer days. You may experience improvement of cognitive and depressive symptoms and related difficulties, in a shorter period of time than is typical. However, this cannot be guaranteed. It is hoped that the information gained from this study will help the investigators learn more about how to better offer rTMS individuals recovering from stroke. There is the possibility of no direct benefit.

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, effort and travel expenses, you will be paid $500 for participation in this study. If you do not complete the study, you will receive the following for each completed procedure:

Consent & Session 1:	$40 for screening and pre-treatment assessments
Session 2:	$50 for the pre-treatment MRI
Sessions 3 to 5:	$120 for rTMS treatment (i.e. $40/day)
Sessions 6:	$50 for post-treatment assessments
Session 7:	$50 for post-treatment MRI
Session 8:	$42 for post-treatment questionnaires (i.e.$14/wk over 3 weeks)
Computerized Exercises:	$4.50/completed 20-minute session (up to $126)

Session 9:	$22 for post-treatment questionnaires at 4 weeks follow-up
Total:	$500 per participant upon the completion of all procedures.

You will receive payments after completion of each Session and after 3 days of TMS.

In the event that you are to complete any portions of the visits remotely, you will receive remuneration appropriately. After remotely completing the consent, safety screen, and a portion of the interview you will receive $20, this amount may be paid by check or cash and mailed to you if withdraw or discontinuation happens before you come in for an in person visit. When you are able to physically come into the lab to complete the Initial diagnostic assessment and cognitive measures you will receive $20. You will then be paid according to the above payment schedule for the rest of the study sessions.

Payment for study visits will be made using a pre-paid debit card, called a ClinCard, cash or checks. The pre-paid debit card 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. At the discretion of the investigator and in the event that any portion of the study is completed remotely, the ClinCard, cash or check may be mailed to you which could take some time anywhere from a few weeks to a month.

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 any study related injury occurs further information may be obtained from the Medical University of SC Hospital Medical Director (843) 792-9537 concerning medical treatment.

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

You will be provided an oral description and summary of your results over the course of the study. If you would like, we will also provide referrals for follow-up care. Additionally, if you would like your results forwarded to another healthcare professional, we will ask you to sign a release of your research related medical records.

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.

M. SIGNIFICANT NEW FINDINGS

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

N. STUDENT AND EMPLOYEE PARTICIPATION

If you are a student or trainee in the MUSC system, 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. Similarly, if you are an employee in the MUSC system 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. If consenting on paper, please initial by your choice below and if consenting electronically scroll to the bottom of the screen and indicate your choice by selecting 'yes' or 'no' and then initial the statement confirming your choice in the item that follows.

____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.

If a participant has completed the Neuromodulation of Cognitive Control Neurocircuits for Stroke Rehabilitation study, Pro00086015, and would like to participate in this study, then their initial intake assessment data will be used, as the intake assessments for both studies are identical.

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 Lisa M. McTeague, Ph.D. at (843) 792-8274. 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.

If you wish to participate, you should sign below if consenting on paper; if you are consenting electronically you should scroll to the bottom of the screen to sign.

_____

Signature of Person Obtaining Consent Date *Name of Participant

_____

Signature of Participant Date

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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.

UNDERSTANDING YOUR PROTECTED HEALTH INFORMATION (PHI)
The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, MUSC Physicians Primary Care, MUSC Health Partners, MUSC Health Alliance, MUSC Strategic Ventures, LLC, and MUSC Strategic Ventures (MSV) Health, Inc.) 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." **We collect, receive, or share 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.**

OUR PLEDGE REGARDING YOUR HEALTH INFORMATION
MUSC is committed to protecting the privacy of health information we create and obtain about you. This Notice tells you about the ways in which we may use and disclose health information about you. It also describes your rights and certain obligations we have regarding the use and disclosure of your health information. We are required by law to: (i) make sure your health information is protected; (ii) give you this Notice describing our legal duties and privacy practices with respect to your health information; and (iii) follow the terms of the Notice that is currently in effect.

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. Business Associates. Your medical information could be disclosed to people or companies outside our Health System who provide services. These companies typically are required to sign special confidentiality agreements before accessing your information. They are also subject to fines by the federal government if they use/disclosure your information in a way that is not allowed by law.
5. 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.
6. 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.
7. 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.
8. Judicial and administrative proceedings. Your PHI may be released in response to a subpoena or court order.
9. Law enforcement or national security purposes. Your PHI may be released as part of an investigation by law enforcement or for continuum of care when in the custody of law enforcement.
10. Military and Veterans. If you are a member of the U.S. or foreign armed forces, we may release your medical information as required by military command authorities.
11. Uses and disclosures about patients who have died. We may provide medical information to coroners, medical examiners and funeral directors so they may carry out their duties.
12. 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.
13. Research. We may use and disclosure your medical information for research purposes. Most research projects are subject to Institutional Review Board (IRB) approval. The law allows some research to be done using your medical information without requiring your written approval.
14. 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.
15. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.
16. Marketing. We may send you information on the latest treatment, support groups, reunions, and other resources affecting your health.
17. 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.
18. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.
19. Disaster Relief Efforts. We may disclose your medical information to an entity assisting in disaster relief efforts so that your family can be notified about your condition.
Note: incidental uses and disclosures of PHI sometimes occur and are not considered to be a violation of your rights. Incidental uses or disclosures are by-products of otherwise permitted uses or disclosures which are limited in nature and cannot be reasonably prevented.

B. You may object to the following uses of PHI:
1. Inpatient hospital directories. Unless you tell us not to, we may include your name, location, general condition and religious affiliation in our patient directory so your family, friends and clergy can visit you and know how you are doing.

2. Information shared with family, friends or others. Unless you tell us not to, 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. Mental Health Records unless permitted under an exception in section A.
3. Substance Use Disorder Treatment records unless permitted under an exception in section A.
4. 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 and/or appointment reminders 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/or receive a copy (an electronic or paper copy) of your medical and billing records or any other of our records 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 cost-based fee. MUSC will act on a request for access or provide a copy usually within 30 days of receipt of the request. We may deny your request in limited circumstances. If you are denied access to your records, you may request that the denial be reviewed by a licensed health care professional. Additionally, we may use and disclose information through our secure patient portal which may allow you to view and communicate with certain health care providers in a secure manner. For more information see our https://mychart.musc.edu/mychart/
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. Notification will be provided within 60 days.
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 349 / 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 U.S. Dept. of Health and Human Services, Office for Civil Rights. The address will be provided at your request or by visiting www.hhs.gov/ocr/privacy/hipaa/complaints/.

CHANGES TO THIS NOTICE

We reserve the right to change the terms of this Notice at any time. The changes will apply to all existing PHI we have about you.. This Notice will always contain the effective date and may be reviewed at http://academicdepartments.musc.edu/musc/about/compliance/privacy.html

EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003 and was last revised on August 2018.

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