Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

Neurocircuit Strategy to Decrease Cocaine Cue Reactivity
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 examine the effects of brain stimulation on craving and behavior.

You are being asked to participate in this study because you are an adult cocaine user. Participation in the study will consist of 3 visits, and telephone follow-ups with study research staff over 3 weeks. The procedures you will go through during this study are urine pregnancy (females only) and drug test, breathalyzer for alcohol use, questionnaires that will ask about your mood and craving, paper assessments to determine eligibility, theta burst (TBS) neural stimulation, and Magnetic Resonance Imaging (MRI). TBS is a form of repetitive magnetic brain stimulation that mimics the natural activity of brain cells. In this study, you will be randomly assigned to either TBS or Sham TBS and will have a 50:50 chance of being in either group. During each of two experimental visits you will be asked to simply relax at rest and to perform a picture viewing task while inside the MRI scanner. MRI uses a magnet and radio waves to record images of brain responses to seeing the images. You will also be asked to complete questionnaires and report your mood, craving, and substance use.

There are potential risks associated with study participation that are described in this document. Some of the risks include claustrophobia in the scanner or temporary minor headaches from the TBS. There will be no direct benefit to you from participating in this study. However, the goal of this study is to gain important information required to have a better understanding of brain mechanisms associated with cocaine use and develop more effective therapies to help stop cocaine use. Your alternative is to not participate in this study.

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

A. PURPOSE OF THE RESEARCH

The overarching goal of this project is to examine the effect of theta burst stimulation (TBS) on cocaine craving and brain response to cocaine-related images. A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of the PI, Dr. Bashar W. Badran and his research team's salaries will be paid by this grant.

Please read this consent form carefully and take your time making your decision. As your study staff member discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The study is being done at one site, the Medical University of South Carolina (MUSC). Approximately 160 people will take part study-wide and all research will take place at MUSC. The investigator in charge of this study is Dr. Bashar W. Badran.

B. PROCEDURES

If you agree to participate in this study, you will take part in 3 separate visits according to the schedule below. The procedures that you will undergo during these visits are described as follows.

SCREENING VISIT:

This visit is to determine if you meet the study criteria for participation. You will undergo the following procedures at this visit:

- Demographic Information: You will be asked to complete 2 online questionnaires that ask about your date of birth, age, sex, race, ethnicity, education, and employment status.

- Pregnancy Screening (Among females): A urine sample to test for pregnancy. If the pregnancy test is positive, you will not be allowed to participate in the study and no other procedures will be performed.

- Urine Drug Screening: A urine sample to test for drugs of abuse.

  Breath BAC test: A breath sample to measure an estimate of your blood-alcohol content (BAC). If your BAC is greater than 0.0, you will not be allowed to participate and no further procedures will be performed.

- Paper Assessments: You will be asked to complete a few paper forms that ask your name, contact information, medical history, smoking history of the past 30 days, and physical pain status.

- Questionnaires: You will be asked to complete questionnaires and report your tobacco, alcohol and caffeine use. You will also be asked to complete questionnaires about your mood and craving.

This visit will last approximately 3 hours.

If you continue to be eligible after the screening measures, you will be given the opportunity to continue onto the next visit.

EXPERIMENTAL VISIT 1:

You will undergo the following procedures at this visit:

- Breath BAC test: A breath sample to measure an estimate of your blood-alcohol content (BAC). If your BAC is greater than 0.0, you will not be allowed to participate and no further procedures will be performed.

- Pregnancy Screening (Among females): A urine sample to test for pregnancy. If the pregnancy test is positive, you will not be allowed to participate in the study and no other procedures will be performed.

- Urine Drug Screening: A urine sample to test for drugs of abuse.

- MRI: Magnetic Resonance Imaging (MRI) system, will assess your brain responses at rest and during the picture-viewing task. MRI uses a magnet and radio waves to record images of brain function. You will be placed on a narrow bed and then slid into a small tunnel approximately 6 feet in length and 25 inches in diameters and will hear machine-like noises while inside. You will be provided with earplugs to dampen the sound. You will remain in the MRI for 60 minutes during each MRI session.

- Questionnaires: You will also be asked to complete questionnaires and report your drug use. You will also be asked to complete questionnaires about your mood and craving.

- Randomization: You will be randomly assigned to 1 of 2 groups and will receive one session of ACTIVE TBS or SHAM TBS. You will have a 50:50 chance of being in either group.

This visit will last approximately 3 hours.

EXPERIMENTAL VISIT 2:

You will undergo the following procedures at this visit:

- Pregnancy Screening (Among females): A urine sample to test for pregnancy. If the pregnancy test is positive, you will not be allowed to participate in the study and no other procedures will be performed.

- Urine Drug Screening: A urine sample to test for drugs of abuse.

- Breath BAC test: A breath sample to measure an estimate of your blood-alcohol content (BAC) will be performed. If your BAC is greater than 0.0, you will not be allowed to participate and no further procedures will be performed.

- TBS: Theta Burst Stimulation involves placing a stimulation coil upon your head. Brief magnetic pulses will be delivered that may result in the twitching of muscles of the face and

arm. The first step will be to determine how sensitive you are to TBS. The investigator will deliver single TBS pulses (which sound like loud clicks) while holding the TBS wand over the part of your brain that controls your right arm muscles. Because the pulses sound like loud clicks you will be required to wear ear protection while we do this. The power of the pulses will be increased until the pulse causes a visible movement of your arm when delivered. This process should take approximately 5-8 minutes.

- MRI: Magnetic Resonance Imaging (MRI) system, will assess your brain responses during rest, wherein you will be asked to simply relax with your eyes open and during the task. MRI uses a magnet and radio waves to record images of brain function. You will be placed on a narrow bed and then slid into a small tunnel approximately 6 feet in length and 25 inches in diameters and will hear machine-like noises while inside. You will be provided with earplugs to dampen the sound. You will remain in the MRI for 60 minutes during each MRI session. There will be two MRIs during this visit.

- Questionnaires: You will also be asked to complete questionnaires and report your drug use. You will also be asked to complete questionnaires about your mood and craving.

In order to continue with the visit, your BAC must be 0.0 and the pregnancy test must be negative. If you continue to be eligible after this point, you will complete study questionnaires to assess mood and to characterize cocaine use-related behavior, and then move on to the rest of the visit, which consists of the first MRI followed by a TBS session. Following stimulation, you will be administered questionnaires that assess mood and craving, as well as TBS tolerability. Then, you will complete another MRI, which will be similar to your first MRI. This visit will last approximately 3 hours.

FOLLOW UPS:

You will be contacted by telephone to follow up with you regarding your craving and mood any drug use the day after your last visit, 1 week after, 2 weeks after and 3 weeks after your last visit.

Voluntary Withdrawal:
Participation in this study is voluntary. You are free to withdraw your consent and discontinue participation in the study at any time throughout the study without negative consequences to your relationship with the Medical University of South Carolina.

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

C. DURATION

Participation in the study will involve 3 visits over a period of 4-5 weeks. There will be one screening visit and 2 experimental visits. Each visit will last 3 hours. You will be contacted to follow up with you regarding your craving and mood any drug use the day after your last visit, 1 week after, 2 weeks after and 3 weeks after you last visit.

D. RISKS AND DISCOMFORTS

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 metal 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.

TBS (Theta Burst Stimulation):
TBS may result in a minor headache or discomfort at the site of stimulation. An additional risk of TBS is a seizure, a condition in which a person briefly loses consciousness and may have uncontrolled movements of the body. There have been no reports of seizures in neurologically healthy individuals or while using appropriate safety procedures, which will be followed in this study. You may also experience a slight twitching of facial muscles during the delivery of **TBS** pulses during the short (~3 minutes) stimulation protocols. This may be uncomfortable for some participants, and you can withdraw from the study at any time without any negative consequences.

Incidental Findings:
Some MRI scans can detect medical conditions, such as cancer, brain injury, and abnormal blood vessels; however, this functional MRI is carried out purely for experimental purposes and we are not looking for brain disorders. Furthermore, the study researchers are not trained in diagnosing brain disorders; therefore, the researchers are not qualified to offer any medical opinions concerning your scan (good or bad). It is possible that the study researchers will notice something in your scan that appears unusual and/or abnormal, and if this occurs, the researchers will inform you of the finding and provide you with a copy of your scan, which you may take to a medical expert for further review and diagnosis. Being told about such a finding may cause anxiety as well as suggest the need for additional tests and financial costs. Any costs associated with clinical follow-up(s) are you and/or your insurance carrier responsibility. If you do not wish to be informed of this type finding, you should not participate in the study.

Breach of Confidentiality:
There is the risk of a breach of confidentiality, despite the steps that will be taken to protect your identity. The investigators in charge of this study have experience dealing with such sensitive information and have experience assuring that data is adequately protected. Safeguards to protect confidentiality include locked records and firewalls around password-protected electronic data, and all study data being coded, with the key linking the code with a subject's identity being kept in a separate, password protected document on a password-protected server.

Pregnancy:
Breast-feeding and pregnant women are not allowed to take part in the study. If you are pregnant or become pregnant, 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.

Randomization:
This is not a treatment study. You will be randomly assigned to 1 of 2 groups and will receive one session of ACTIVE TBS or SHAM TBS. You will have a 50:50 chance of being in either group.
The group you are assigned to may have more side effects than another group.

Questionnaires:
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.

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

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

This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless you have consented to the disclosure. More specifically, identifiable information or biospecimens will not be shared with your medical providers who are not involved in this research unless you authorize the study to disclose information to them, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

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

medical record. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must authorize the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include: child abuse and neglect, or harm to self and others, but there could be others.

Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

F. BENEFITS

There will be no direct benefit to you from participating in this study. However, it is hoped that the information gained from the study will help in the treatment of future patients with conditions like yours/will help the researcher learn more about Cocaine Use disorder.

G. COSTS

There will be no cost to you as a result of participation in this study.

H. PAYMENT TO PARTICIPANTS

- You will be paid up to $250 for participation in the study.
- You will receive no payment for the phone/online screening that you have already completed, which helped determine your eligibility to be able to participate in the study.
    - **Visit 1: Screening:** At the screening visit, if you are eligible, you will receive $25 upon completion of all assessments.
    - **Visit 2: Experimental Visit 1:** At the first experimental visit, you will receive $80 for completion of the entire visit.
    - **Visit 3: Experimental Visit 2:** At the second experimental visit, you will receive $80 for completion of the entire visit.
    - **Follow ups:** You will also receive $10 for each follow up phone call, Up to $40 for the day after your last visit, 1 week after, 2 weeks after and 3 weeks after you last visit.

- **Bonus:** Upon completion of the study and all study procedures and follow ups, you will receive a $25 bonus.

In the event that you should wish to discontinue your participation, which you may do at any time, you will be paid for the time you have already invested in the study (rounded up to the nearest half-hour). Payment will be made in cash for each session completed and will not be contingent upon completion of the entire study. Upon completion of all study visits and follow ups you will be asked to come in at your convenience, during business hours, to collect the payment for the phone follow ups and bonus, totaling in up to $65.

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.

K. DISCLOSURE OF RESULTS

The final results of the study will not be known until the conclusion of the trial. The results will be made available to you upon publication of the manuscripts. You will not be directly notified of the results of the 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.

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

_____Yes, you may use my protected health information for the optional research portions of this study.
_____No, you may not use my protected health information for the optional research portions of this study.

M. SIGNIFICANT NEW FINDINGS

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

N. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

O. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

P. CLINICAL TRIALS.GOV

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

Q. COLLECTION OF SPECIMENS

Urine will be collected for laboratory tests (urine drug screen and urine pregnancy test for females) to determine if you are able to participate in the study. For females, the urine pregnancy test will be done before any other testing, including the urine drug screen.

Genetic research: Genetic research studies may present unique risks to human subjects and their relatives. These involve medical, psychosocial and economic risks, such as the possible loss of confidentiality (private information), loss of insurability and employability, paternity, and social stigmas. Knowledge of one's genetic make-up may also affect one's knowledge of the disease risk status of family members. Genetic research raises difficult questions about informing you and other subjects of any results, or of future results. Some people feel anxious about the possibility of having a defective gene that would place them or their children at risk. Some people want to know what is found out about them; others do not. The risks of knowing include anxiety and other psychological distress. The risks of not knowing what is found include not being aware if there is treatment for the problem being studied. But these risks can change depending on whether there is a treatment or cure for a particular disease and on how clear the results are. If there is a medical reason to seek specific information from you, your doctor will tell you this. A process called "genetic counseling" is often appropriate in such cases; you should ask your doctor or nurse about this if you have any questions.

South Carolina law mandates that your genetic information collected from any test or from this research, be kept confidential. Our state law prohibits an insurer using this information in a discriminatory manner against your or any of your family in issuing or renewing insurance coverage for you or your family. Our state law further prohibits our sharing your genetic information with anyone except in a few narrow circumstances, one of these being a research project of this type, approved by the Institutional Review Board and then we must take all steps to protect your identity. You will still be responsible for paying for health care, however. The Medical University of South Carolina will not be responsible for such costs, even if care is needed for a condition revealed during research or clinical testing.

GENETIC INFORMATION NONDISCRIMINIATION ACT (GINA): A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:
• Health insurance companies and group health plans may not request your genetic information that we get from this research.
• Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.
Be aware that this new federal law does not protect you against genetic discrimination by companies

that sell life insurance, disability insurance, or long-term care insurance, nor does it protect you against genetic discrimination by all employers.

Biospecimens will not be used for commercial profit.

As part of this study, we would like to store specimens collected from you for future research on cocaine use and addiction disorders. Samples may be used for genetic and/or hormone testing. This future research may be conducted by Dr. Bashar W. Badran or by other researchers who obtain IRB approval for their research. The specimens will be coded to protect your identity. This will protect your confidentiality and anonymity. Whole genome sequencing will not be conducted with these samples.

Please indicate whether you agree to have your urine sample stored for future research. Please initial by your choice below:

____Yes, I agree

____No, I do not agree

R. 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. Bashar W. Badran at 843-792-6076***. 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.