Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

Title of Research: Testing the effects of individualized and 4mA tDCS

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 the most effective dose of transcranial direct current stimulation (tDCS) to stimulate the motor cortex in the brain. To test this, we will deliver six different doses to each participant on different days.

If you agree to participate, you will undergo an eligibility screening that assesses the safety of your receiving a magnetic resonance imaging (MRI) scan of your brain, tDCS, single pulses of transcranial magnetic stimulation (TMS), and five single pulses of transcranial electrical stimulation (TES). In each instance, the brain stimulation will be noninvasive and applied to your scalp.

This study entails 7 experimental visits. In Visit 1, we will first determine the threshold of TMS and TES required to stimulate your motor cortex. You will then undergo a 45 minute MRI scan. In Visits 2-7, you will undergo a baseline assessment of motor cortex excitability before 20 minutes of tDCS at six different doses in a randomized order. Each participant will receive each dose on different days. We will then reassess your motor cortex excitability using single pulses of TMS every 5 minutes for 30 minutes. We will repeat this protocol 3 times per day. We anticipate that each visit will last approximately 3 hours.

There are risks to the study treatment that are described in this document. Some of the risks include potential risk of seizure, hearing loss, facial twitching or skin irritation, risk of a first-degree burn, and MRI risks. We do not anticipate that any of these side effects would last long or have enduring effects. 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 purpose of this study is to study the effects of four different doses of transcranial direct current stimulation (tDCS) on motor cortex excitability. The study will take place over seven days, with each visit lasting about 3 hours. If you are interested in learning more about this study, please read this consent form closely and ask any questions you may have.

tDCS works through electrodes placed on your scalp that pass small amounts of electrical current to your brain. tDCS is an FDA-investigational device and is not yet approved for the treatment of any brain condition. We will also use brief, single pulses of transcranial magnetic stimulation (TMS) to test your brain's response before and after applying tDCS. TMS works by passing brief amounts of electricity through a wire that passes electromagnetic current through the skin and skull and into the brain. This electromagnetic current can activate the brain, and when positioned over the motor cortex, it can cause the hand on the opposite side of the body to move. We will use electrodes attached to your right hand to measure the amount that your hand moves from TMS, and how this might change from tDCS. It is our hope that by studying how different doses of tDCS affect your brain and motor cortex, it will someday become a more widespread and effective clinical approach.

You are being asked to participate in this study because you are a healthy adult control or someone who has experienced a chronic stroke. Your total participation would include an initial MRI scan of your brain and six visits in which you receive different doses of tDCS. Each participant will receive each of four different doses of tDCS.

Participation is entirely voluntary. Your participation may help develop a method of individually dosing tDCS. If you consent and then change your mind at any time and for any reason you are free to discontinue. Some participants receiving tDCS experience mild skin irritation. 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.

The investigator in charge of this study is Mark S. George, M.D. This study is being conducted at one site (MUSC) and will involve approximately 60 volunteers.

This study is sponsored by a grant from the National Institutes of Health (NIH). This research funding will cover the expenses of the study.

B. PROCEDURES

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

You will meet with research staff to sign up for the study and learn more about the study details. If you are female, you will receive a urine pregnancy test. You cannot participate in this study if you are pregnant. We will use single pulses of transcranial magnetic stimulation (TMS) and transcranial electrical stimulation (TES) to test for your motor cortex location in your brain. TMS uses electromagnetic energy, and TES uses electrical energy, in order to stimulate your brain. We will use TMS and TES to determine where in your brain, and at what intensity, the stimulation moves your hand. Next, you will undergo an MRI scan of your brain. With study personnel, you will schedule a 6-day treatment schedule that best suits your other demands such as your work, family, and healthcare. On each of the six days, you will receive 20 minutes of tDCS at one of four different doses. We will use single pulses of TMS and electrodes placed on your right hand to test the effects of each dose on your brain and motor excitability.

In Visit 1 (approximately 2 hours)

1) You will receive single pulses of TMS and TES to determine the motor cortex location (approximately 30 minutes)
2) You will undergo an MRI scan lasting approximately 45 minutes

In Visits 2-7 (approximately 3 hours each):

1) You will receive single pulses of TMS to determine your baseline brain activity and excitability.
2) You will receive 20 minutes of tDCS at one of four different doses. This is to determine which dose might be optimal.
3) You will receive single pulses of TMS every 5 minutes for 30 minutes to determine how tDCS might have changed your brain activity and excitability. This will be repeated up to 3 times per visit with 30 minutes between each tDCS session.
4) You will fill out questionnaires that ask about any side effects that you might have experienced before and after tDCS.

How your doses of tDCS will be determined

All participants will receive active tDCS at different intensities. Two visits might involve placebo stimulation. One dose will be individualized based on your MRI brain scan.

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, it is unclear how TMS, TES, tDCS, or MRI 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 not according to the protocol.
- You withdraw consent to participate in the study.
- You are noncompliant with procedures stated 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.

If you inform research staff of an intention to withdraw from the study you will be asked to return for a final safety visit, whereby the complete range of post-treatment assessments will be performed.

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 7 visits over a period of approximately 1 month. The breakdown of sessions is as follows:

Visit 1 (TMS, TES, MRI scan) = 2 hours
Visits 2-7 (TMS, tDCS, questionnaires) = 3 hours each (total of 18 hours across 6 visits)

D. RISKS AND DISCOMFORTS

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

Common adverse events occurring in approximately 20% of subjects:

tDCS and local skin irritation. tDCS participants sometimes experience localized skin irritation that can feel like light itching/tingling/burning sensations. If prevalent, this often occurs at the start of tDCS and dissipates over time. Note that while every tDCS dose has previously been used and has been found to be safe, this trial is the first to study the functional effects of certain doses.

Common adverse events occurring in approximately 5% of subjects:

tDCS and fatigue/nausea. Some participants experience mild fatigue during tDCS that does not usually last longer than when the stimulation is applied. Similarly, some participants experience mild nausea during stimulation that usually does not persist past when the tDCS is applied.

MRI and pain. Some people report some mild back and/or neck discomfort due to remaining still in the scanner.

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

TMS and headaches: Some people report some mild discomfort when the magnetic pulses are applied over the scalp, and a small number of people (~5%) report headache following rTMS. However, the headaches are temporary and manageable with common over-the-counter pain remedies. In addition, we will stimulate over the motor cortex which further reduces the likelihood of headaches.

Less common adverse events occurring in fewer than 0.5% of subjects:

tDCS and skin burning. It is possible that tDCS could burn the skin underneath the electrode. To reduce the likelihood of this occurring, we will carefully dampen the sponges with fluid and ask for your feedback throughout the tDCS application.

MRI and 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 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. 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.

TMS and seizure. TMS stimulates neurons at a level below what triggers seizures. Although single pulses of TMS are generally safe and well tolerated without enduring side effects, a total of 8 cases of seizure have been induced out of likely millions of stimulation sessions from similar TMS protocols. The risk is estimated to be less than 0.5% across individuals. Nonetheless, we will watch you closely for any signs of seizure throughout all procedures. This will include sensors that we will place on your hand. These will provide very early signs of seizure risk and we will immediately discontinue if warranted.

TMS and hearing loss. The TMS pulses can generates a high-energy click that may cause damage to your hearing. Humans exposed to TMS have shown temporary

increases in the lowest audible intensity of sound (especially at high frequencies) lasting at least 5 minutes and less than 4 hours. However, this research study will use low frequency TMS (<1 pulse per second). In addition, foam earplugs can protect against these effects and will be worn during TMS sessions.

TES and seizure. There is a theoretical risk that TES might induce a seizure. The risk is extremely low (probably <1 in 10,000) because we will be administering single pulses of TES, and all pulses except for the last one, are not even powerful enough to make your thumb twitch. The study personnel are trained in managing a seizure should it occur. The other main risk of TES is that it is not comfortable, and can hurt. We will work with you to minimize the discomfort, and you are free to stop the TES if it is too uncomfortable for you.

Confidentiality Risks. All study records 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.

Incidental Findings from 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

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

F. BENEFITS

There will be no direct benefit to you from participating in this study. However, it is hoped that optimizing tDCS dose in healthy adults or chronic stroke could advance the ability of tDCS to effectively treat multiple neurological and psychiatric conditions including stroke, depression, mild cognitive impairment, and others. We hope that these findings will help to inform future clinical trials using tDCS at optimized doses.

G. COSTS

There will be no cost to you as a result of participation in this study. The costs of all tests associated with this study will be covered by the study.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid $350 for completing this study. If you do not complete all study visits, you will receive the following for each complete procedure:

- Visit 1 (including the TMS and TES procedure and MRI scan): $50
- Visit 2 (tDCS Visit 1): $50
- Visit 3 (tDCS Visit 2): $50
- Visit 4 (tDCS Visit 3): $50
- Visit 5 (tDCS Visit 4): $50
- Visit 6 (tDCS Visit 5): $50
- Visit 7 (tDCS Visit 6): $50

For study visits compensating using ClinCard service, payments 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, outlined in the payment schedule above.

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.

I. ALTERNATIVES

This is a scientific investigation and not part of standard clinical care. This study is voluntary and you may choose to not participate in this study. Whether or not you choose to participate in this study will not affect your relationship with any current treatment provider you may have, or your right to health care or other services to which you are otherwise entitled now or in the future.

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. SIGNIFICANT NEW FINDINGS

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. 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.

N. 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.

O. 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. Mark S. George at (843) 876-5142. 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.