Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Characterization of Physiological Changes Induced Through Motor Evoked Potential (MEP) Conditioning in People with Spinal Cord Injury (SCI)
NCT04286191
Principal Investigator: Aiko Thompson

You are being asked to volunteer for a research study. Participation is completely voluntary. Research studies include only people who choose to take part. The purpose of this research study is to examine the effect of a brain stimulation training to improve the function of brain-spinal cord- muscle connections.

If you agree to participate, we will review your medical records, look at the way you move your legs during walking, and examine your muscles' responses to movements and brain or nerve stimulations. This will help us determine if it is safe for you to participate and if our training studying is appropriate for you. This study will require about 60 visits over the first 3.5 months, and another 8 visits over the additional 3 months. Each visit will take about an hour.

This study is experimental and guarantees no direct benefits to you. There may be benefits to many people after spinal cord injury. The risks of this study include mild discomfort and loss of confidentiality. Researchers will take appropriate steps to protect any information they collect about you. There is no penalty for declining to participate. Outside of research like this study, currently there are no medical treatments to improve the brain-spinal cord-muscle connections after spinal cord injury; however, to improve the ability to use/move your leg, you could seek standard physical therapy treatment.

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

A. PURPOSE OF THE RESEARCH

Over many years, researchers have found that the brain-to-muscle connections are very flexible and change in response to injury or training. Because these pathways are very important for producing and controlling movements, strengthening them may help to improve movement recovery after injuries. To examine the brain-spinal cord-muscle connections, We use transcranial magnetic stimulation (TMS), which is a minimal risk device cleared by the FDA. TMS can stimulate brain cells with little or no discomfort.

This study is to examine the effect of a brain stimulation training to improve the function of brain-spinal cord-muscle connections. Spinal cord injury causes damage to the brain-spinal cord-muscle connections. However, when the injury is "incomplete", there is a possibility that some of these pathways are still connected and may be trained to improve movement function. We hope that the results of this training study will help us develop new treatments for people who have movement disabilities.

Please read this consent form carefully and take your time making your decision. As the 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 volunteer for a research study because you are an adult with a spinal cord injury. The investigator in charge of this study is Dr. Aiko K. Thompson. A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Aiko K. Thompson's and her research team's salaries will be paid by this grant. This study is being done at research laboratories in the College of Health Professions Research Building on the MUSC campus and approximately 44 volunteers will take part in this study.

B. PROCEDURES

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

1. To find out if you can be in the study and make sure that you are not put at unnecessary risk during the study, you will go over a few screening questions with a doctor or a clinical researcher. We may also ask to review your medical records. Examples of some of the information we will ask about is time since injury, medications you are currently taking, that you do not have a known cardiac condition, and that you do not have any implanted medical devices such as a pacemaker or a cochlear implant. If you are a woman and of childbearing age, you will be asked to take a urine pregnancy test (approx. 30 min)
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 the operant conditioning training group and the control training group.
3. You will be seated in a chair with either one of your legs secured onto a fitted form. This is to minimize movement during testing. Then, after cleaning the skin with alcohol, surface electrodes will be placed on your skin over leg and arm muscles for monitoring muscle activity. We will also place stimulating electrodes over the nerve that controls the muscle being tested. Short electrical pulses will be sent to the stimulating electrode. This may cause a brief sensation. Electrode location will be adjusted so that you will have no discomfort (approx. 5 min)
4. We will measure the greatest level of muscle activation. You will be asked to push or pull your leg as hard as you can for just a few seconds (approx. 5 min)
5. You will see your muscle activity level on the monitor. You will be asked to maintain the muscle activity level within the preset window on the screen. Shortly after you achieve the preset level, magnetic stimulation will be applied to your brain by a coil held next to your scalp. (approx. 5 min)
6. We will then find locations on your scalp where transcranial magnetic stimulation can produce a muscle response. Once we find the best stimulus location, we will record your muscle responses to different stimulus intensity levels. (approx. 5-10 min)

7. Magnetic stimulation will be applied as single-pulse or double-pulse stimulation. (approx. 25-35 min)
8. In some sessions, a cloth cap containing small metal disks for recording brain activity will be placed on your head. Small amounts of gel used in hospitals every day will be placed on each disk. After recording is finished, the gel will wash out of your hair with soap and water. (approx. 5 min set up)
9. Before, between, and after 36 brain-stimulation training sessions, researchers will assess your brain-muscle connections using electrical and magnetic stimulation and monitoring of muscle activity and joint movement during walking. For these assessments during walking, you will wear a harness attached to a support frame to make sure that you do not fall. A physical or occupational therapist will test your mobility, walking speed, and distance. You will also be asked to complete a questionnaire regarding spinal cord injury. (approx. 1 hour)
10. Remember that you always have the right to stop participation in this transcranial magnetic stimulation study at any time.
11. 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.

C. DURATION

Participation in the study will take about 60 visits over the first 3.5 months, and another 8 visits over the additional 3 months. We ask you to come in for baseline and training sessions 3 times per week for about 15 weeks, and each session will last about 1 hour.

D. RISKS AND DISCOMFORTS

1. **Confidentiality**. There is a risk of loss of confidentiality of your information that is used in this study. All the experimental data will be de-identified for the purpose of data analysis and reporting. Subject names will never be used explicitly in any presentation or discussion of the data obtained. Only the principal and co-investigators and the research coordinator will have access to the subject's confidential information. Any hard copy materials that contain the confidential information will be kept in locked cabinets for the duration of the study and then destroyed.
2. **Transcranial Magnetic Stimulation (brain stimulation)**: In a small population of people with previous history of seizure, a transcranial magnetic stimulation may induce an epileptic seizure. You cannot participate in this transcranial magnetic stimulation study if you have a history of epileptic seizures. You also 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 any seizure history, cognitive impairment, and hearing aides. Please let us know if the headaches cause you to want to withdraw from these experiments.

3. **Reactions to surface electrodes for muscle and brain activity monitoring**: There is a very small possibility that the recording and stimulating electrodes for measuring muscle activity will produce minor irritations, such as itchiness, but this is extremely unlikely in the short period (usually less than 1 hour) of experiment. If itchiness ever occurs after the experiment, an over-the-counter topical cream will be provided to apply to the skin to reduce this temporary irritation. When you wear a cloth cap with electrodes for monitoring brain activity, you may experience a transient coolness of the gel on your scalp.
4. **Pregnancy:** We do not know if the study treatment will affect mother's milk or an unborn fetus. Therefore, breast-feeding and pregnant women are not allowed to take part in the study. Women who can become pregnant must take a pregnancy test before the start of the study.
5. **Walking on the treadmill:** The risk associated with treadmill walking is no greater than the risk of regular over ground walking. To prevent a fall, you will wear a safety harness while you walk on the treadmill. If you are not comfortable walking on the treadmill, please let us know. Also, if you have a known heart problem, please let us know.
6. Randomization: If you are eligible for the study, you will be randomly assigned to one of the two study treatment groups. The treatment you receive may or may not be less effective than the other study treatment, and may or may not have more side effects than the other study treatment.
7. **Unknown Risks**: The experimental procedures 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

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

This clinical study is experimental and there will be no direct benefits to you. There may be benefits to many people with spinal cord injuries.

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 $15.00 per session (up to $750.00 + transportation costs) for study participation. The payment will be made even if you do not complete the session. You will be reimbursed at the federal mileage reimbursement rate per mile for transportation costs; or if you are using a transportation service (CARTA, etc.), the fee may be reimbursed. If you are traveling from further than 100 miles away, we can discuss other potential types of travel reimbursement (i.e. accommodations). In some of the training sessions, you may also be able to earn an extra monetary reward (up to $10/session) for the training targets met.

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: ClinCard, checks, cash, gift certificates/cards. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

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

Reimbursement for additional costs, if any, will be made directly by MUSC via check.

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.

K. DISCLOSURE OF RESULTS

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

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 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

MUSC STANDARD PARAGRAPHS:

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 investigators associated with this study, the sponsor, 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 that you are injured as a result of participation in this study, 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. 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 the study coordinator Blair Dellenbach at (843) 792-6313 or the Primary Investigator Aiko Thompson at (843) 792-7136. 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.