Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

Varenicline for the Treatment of DSM 5 Cannabis Use Disorder in Adults

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 evaluate the safety and effectiveness of varenicline (sometimes known as Chantix) compared to placebo (an inactive substance) in the treatment of Cannabis Use Disorder. Varenicline is not FDA approved for treatment of Cannabis Use Disorder.

If you agree to participate, you will undergo a screening process where you will have a psychiatric and substance use assessment, a medical history taken, and blood drawn to assess your health. If your test results show you are able to continue, you will be randomly assigned to receive either varenicline or placebo. You will have a 50:50 chance of being on varenicline (like the flip of a coin). Neither you nor your study doctor will know what group you are in. You will take the study medication twice a day for 12 weeks, and will have study visits once a week for those 12 weeks, with 1 follow up visit a week after that, so that the total duration you are in the study will be approximately 14 weeks. You will be asked to complete questionnaires about substance use at each visit. Urine will be sampled weekly.

There are risks to the study drug that are described in this document. An example of a risk is nausea (upset stomach). If you are randomized to placebo, you will go without treatment for your condition for 12 weeks. Also with randomization, neither you nor your doctor will decide to what group you are assigned. If you have a strong opinion about what treatment you receive or would like your doctor to decide what treatment you receive, you should not participate in this study.

It is unknown if varenicline will help your condition, however you will be followed closely with weekly visits, and you can stop participating in the study at any time. It is possible that your symptoms will improve, but that cannot be guaranteed. You do not have to participate in this study to have your condition treated. Alternative treatments include special counseling and other therapies.

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

A. PURPOSE OF THE RESEARCH:
You are being asked to volunteer for a research study designed to evaluate the effects of a medication (varenicline) to help people quit using cannabis.

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. To confirm your understanding, you will be asked to complete a consent quiz before signing this form.

You are being asked to participate in this study because you use cannabis regularly. The study is sponsored by the National Institute on Drug Abuse. The investigators in charge of this study at MUSC are Aimee McRae-Clark, PharmD, and Kevin Gray, MD. The study is being done at 2 sites. Approximately 174 people will take part study-wide and approximately 87 will take part at this institution.

B. PROCEDURES:
If you agree to be in this study, you will first be evaluated and the results of the evaluation must meet entrance requirements. This first evaluation will include psychiatric interviews, an assessment of your alcohol and drug use, and a medical history. You will have blood drawn (about 2 teaspoons) to assess your general health. You may be asked to meet with medical staff at your randomization visit for a physical exam if they think it is necessary based on your medical history or bloodwork. You may be asked to provide a urine sample to test for drugs of abuse. If you are female and of child-bearing potential, you will have a pregnancy test prior to urine drug screening. You will be asked to fill out several forms dealing with how often and why you use marijuana, your mood symptoms, and sleep quality, either in the clinic or via a survey link.

This initial evaluation visit may also be done remotely. In that case, the consent will be emailed to you prior to the screening appointment. You will be asked to find a private location to have a video call with study staff. On the video call, study staff will obtain informed consent and do the initial interview. You will also speak with study medical staff to review your medical history. You may be asked to meet with medical staff at your randomization visit for a physical exam if they think it is necessary based on your history. If determined eligible after your video call, you will be asked to have your blood drawn to assess general health, and test for pregnancy if female (either at MUSC, LabCorp or AnMed, depending on your location). You will be sent online survey links to complete questionnaires.

If you meet all entrance requirements, you will come to the clinic for a randomization visit. At this visit you will be asked to provide a urine sample to test for drugs of abuse and nicotine. You will also complete assessments regarding marijuana use and mood, and you will receive study medication, either varenicline or placebo (a capsule that does not contain any active medication). Neither you nor the study staff will know which medication you are taking as both varenicline and placebo will be given as capsules identical in appearance. You will be randomly assigned to receive either varenicline or placebo. This means that you have a 50/50 chance (like flipping a coin) of being in either group. Neither the researchers nor you will make the choice regarding to which group you are assigned. The medication will be provided at the standard recommended dose of 0.5mg daily for three days, then 0.5mg twice daily for four days, and then 1mg twice daily for the remainder of the twelve-week treatment period.

You will be required to take your medication twice daily while enrolled in this study. You are asked to take one capsule at 8:00AM each morning and the other at 8:00PM each evening.

You will also be asked to record and upload a video of yourself taking your morning and evening medication to research staff using a smartphone and a secure web application. When uploading the morning medication video, you will also be asked to complete a survey regarding your marijuana use the previous day. You will be trained on how to do this at your randomization visit. If you do not have a smartphone or do not wish to use your own, we will provide one to you for the duration of the study. If you use an Android smartphone, your medication videos may be automatically stored on your phone prior to sending them, thus you will need to delete each video file from your phone. If preferred, the daily substance use reports can be completed on a computer.

You will have weekly study visits for twelve weeks. At these visits, you may be asked to fill out forms and answer specific questions concerning your substance use, mood symptoms, and your feelings in general, either in clinic or via survey link. Your urine will be tested at each visit to check for drugs of abuse and nicotine. If you are female, you will be screened for pregnancy monthly. In some extenuating instances, such as in the case of a pandemic, your weekly study visits and procedures may be conducted remotely via a telehealth platform, and/or in-person visits may be limited to less than weekly.

You will be required to complete one follow-up visit approximately one week after you finish study procedures.

We may ask you to identify an individual who can be contacted to help locate you if needed. A family member or a significant other/spouse is preferred. You will need to sign a release of information form to allow the study team to contact the individual.

Participation in this study is totally voluntary, and you may choose not to participate. You may also withdraw your consent and discontinue participation at any time. Discontinuation will in no way jeopardize your ability to receive treatment at this Institution now or in the future. You may be withdrawn from the study without your consent if the researchers believe it is in your best interest.

C. DURATION:
Participation in this study involves approximately 16 visits over a period of about three months. The initial screening visits will take between 1 and 2 hours each. The rest of the visits will take approximately 30-60 minutes each.

D. RISKS/DISCOMFORTS:
Participation in this study may involve risks. There may be risks and side effects that are not known at this time. Possible risks from study participation include:

Risks associated with varenicline: The most commonly observed side effects associated with varenicline treatment (incidence > 5% and at least twice the rate of placebo) are nausea, abnormal (e.g., vivid, unusual, or strange) dreams, constipation, flatulence, and vomiting. In individuals with major depressive disorder and other psychiatric disorders, medications like varenicline may increase suicidal thoughts and behavior in children, adolescents, and young adults. Watch for these changes, and inform the study staff immediately if you notice new or sudden changes in mood, behavior, actions, thoughts, or feelings, especially if severe.

Risks associated with screening/assessment: The interviews that you will undergo at screening involve no specific risks or discomforts beyond those of a standard clinical interview situation, such as feeling upset at the review of your psychiatric status, boredom, or fatigue. If a question makes you feel uncomfortable you may refuse to answer it.

Risk of loss of confidentiality: There is a risk of a loss of confidentiality as a result of participation in this study. Information about you, as well as your image, will be kept in password-protected databases and computers or a locked research clinic area, and will only be accessible by the principal investigator and the research staff. Video clips will only be viewed by approved research staff. Those video clips will be deleted when the study has ended and data analysis is complete. In order to ensure confidentiality, all participant information (questionnaires and identifying information) will be identified only by your name and/or a code number and kept under lock and key and in password-protected databases.

Risks associated with blood drawing: The risks of drawing blood include temporary discomfort from the needle stick, bruising, and infection. Fainting could occur.

Additional risks: You will be assigned to treatment by chance. The treatment you receive may prove to be less effective or to have more side effects than the other study treatment or other available treatment. If you are in the group that receives placebo, you will not receive active medication.

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.

If you are a female of childbearing potential, you will receive a pregnancy test, and if pregnant, you will not be allowed to participate in the study. If you are capable of becoming pregnant, you must be using a medically approved method of birth control (such as contraceptive pills, diaphragms, or other forms of barrier contraceptives) and you must continue to do so during the course of the study. Should you become pregnant during the study you must immediately contact your study doctor and discontinue treatment since the risk to your baby due to varenicline is unknown.

Your urine will be screened for the presence of marijuana and other potentially abused or illegal drugs. These results will not be part of your medical record but will be kept in research records maintained by the investigator. Every effort will be made to protect the confidential nature of this information. However, there may be circumstances under which the investigator may release this information. If you are pregnant or become pregnant and test positive for illegal drugs, the SC Department of Social Services (DSS) may be notified. You could be at risk of going to jail or losing custody of your children.

E. CERTIFICATE OF CONFIDENTIALITY

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

Information about your study participation will not be in your MUSC medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must authorize the researchers to release it.

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

You may receive a medication that may be effective in reducing your marijuana use. Of course, this cannot be guaranteed or promised. The results of this study may also benefit other patients who might later be treated with the same medicine.

G. COSTS:

If you choose to use your own smartphone to upload your daily medication videos, any cellular data and usage rates assessed by your carrier will apply.

H. PAYMENT TO PARTICIPANTS:
In return for your time and effort, you will receive $50 for completing the screening visits ($25 for the interview and $25 for the bloodwork). You will be compensated $50 for the End of Treatment visit (Week 12). If you receive a study smartphone but do not return it at this End of Treatment visit, you will receive $25 for attending the EOT visit (versus $50). You will receive $50 for all other weekly clinic visits and the follow up visit. Therefore, you could earn up to $750 if you complete all study visits. You will also receive $2.50 for each uploaded morning medication video and survey and $2.50 for each evening medication video- videos and surveys must be complete to receive this compensation. Your total overall compensation for study participation and procedures will depend on how many visits you attend, how many surveys and videos you upload, and if you return a borrowed smartphone. Lost or stolen iPhones may be reported to the federal funding agency.

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 or mailed 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 below. 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:
There are alternative treatments for marijuana use. These include special counseling and other therapies (such as twelve step groups and classes on relapse prevention) aimed at decreasing substance use. You may also choose not to participate.

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

K. DISCLOSURE OF RESULTS

If, for any reason, you would like your medical records released to anyone other than the investigators, you will be asked to sign an additional release of information form.

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;
- Other investigators within the Addiction Sciences Division conducting similar research studies;
- Data Safety Monitoring Boards;
- LabCorp
- AnMed
- 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. RECRUITMENT OF SUBJECTS:
You are invited to participate in the recruitment of other subjects for this study. If you choose to participate, we will provide you with coupons that you may give to other people (e.g., peers, acquaintances) who you think would be eligible and interested in this study. You may choose to tell people to whom you give these coupons to call the study office if they are interested in participating in the study. These individuals will not be identified unless they contact the study office themselves. If any of your coupons result in successful study recruitment, you will receive $20 for each one. Participation in the recruitment process is completely voluntary, and if you elect not to participate your participation in this study will not be affected in any way.

N. NEW INFORMATION:
If there are any significant new findings during the course of the study, you will be notified.

O. STUDENT PARTICIPATION:
Your participation or discontinuance will not constitute an element of your academic performance nor will it be part of your academic record at this Institution.

P. 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.

Q. INVITATION TO PARTICIPATE IN FUTURE STUDIES:
From time to time we have other research studies that you may be eligible to participate in. We are inviting you to allow us to contact you by phone, mail, or both to see if you would be interested in participating in any future studies. By initialing the "yes" line below, you are indicating that you would like to give us your phone number, any alternate phone numbers, and address so that we may contact you if another study becomes available that you might qualify for. **To maintain your confidentiality, we will <u>not</u> leave identifiable messages or any identifiable information on letters or envelopes that are mailed to you.** By checking the "no" box below, you are indicating that you do not want study personnel to contact you for any future studies. You may still participate in the current study if you initial "no" and you will not suffer any adverse consequences in doing so.

_____Yes. I would like to be re-contacted for future studies. I give permission for study personnel to contact me by phone or by mail to inform me of other available studies I may be eligible for.

_____No. I do not wish to be re-contacted for any future studies.

R. CLINICAL TRIALS REGISTRY:
A description of this clinical trial will be available on 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.

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 ***Aimee McRae-Clark, PharmD***. 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

_____ _____

Signature of Participant Date *Name of Participant

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.