Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

Title of Research: Safety and Efficacy of an Accelerated Protocol of Intermittent Theta Burst Transcranial Magnetic Stimulation (TMS) to Enhance Performance and Promote Resilience in Astronauts (TRISH BRASH): **Study 4 Dose Finding**

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 brief, repetitive transcranial magnetic stimulation (rTMS) for improving cognitive function such as attention and memory as well as to improve the ability to recover from stressful situations (stress resilience).

If you agree to participate you will undergo an eligibility screening that assesses current and past history of physical and mental health, along with current and past medical history. Once screening is complete, participants will complete interview and computerized forms (3-4 hours) that assess cognitive abilities and stress resilience along with a MRI scan (1-2 hours) and EEG assessment (1-2 hours). Due to COVID19 precautions and as a means to limit the time necessary for in-person visits, a portion of the interview can be completed remotely over the phone and video conferencing.

These tasks can be scheduled for different days. After completing the forms participants will be able to begin their repetitive transcranial magnetic stimulation (rTMS) treatment visits. All participants would then receive treatment on five different days. To allow some flexibility in scheduling, the five days of treatment can be completed within eight days. On each treatment day, you would receive repetitive TMS (rTMS) in 10 three-minute sessions, each separated by approximately 10 minutes (or more if that works better for your schedule).

After the final treatment session, you will meet for an in-person appointment to repeat the initial assessment (computerized test, and/or EEG/MRI). You will additionally meet in person 1 month after completing your treatment to repeat the initial assessments. Total study duration is about one and half months.

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

A. PURPOSE OF THE RESEARCH

The purpose of this study is to determine if an accelerated treatment course of a kind of transcranial magnetic stimulation (rTMS) can be improved by assessing different amounts of rTMS as a treatment for improving cognition and stress resilience. The entire treatment will be given over eight days. If you are interested in learning more about this study, please read this consent form closely and ask any questions you may have.

Repetitive transcranial magnetic stimulation (rTMS) works by rapidly turning a focused magnetic field on-and-off repeatedly over your head, which passes directly through your hair, scalp, and skull and onto your brain, and can temporarily increase brain activity under the magnetic field. Repetitive transcranial magnetic stimulation (rTMS) is an FDA approved treatment for depression, and is used commonly to treat people for their depression. The rTMS treatment regime used in this study is different from the FDA approved treatment because you will receive up to ten treatments per day over five days instead of the FDA approved rTMS treatment regime of 25 treatments over 25 days. This sort of accelerated or high dose protocol has been shown to be safe and effective in the treatment of depression. We are hoping to find out if this treatment can be used as a treatment for improving cognitive function and stress resilience.

You are being asked to participate in this study because you are a healthy adult control that has demographics of the astronaut population. Your total participation would include an initial interview and EEG assessment and MRI scan. Treatment would then consist of multiple, 3-minute sessions on each weekday for one-week followed by another post-treatment assessment and MRI scans. You would then come to one more post treatment visit to repeat the initial assessments 1 month after completing your treatment.

Participation is entirely voluntary. Your participation may help develop an accelerated intervention for improving cognitive function and stress resilience. If you consent and then change your mind at any time you are free to discontinue. Some participants receiving rTMS experience headaches and thus choose to stop. 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 Donna Roberts, M.D. This study is being done at one site and will involve approximately 50 volunteers.

This study is sponsored by a grant from NASA. Portions of Dr. Roberts' and her research team's salaries will be paid by this grant.

B. PROCEDURES

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

You will meet with research staff once to sign up for the study and learn about improving cognitive function and stress resilience. If you are female, you will receive a urine pregnancy test. You cannot participate in this study if you are pregnant. You will then complete an MRI scan of your brain and an EEG and physiological assessment during a stressful task. With study personnel you will choose a 5-day treatment schedule that best suits your other demands such as your work, family, and healthcare. On each of five days, you will receive up to 10, three-minute treatments of rTMS. These will be separated by 10 minutes or more depending on what works best for your schedule. An observational sub-study which will not require additional time on your part will also be included during each of the five days. Additionally, you will complete a post-treatment MRI scan and EEG/physiological assessment. One follow up visit (1 month) after treatment you will complete the same forms to see if the rTMS helped your cognitive abilities and stress resilience.

On your first visit:

1) You will complete several computerized forms and tasks and a staff member will ask you several questions (3-4 hours). These questions will ask about your physical and mental health, and medical history. If you are female, you will receive a urine pregnancy test. You cannot participate in this study if you are pregnant or trying to become pregnant.

On your second visit:

1) You will complete an MRI scan (approximately 1-2 hours). MRI machines use a strong magnet and radiofrequency magnetic fields to make images your body. You will be asked to lie on a long narrow couch while the machine gathers data. During this time, you will not be exposed to x-rays, but rather a strong magnetic field and radiofrequency magnetic fields, which you will not feel. You will, however, hear repetitive tapping noises that arise from the Magnetic Resonance scanner. We will provide earplugs or headphones that you will be required to wear. There will be a device that looks like a birdcage around your head, which helps to make the images of your brain. The space within the large magnet in which you lie is somewhat small, although we have taken steps to relieve the "claustrophobic" feeling. If you feel uncomfortable in the scanner, you are free to discontinue at any time. During this we will collect a picture of the structure or your brain (structural MRI) as well as a scan of how different brain areas communicate (functional MRI) while you are at rest.

2) You will complete several computerized forms (approximately 1 hour). You have the option to complete these on paper.

3) You will also complete an assessment of your reactivity during a stressful cognitive task. During this you will be wearing an EEG cap, which records electrical activity from the brain. You will also have sensors on your face, hands, and arms that measure how your body responds under stress, including heart rate and sweating response.

How your amount of TMS will be determined.

All participants will receive active rTMS. You will be randomized to one of 10 possible doses like drawing numbers out of a hat.

On your treatment visits:

Again, repetitive transcranial magnetic stimulation (rTMS) works by rapidly and repeatedly turning a focused magnetic field on-and-off over your head, which passes directly through your hair, scalp, and skull and onto your brain, and can temporarily increase brain activity under the magnetic field.

1) You will join us for a total of 5 treatment days. During these days, you will receive ten, 3- minute treatments separated by about 10 minutes for about 3 hours.
2) Prior to your first treatment, we will determine the intensity of rTMS for you. In order to do that we will put the TMS coil over the part of your brain that moves your hand, and find the lowest amount of magnetic stimulation needed to move your hand.
3) You will then receive 10 treatments each day. Each treatment takes about 3-minutes. You will wait about 10 minutes between treatments. You can wait longer between same-day sessions if you prefer. Just let us know.

After your final rTMS treatment visit:

1) We will meet with you in person for an appointment immediately after finishing your five days of treatment to repeat the initial assessment (computerized test and forms), MRI scan, and EEG assessment (3-4 hours).
2) You will additionally meet with us in-person 1-month after completing your treatment. During this session you will repeat the computerized battery and forms you completed at your initial assessment. As such, the session will be 3-4 hours, identical to the first visit.
3) At 1-month assessment, you will also complete an EEG assessment (3-4 hours).

Birth control precautions.

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

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

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

- You are found to have entered the study 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.
- You display abnormal laboratory, medical or clinical findings for which clinical intervention should be prioritized over study participation including:
- a) Development of mania/hypomania
- b) Generalized seizure
- c) Inpatient hospitalization

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 about 10 sessions over a period of 1-and-a-half months. You have already completed the phone screen. The breakdown of additional sessions is as follows:

Session 1 (interview; questionnaires and computerized testing) = 3-4 hours
Session 2 (MRI and EEG assessments) = 3-4 hours

Sessions 3-7 (Ten 3 minute rTMS sessions) on each of five days = 2-4 hours/day

After you complete all sessions of rTMS, the following will be completed:
Session 8 (Computerized testing; questionnaires) = 2-3 hours
Session 9 (MRI and EEG assessments) = 3-4 hours

Session 10 (Computerized testing; questionnaires; EEG 1 month post-rTMS) = 3-4 hours

D. RISKS AND DISCOMFORTS

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

Common adverse events occurring in approximately 15% of subjects:

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

Common adverse events occurring in approximately 5% of subjects:

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

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

MRI, EEG & Claustrophobia. Having a MRI may mean you may be bothered by feelings of claustrophobia and by the loud banging noise during the study. Having an EEG and physiological assessment also infrequently prompts feelings of claustrophobia.

MRI & Metal. Because the MRI machine acts like a large magnet, it could move iron-containing objects in the MRI room during your examination, which could in the process possibly harm you. Precautions have been taken to prevent such an event from happening; loose metal objects, like 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.

Less common adverse events occurring in 0.5% of subjects:

rTMS & Seizure. TMS stimulates neurons at a level below what triggers seizures. Although rTMS is generally safe and well tolerated without enduring side effects, with a sample size of several thousand patients and healthy volunteers a total 20 cases of accidental seizures induced with rTMS were reported. The risk is estimated to be probably less than 0.5% across individuals. There has been one report of seizure in a patient recovering from chronic stroke. This individual was receiving rTMS over the motor cortex, a region more sensitive to the possibility of seizure. In this study you will receive rTMS to the frontal cortex. This part of your brain is involved in problem solving and attention and is less prone to seizure. Nonetheless, we will watch you closely for any signs of seizure throughout all procedures. 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.

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

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

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

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.

You should also know that if you threaten to harm yourself or others or give information

about child or elder abuse, this information will be reported to appropriate clinical staff and other persons outside the research program as necessary to protect yourself and others and as mandated by law.

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

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.

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

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

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

Risk of Randomization. All doses to which you might be randomized have been shown to be safe and therapeutic for treatment of depression. There is, however, a risk that you may not be randomized to the most effective dose as we cannot yet determine what dose that may be.

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

Regardless of the amount of rTMS you receive, you will receive a number of rTMS treatments that has been used typically to treat depression but over fewer days. You may experience improvement of cognitive abilities and stress resilience, in a shorter period of time than is typical. However, this cannot be guaranteed. It is hoped that the information gained from this study will help the investigators learn more about how to better offer accelerated rTMS protocols to individuals with emotional and cognitive difficulties. There is the possibility of no direct benefits.

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, effort and travel expenses, you will be paid $600 for participation in this study. If you do not complete the study, you will receive the following for each completed procedure: Initial diagnostic assessment and scan $50; 5 days of rTMS sessions in week 1 $250; 1-week post-treatment follow-up assessment/scan $125; 1-month post-treatment follow-up assessment/scan $175.

You will receive payments after completion of each assessment and after 5 days of rTMS.

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..

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.

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 Donna Roberts, M.D. at (843) 792-8274. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, please sign below if consenting on paper. If consenting electronically, please scroll to the next screen to sign.

_____ _____
Signature of Person Obtaining Consent Date *Name of Participant

_____
Signature of Participant Date

Participant's Personal Representative (if applicable):

_____
Name of Personal Representative *(Please print)*

_____
Signature of Personal Representative Date

Relationship: ___ Spouse ___ Parent ___Next of Kin ___Legal Guardian* ____ DPOA for Healthcare*
**(If you are the health care agent or guardian, please provide proof of your authority to act on behalf of the patient)*

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.

The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, and MUSC Physicians Primary Care) 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." W**e collect or receive 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.**

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. 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.

5. 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.

6. 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.

7. Judicial and administrative proceedings. Your PHI may be released in response to a subpoena or court order.

8. Law enforcement or national security purposes. Your PHI may be released as part of an investigation by law enforcement.

9. Uses and disclosures about patients who have died. We provide coroners, medical examiners and funeral directors necessary information related to an individual's death.

10. 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.

11. Research. We may use your PHI if the Institutional Review Board (IRB) for research reviews, approves and establishes safeguards to ensure privacy.

12. 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.

13. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.

14. Marketing. We may send you information on the latest treatment, support groups and other resources affecting your health.

15. 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.

16. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.

B. You may object to the following uses of PHI:

1. Hospital directories. Unless you object, we may include your name, location, general condition and religious affiliation in our patient directory for use by clergy and visitors who ask for you by name.

2. Information shared with family, friends or others. Unless you object, 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. Psychotherapy notes.

3. 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 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 receive a copy of your PHI (including an electronic copy), which is contained in a designated record set that may be 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 fee for copying, mailing or other costs associated with your request. We may deny your request to inspect and receive a copy in certain very limited circumstances. If you are denied access to PHI, you may request that the denial be reviewed.

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.

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 369 / 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 Office of Civil Rights. The address will be provided at your request.

CHANGES TO THIS NOTCE
We reserve the right to change the terms of this Notice at any time. We also reserve the right to make the revised or changed Notice effective for existing as well as future PHI. This Notice will always contain the effective date. You may view this notice and any revisions to it at: http://www.musc.edu/privacy.

EFFECTIVE DATE OF THIS NOTICE
This Notice went into effect on April 14, 2003.
Revised September 2013.