Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Concomitant sensory stimulation during therapy to enhance hand functional recovery post stroke

NCT04569123

SUMMARY

You are being asked to consent to participate in a research study. Your consent is voluntary. The purpose of this study is to determine the safety and effectiveness of using wrist vibration during upper limb therapy compared with therapy alone in stroke survivors. The participation will last 2.5 months, involving about 25 visits. You will be asked to participate in an upper limb therapy program (1-2 hours/session, 3 sessions/week for 6 weeks) while wearing a watch on your affected wrist. The watch will provide either treatment vibration or no vibration. You will also be asked to participate in assessments of your upper limb function and brain activity. Potential risks include irritation or discomfort from the watch or the vibration, physical and mental fatigue from engaging in the study activities, discomfort in having sensors on your body. In addition, MRI (Magnetic Resonance Imaging) will be administered to obtain the brain image, and TMS (Transcranial Magnetic Stimulation) will be administered to identify the area of the brain that controls the hand muscle. If you have any contraindications associated with MRI or TMS (i.e., metal in your body, implanted medical devices, etc), you will not complete MRI or TMS in the study. The potential benefit is that the vibration, if received, may help hand functional recovery, although this cannot be guaranteed. The knowledge regarding the potential of using vibration to augment recovery may guide rehabilitation for stroke survivors in general. Alternatives to participating in this study include standard occupational therapy or physical therapy.

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. You are being asked to participate in this study because you have experienced a stroke at least 6 months ago and have an upper limb impairment. Use of watch vibration to increase upper limb recovery has not been approved by the FDA. The study is sponsored by the Medical University of South Carolina. The investigator in charge of this study at MUSC is Na Jin Seo, PhD. The study is being done at 1 site. Approximately 76 people will take part in this study.

B. PROCEDURES

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

1. You will have the physical exam and medical history to make sure that you are eligible. You will also complete a safety screening as a precautionary measure to identify any contraindications to testing procedures such as TMS (Transcranial Magnetic Stimulation) and

MRI (Magnetic Resonance Imaging). These include the presence of any metal in your body and history of epilepsy. You may still be eligible to participate in this study if you have any of these contraindications; however, you will be excluded from participating in these tests. The risks associated to pregnant women are unknown. If you are pregnant, think you are pregnant, or are trying to get pregnant please notify study staff. If you are pregnant, we will not include you in these tests. If you are a woman and of childbearing age, you will be asked to take a urine pregnancy test. This is to make sure that you are not put at risk during any parts of the study.

2. If you are eligible for the study, you will be randomly assigned to one of two groups. This means that you have a 50/50 chance (like flipping a coin) of being in either group. Neither the researchers nor you will make the choice to which group you are assigned. The two groups are Group A (receiving vibration during therapy) and Group B (receiving no vibration during therapy). The Group A's vibration will be adjusted to the level that you cannot feel. Thus, regardless of which group you are in, you will not be able to feel vibration.

3. For both groups, you will be asked to participate in an upper limb therapy program (1-2 hours/session, 3 sessions/week for 6 weeks) while wearing a watch on your affected wrist. The watch will vibrate for Group A or not vibrate for Group B. The therapy program involves repeating challenging upper limb tasks that are relevant for activities of daily living. To improve upper limb use at home, your hand use in daily tasks will be monitored and encouraged

4. You will have 7 assessment visits. Specifically, you will have three assessment visits before therapy, two assessment visits after therapy, and two visits 1 month after therapy completion. Each assessment visit will take approximately 2-5 hours.

5. The assessment visits will include assessment of upper limb function, TMS, EEG (electroencephalogram), and Magnetic Resonance Imaging (MRI).

   For upper limb function, you will be asked to move your hand and arm and move objects around the table with the hand as best as you can, while being videotaped. Position sensors will also be placed on the hand and arm using tape. You will also answer questions regarding your perceived abilities for activities of daily living and perception of the intervention. You will also be asked to wear an accelerometer on each wrist for 3 full days. This device measures your activity (similar to tracking your steps) throughout the day.

   TMS is administered to identify the area of the brain that controls the hand muscle. Because of the stroke, the typical brain area that controls the hand muscle may no longer be available and other part of the brain may be in use to control the hand muscle. TMS is used to identify the functional brain area for the hand.

   For TMS, you will be seated and rest, while a noninvasive brain stimulation using TMS is delivered. During this time, a clicking sound will be heard as the paddle produces magnetic energy which you may feel as a light tap against your scalp. The magnetic pulse stimulates the brain nerves controlling your hand. Therefore you may or may not feel your hand muscle briefly twitch depending on the strength of the TMS pulse. You might also feel your facial muscles twitch slightly around your eye. This twitch is a result of the TMS directly stimulating the facial nerves and muscles that run directly under your scalp. The TMS pad may be moved around your head until the best position is located to give a contraction of the hand muscle.

This contraction will be measured by a muscle activity sensor that will be placed on your hand skin with a sticky pad and/or tape.

For EEG, you will wear a cap containing electrodes on your head. The electrodes will record your brain activity. These electrodes contain gels which can make your hair messy. You may want to bring a hat to wear after this assessment. You will be seated and either rest or grip with your hand.

In addition, you will have a Magnetic Resonance Imaging (MRI) exam one time. You will lie down on a narrow bed which will then be placed in a tunnel that is 6 feet by 22 inches wide and open at each end. You will lie there quietly for about 20 min, during which time you will hear a loud noise. You may feel warm during this procedure.

You may be withdrawn from the study without your consent if the researchers believe it is in your best interest or if you fail to follow study procedures.

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.

____Yes, I agree to allow the data collected in the study to be included in the RESTORE Database.

____ No, I do not agree to allow the data collected in the study to be included in the RESTORE Database.

C. DURATION

Participation in the study will take about 25 visits over a period of 2.5 months.

D. RISKS AND DISCOMFORTS

1. **Loss of confidentiality**: There is a risk of a loss of confidentiality of your personal information as a result of participation in this study.

2. **Randomization**: You will be assigned to a group by chance. The treatment you receive may

prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.

3. **Placebo**: If you are in the control group, your condition will go without active treatment except for therapy for 6 weeks.

4. **Vibration**: If you are in the group that receives vibration, prolonged vibration may numb although it is very unlikely because the vibration you will receive is very small to the extent that it is imperceptible.

5. **EEG**: It may be uncomfortable to wear a head cap attached with a bundle of wires during evaluation. Also, the gel used for the electrodes will get your hair messy. The gel is washed off with shampoo.

6. **TMS**: Historically, transcranial magnetic stimulation has been thought to increase a chance of inducing an epileptic seizure in a small population of people. However, more recent extensive review studies suggest such concerns would not be applicable to the current uses of magnetic stimulation. You cannot participate if you have any implanted biomedical devices in or above the chest (e.g., pacemakers, cochlear implants, etc.). There is also a possibility that you may experience a mild short-lasting headache after the experiment. Some other common minor short-term side effects include: scalp discomfort at the stimulation site, tingling or twitching of facial muscles, lightheadedness, and discomfort from stimulation noise. Uncommon but theoretically possible side effects include: seizures, hearing loss, and cognitive impairment. To avoid these uncommon and more serious side effects, the exclusion criteria of this study exclude individuals with epilepsy and metal implants. Please let us know if the headaches cause you to want to withdraw from these experiments. Safety of TMS in pregnancy is unknown. If you are pregnant, you should not have the TMS stimulation. You will have to pass a TMS screen to decrease the risk of adverse events.

7. **MRI**: 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 pocket knives 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. Having a MRI may mean some added discomfort to you. In particular, you may be bothered by feelings of claustrophobia and by the loud banging noise during the study. Temporary hearing loss has been reported from the loud noise. This is why you will be asked to wear earplugs. At times during the test, you may be asked not to swallow for a while, which can be uncomfortable. If you are pregnant, you should not have MRI.

8. **Others**: There is a risk of physical and mental fatigue from engaging in the study activity. There is a minor risk of skin irritation from wearing the watch. There is a minor risk of discomfort in moving the arm/hand while wearing a watch on the wrist. The use of tape or other adhesives to secure sensors during testing may cause mild skin irritation.

9. **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.

CERTIFICATE OF CONFIDENTIALITY

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.

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

There will be no direct benefit to you from participating in this study. The potential benefit to you is that the treatment you receive may prove to be more effective than the other study treatment or than other available treatments, although this cannot be guaranteed.

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 $15 per therapy visits for a total of 18 times, $75 for the complete assessments ($55 if no TMS) for a total of 3 times, $15 for weekly clinical assessment for a total of 6 times, and $20 for the one-time MRI exam. If you complete all evaluations, you will receive a total of $605. If the payment per visit is less than the IRS-issued standard business mileage rate for your driving, you will be reimbursed the IRS-issued standard business mileage rate for round trip instead of the visit payment amount. If you use taxi, your taxi cost may be covered, and your visit payment will decrease by half. We can also discuss alternative methods that cost less (e.g., accommodation). You will receive payments for only the sessions you complete. If you stop participating in the study, you will keep the payments you already received and will not receive additional payments.

Payments for taking part in this research study will be put onto a "ClinCard". The card will be provided to you and payment will be loaded approximately biweekly. ClinCard is managed by a company named Greenphire. Your personal information, such as your name, date of birth, and social security number will be shared with Greenphire in order to put study payments onto the ClinCard. While the ClinCard is not a credit card, Greenphire may use your information like a credit card company would. You should review the terms and conditions of ClinCard when deciding whether to take part in this study, which will be made available to you.

If you are found ineligible to participate in the study at your first visit, you will be paid $10 to compensate for your time and expenses.

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. Mileage reimbursements are not taxable.

If you have transportation restrictions (inability to safely drive yourself, lack of caregiver who can provide transportation, inability to safely take public transportation) that would prevent you from otherwise being able to participate in this study, we can request approval for transportation assistance. Upon approval, we can offer you transportation via taxi from your home to and from study visits. If needed, we can offer a taxi with wheelchair accessibility.

I. ALTERNATIVES

If you choose not to participate in this study, you could receive other treatments for your condition. The standard therapy for your condition is occupational therapy or physical therapy.

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.

K. DISCLOSURE OF RESULTS

Your test results will be disclosed to you upon your request.

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.

In addition to the main study, you have the option of participating in the optional research. Your protected health information may be used or shared with others outside of MUSC for this research as well. Please initial below if we may use/disclose your protected health information for the optional research portion/s of this study.

____ Yes, you may use my protected health information for the optional research portions of this study.
____ No, you may not use my protected health information for the optional research portions of this study.

M. SIGNIFICANT NEW FINDINGS

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

N. 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.

O. 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.

P. 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.

Q. 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. Na Jin Seo at 843-792-0084**. 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

MUSC
Medical University of South Carolina

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.