Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Effects of tDCS on post-stroke fatigue and inflammation

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 research study is to determine the effectiveness of transcranial direct current stimulation (tDCS) for the treatment of fatigue post-stroke. We define fatigue as a feeling of lacking physical and/or mental energy that you feel/think interferes with your ability to initiate/perform usual and desired activities that is not improved by rest/sleep. tDCS is a form of non-invasive brain stimulation and is delivered by a device powered by 9-volt batteries.

Prospective participants will undergo a 2-day screening that includes completing surveys of their mood and physical function, a blood draw, magnetic resonance imaging (MRI), and an assessment of how their nervous systems function. Once screening is complete, eligible participants will be randomly assigned to receive either the real tDCS or sham/placebo tDCS. For the investigational tDCS treatment visits, enrolled participants will be asked to come to the laboratory on five consecutive days and receive 20 minutes of real or placebo tDCS applied to the top of their heads. The screening visits will take about 2 hours and each of the investigational tDCS treatment visits will take approximately 30 min. Once a participant has completed the five days of investigational tDCS treatment, the measures performed during the screening visits will be repeated. Participants will also receive a follow-up phone call to assess their levels of fatigue one, two, and four weeks after the completion of the intervention.

Participation in this study may improve your levels of fatigue, but that cannot be guaranteed. The greatest risks of the study include irritation/minor burn of the skin and the loss of confidentiality.

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 measure the effects of a form of non-invasive brain stimulation on the severity of post-stroke fatigue and indicators of inflammation. Post-stroke fatigue is defined in this study as a feeling of tiredness/weariness that negatively affects your ability to perform social and physical activities, and is not typically relieved with rest. You are being asked to participate in this research study because you have indicated to the research staff that you had a stroke more than six months ago and are affected by fatigue.

The type of non-invasive brain stimulation used in this study is called transcranial direct current stimulation, or tDCS. The tDCS device uses a small amount of electric current passed between two pads/electrodes. The tDCS device is powered by 9-volt batteries. This device has been shown to be

safe when operated under the manufacturer's regulations and usage instructions. This method was chosen, in part, because tDCS has been reported to reduce certain indicators of inflammation and these markers may be associated with the feeling of fatigue.

If you chose to participate you will be randomly assigned to the real-tDCS or sham-tDCS group. Your group assignment will be done using a computer that randomly places you into a group. The sham-tDCS procedures are exactly like the real-tDCS procedures, except that the tDCS device will be turned off after 30 sec. In addition to this brain stimulation technique, we will also assess how your brain communicates with your muscles using another form of non-invasive brain stimulation called Transcranial Magnetic Stimulation (TMS). We will do this before and after you receive five applications of tDCS.

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 indicated that you are affected by fatigue after having a stroke. The study is sponsored by a grant from the National Institutes of Health, National Center for Neuromodulation for Rehabilitation, Portions of Dr. Kindred's salary will be paid by this grant. The investigator in charge of this study at MUSC is Dr. John H. Kindred. Approximately 24 people will take part in this study.

B. PROCEDURES

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

Visit One

You will complete several self-reported questionnaires to assess your levels of fatigue, mood, pain, and balance. Next, you will walk over a pressure-sensitive mat at your comfortable/preferred and fastest comfortable walking speeds while wearing a harness attached to the ceiling to prevent you from falling in case you lose your balance. These tasks will allow us to confirm your eligibility to participate in the study. In addition, if you are of childbearing potential, you will be asked to take a pregnancy test (urine analysis) to confirm you are not pregnant. After your eligibility is confirmed you will be scheduled for your second visit to the laboratory. This visit will last approximately 1.5 hours

Visit Two

You will undergo magnetic resonance imaging (MRI) to assess how parts of your brain are connected to each other and how your brain uses energy. We are doing this to determine how tDCS might work to reduce fatigue and what role inflammation may play in fatigue. MRI uses a magnet and radio waves to make diagnostic medical images of the body. You will be placed on a narrow bed and then slid into a small tunnel approximately 6 feet in length and 25 inches in diameter. You will hear a loud machine-like noise. This visit will last approximately 1.5 hours.

Visit Three

You will be randomly assigned to the real-tDCS treatment group or the sham/placebo treatment group prior to your arrival by an automated computer program. During this visit, you will undergo a neurophysiological examination using transcranial magnetic stimulation (TMS). The use of TMS will allow us to assess how your brain communicates with your muscles. You will be seated in a chair while the TMS magnet is turned on and off while being placed on your head. Your responses to the magnet will be recorded using sensors placed on the muscles of your lower leg. During this visit, you will also be providing a blood sample by a standard blood draw. We will collect a little more than one-half of a tablespoon of blood to measure indicators of inflammation within your blood. After the TMS assessment and blood draw, you will receive the first 20-min investigational tDCS treatment based on your random group assignment. The investigational tDCS treatment consists of 5 consecutive days of brain stimulation lasting 20-min each. During this time you will be resting in a chair comfortably with a pad placed on your head and one on your shoulder. The real-tDCS group will have a small amount of electric current applied by the tDCS device. The sham/placebo procedures are the same as real-tDCS except the current will be turned off after 30 sec. Before and after the application of tDCS we will assess your current level of fatigue. This visit will be no more than seven days after Visit One and should last approximately 3 hours.

Visit Four, Five, and Six
You will receive 20 minutes of tDCS and provide measures of your current fatigue before and after the application. This visit should last approximately 45 min.

Visit Seven
This will be your last day receiving tDCS. After you have received your last session of tDCS we will reperform the TMS examination, to see if/how your brain communicates with your muscles has changed, and you will provide a second/final blood sample, about a little more than one half of a tablespoon. This visit should last approximately 2.5 hours.

Visit Eight
In the last in-person visit you will have a second MRI performed and undergo a reassessment of your fatigue levels, mood, and pain. This visit should last approximately 1.5 hours.

Follow-up Phone Calls
You will receive a phone-call one, two, and four weeks after your last visit when you received tDCS. During these calls, we will have you answer questions about your current state/perception of fatigue and how fatigue has affected you over a certain period of days. These phone calls should take approximately 15 minutes.

Visit 1		
Consent		30 min
Fatigue, mood, pain, quality of life	Self-reported questionnaires	30 min

Walking test Pregnancy test (if applicable)	Walk over a pressure-sensitive mat w/ harness Urine analysis	10 min 10 min
Visit 2		
Brain imaging	MRI center	60 min
Visit 3		
Brain muscle connection test Blood sample Brain stimulation	Transcranial Magnetic Stimulation (TMS) Blood draw tDCS (based on random group assignment)	90 min 20 min 30 min
Visit 4 – 6		
Brain stimulation	tDCS (based on previous random group assignment)	30 min
Visit 7		
Brain stimulation Brain-muscle connection test	tDCS (based on previous random group assignment) Transcranial Magnetic Stimulation (TMS)	30 min 90 min
Visit 8		
Brain imaging Blood sample Fatigue, mood, pain	MRI Center Blood Draw Self-reported questionnaires	60 min 20 min 30 min
Follow-up		
Fatigue assessment	Phone calls 1,2, and 4 weeks after Visit 6	15 min

C. DURATION

Participation in the study will take about **8 visits over 2.5 weeks**, with three follow-up phone calls one, two, and four weeks after your last visit when you received tDCS.

D. RISKS AND DISCOMFORTS

There are risks to taking part in this research study. The risks associated with each of the individual procedures are outlined below along with the steps the study team will take to minimize those risks.

tDCS: Commonly reported side effects are as follows: local skin irritation with light itching/tingling/ burning, mild headache, or nausea. There have also been rare cases of mild burns at the procedure site.

TMS: There is a very low risk of a seizure after TMS. The risk of a seizure directly caused by this protocol has been thoroughly assessed and the TMS parameters have been chosen to be well within the medical safety guidelines for using TMS in people. To minimize your risk, we will only use one or two TMS pulses at a time, as the majority of known adverse events have occurred after using many TMS pulses in a very short period. We will follow all medical safety guidelines. If you have a history of seizures, you will not be allowed to participate in this portion of the study. You will have to pass a TMS screen to ensure you are not at risk for adverse events.

Blood Draw / Venipuncture: Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting is possible, although unlikely.

MRI: There have been no ill effects reported from exposure to the magnetism or radio waves used in this test. A known risk is that the magnet could attract certain kinds of metal. Therefore, we will carefully ask you about metal within your body (this includes certain dyes found in tattoos). If there is any question about potentially hazardous metals within your body, you will be excluded from participation in this research study. We will also keep the examining room locked so that no one carrying metal objects can enter while you are in the scanner. Please inform the study staff if you have a history of claustrophobia (extreme anxiety in close spaces). This may also be a contraindication to participation in the study.

Walking Tests: Some of the activities performed during this study will be performed while you are walking or standing. During these activities, you may lose your balance or become unsteady. To ensure that you do not fall you will be asked to wear a safety harness that is attached to the ceiling. This harness will prevent you from hitting the ground in the event you lose your balance or become unsteady.

Pregnancy: We do not know if the study intervention will affect mother's milk or an unborn fetus. Therefore, breast-feeding and pregnant women are not allowed to take part in the study. If you are pregnant or become pregnant your participation in the study will be ended as there may be risks to the embryo or fetus that are unknown at this time. Women who can become pregnant must take a pregnancy test before the start of the study.

You should not father a child while on this study as the treatment may indirectly affect an unborn child. If you are sexually active and are at risk of causing a pregnancy, you and your female partner(s) must use a method to avoid pregnancy that works well or you must not have sex.

Unless you cannot have children because of surgery or other medical reasons, you must be using an effective form of birth control before you start the study. You must also agree to continue to use an effective form of birth control for 1 month after completing the study.

Emotional Distress: The questions that will be asked may be sensitive in nature and make you feel uncomfortable. You may be asked personal questions that you find distressing. You may refuse to answer any question(s) that you do not wish to answer.

Randomization: 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.

Loss of Confidentiality: There is a risk of loss of confidentiality of your personal information as a result of participation in this study. To minimize this risk, we will use a random identification number to label

all your collected data. Any data collected on physical media will be stored in locked file cabinets where only authorized research personnel have access.

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

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

Information about your study participation will not be put 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

The potential benefit to you is that the tDCS stimulation you receive may prove to be more effective than the other study tDCS stimulation or 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 other than your transportation to and from the laboratory. A parking pass will be provided for you to park at the research building.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid up to a total of $100 for participation in this study. You will receive $25 after your initial MRI is completed, $10 for each visit you receive real or sham/placebo tDCS (5), and another $25 after the post-study follow-up phone calls.

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.

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

Your alternative is to not participate in this study.

J. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

We would like to include data collected in this study in the Clinical Database for Rehabilitation Research in Neurological Conditions. Agreeing to include your data from this study in the Clinical Database will allow researchers in the Center for Rehabilitation Research in Neurologic Conditions to have 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 participants by reducing the duplicative efforts of collecting common data and characteristics requested by multiple studies and storing them in one centralized and secure location. Please initial next to your choice to have data collected from this study shared with the Clinical Database:

_____ Yes, I agree to have the data collected shared with the Clinical Database

_____ No, I do not want to have my data included in the Clinical Database

K. DISCLOSURE OF RESULTS

There is no disclosure of results to you as part of this study.

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. CLINICAL TRIALS.GOV

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

N. COLLECTION OF SPECIMENS

For this study, we will collect and store blood samples taken from you at the beginning and end of the study period. These samples will be used to measure circulating indicators of inflammation in your blood. The analysis of these samples will be performed at the completion of the study. Additional future research may be conducted by our research group or by other researchers who obtain IRB approval for their research. This research may involve genetic studies. There are several things you should know before allowing your (tissues, cells, urine, and/or blood) to be studied or to be stored.

1. The specimens will be labeled with a code that only study personnel can link back to you. Researchers outside of this study will not be given a link between the code number and your name or any other identifying information. While we hope this will prevent any potential loss of privacy or confidentiality, we cannot make any guarantees.

2. In addition to your name, other information about you might be connected to your sample. For instance, information about race, ethnicity, sex, your medical history, and so forth might be available to investigators studying your specimen. Such information might be important for research or public health. It is possible that this information (including genetic information) might come to be associated with your racial or ethnic group.

3. The specimens obtained from you in this research may help in the development of a future commercial product. There are no plans to provide financial compensation to you should this occur.

4. In this study, investigators will not tell you what they find out about you, nor will they contact you if a test becomes available to diagnose a condition you might have or later develop.

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

P. 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 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. John H. Kindred at (843) 792-4328 or kindred@musc.edu***. 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.