Targeting Foundational Memory Processes in Nicotine Addiction: A Translational Clinical Neuroscience Study of a Retrieval-Extinction Intervention to Reduce Craving and Smoking Behavior

Informed Consent Form

NCT03744559

November 30, 2021

MEDICAL UNIVERSITY OF SOUTH CAROLINA

CONSENT TO BE A RESEARCH PARTICIPANT

STUDY TITLE: Targeting Foundational Memory Processes in Nicotine Addiction: A Translational Clinical Neuroscience Study of a Retrieval-Extinction Intervention to Reduce Craving and Smoking Behavior

This study uses an electronic informed consent process. Please notify the study staff if you prefer a paper-based informed consent process.

This study is being conducted for research purposes, and your participation in this study is voluntary, which means you may stop taking part in this study at any time. The purpose of this study is to see whether certain behavioral cues and tasks can help people quit smoking. This will be done in 12 total visits over a 6-month period. This study involves looking at smoking cues, as well as urine and breath tests; there will also be collection of saliva samples, your heart rate will be measured, and there is an option to also do a brain scan. The risks of this study include nicotine withdrawal symptoms, uncomfortable interviews, risks from the optional brain scan, and possible loss of confidentiality. The benefits of this trial include helping future smoking research and the possibility for participants to quit smoking. Alternatives include not participating in this research study or using other already approved smoking treatment options.

A. PURPOSE AND BACKGROUND:

You are being asked to volunteer for a research study. The Medical University of South Carolina and the National Institutes of Health sponsor this research. The study examines the use of smoking cues to change your interest in smoking; this may lead to an effective treatment for smokers. You are being asked to participate in this study because you are between the ages of 25 and 65 years old and currently smoke cigarettes. The investigator in charge of this study is Dr. Michael Saladin. This study is being conducted at the Medical University of South Carolina and will involve approximately 166 volunteers.

The purpose of this consent form is to give you the information you will need to help you decide about participating in the study. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called 'informed consent'. We will email you a copy of this form for your records.

B. PROCEDURES:

If you agree to participate and are consented remotely, you will also be asked to completed a consent form and questionaires remotely. Subsequent research visits which require you to be seen in person will be scheduled and are described below".

You will be evaluated via telephone first to see if you meet the study requirements for participation. If you meet study requirements, you will either be consented in person or, if you have internet access, the study team may discuss the consent form with

you by phone and send you the form by email to review and sign electronically. If you sign the consent form electronically, you will then be prompted to complete some additional study documents online, including questionnaires. If you do not have internet access, after your phone evaluation, the study team will schedule an in-person visit to discuss the consent form and complete additional study documents. All participants will be asked to come in person to complete a urine sample, breath test, psychiatric interview, and an EKG measurement. You will then be scheduled for an initial (baseline) laboratory visit. It will be required that you refrain from smoking starting the night before this initial evaluation up until the visit's completion (which we will confirm by both your self-report and by breath assessment at the onset of the evaluation). Both visits may be done in one day if there is availability. Additionally, abstinence from alcohol/other drug use will be assessed with breath and urine samples. Failure to meet abstinence requirements will result in rescheduling. Research personnel will ask you questions about your psychiatric, substance use, and medical history. If you are found to be eligible to participate, you will be randomly assigned (like rolling a die) to one of two groups that determines the images, video and physical objects/stimuli you experience in your lab sessions. From those groups you may be randomized again to either a) receive a functional magnetic resonance imaging (fMRI) scan or b) not to receive an fMRI. The fMRI is a simple and brief and is designed to assess blood flow in the brain while you are resting and viewing pictures. You will then complete a brief cue reactivity (CR) laboratory session in which your responses to smoking cues will be assessed. During this lab session, the following will occur:

You will first be seated comfortably in front of a computer for 10 minutes, after which we will monitor your heart rate (HR; the number of times your heart beats per minute) and skin conductance (SC; like sweating palms) for 50 seconds via sensors (small wires attached to tape) that will be placed on your body in places, such as along your rib cage and on your fingers. Immediately after, your blood pressure (BP), craving, and mood will be measured via questionnaires.

If you are randomized to the fMRI group, you will then be escorted to the fMRI suite. You will first become familiar with the scanning process by laying in a mock (imitation) scanner and doing mock (practice) tasks. After practicing, you will then be administered the fMRI procedures. Magnetic resonance imaging (MRI) uses a magnet and radio waves to make medical images of the body. You will be placed on a narrow bed and then slid into a small tunnel approximately 6 feet in length and 25 inches in diameter. You will hear a loud machine-like noise. Once you are in the fMRI machine, we will collect a structural image of your brain. You will then be asked to sit quietly with your eyes closed for several minutes.

Then, you will be scanned while you perform an eight and half minute task that involves viewing alternating blocks of neutral cues (40 sec), fixation and ratings (30 sec), and smoking cues (40 sec).

If you are not randomized to the fMRI group, you will remain in the CR laboratory.
Both groups, regardless of location, will perform the same task. You will perform an eight and half minute task that involves viewing alternating blocks of neutral cues (40 sec), fixation and ratings (30 sec), and smoking cues (40 sec). Those in the fMRI group will be scanned during the task.

Sensors will then be removed and you will receive the scheduled compensation. You will schedule your next visit with the study coordinator, and you will be reminded that your quit attempt will begin the night before and that it will be the first of four daily

visits (one each day for four days in a row) for which you will be compensated for not smoking (abstinence requirements for the 4 days will be the same as those for the initial CR laboratory visit).

You must begin abstinence from smoking (and any drugs/alcohol) the night before the start of your four days of lab sessions. Abstinence will be confirmed with urine and breath samples. You will receive monetary compensation for successful abstinence. The first three of the four sessions will involve "treatment." At the beginning of the session, we ask that you place your cell phone in a box labeled "Phone Box" placed next to you to ensure that no distractions occur during the session. Those sessions will run as follows:

You will first watch a 5-min video containing either smoking content or non-smoking, neutral content. Continuous HR and SC will be collected (as previously described above) during the video, with BP, mood, and rating measurements collected after the video.

Then, over the course of an hour, you will be exposed to a sequence of smoking-related pictures, videos, and objects four times. HR and SC will be collected at the beginning of every sequence, and the other assessments will be completed following each sequence.

The fourth session, 24 hours later, will be considered the first of seven "test" sessions and will involve a cue reactivity (CR) assessment identical to the one done on your first visit (described above), except that there will also be 5 minutes of smoking-related pictures shown, during which HR, SC, BP, craving, and mood will be assessed. Individuals who participated in the initial fMRI will undergo a second, identical fMRI scan after the CR assessment. Individuals who did not participate in the fMRI will undergo the same CR assessment in the CR laboratory. Please be aware that you will be repeatedly reminded that you are being compensated/paid to refrain from smoking and other substance use during both treatment sessions and the first test session.

You will have six additional test sessions, two weeks, four weeks, 6 weeks, 2 months, 3 months, and 6 months later, nearly identical to the first one described above.

Although strongly encouraged, smoking abstinence will not be a requirement for participation in these sessions (nor will you be given a monetary reward for abstinence). However, abstaining from other substance use (alcohol and other drugs) prior to these test sessions will still be necessary (failure to comply with that requirement may result in rescheduling).

Also, you will be given a smoking diary at the end of each test session (except the last at 6 months) in which to record the occurrence of (i) daily smoking behavior and (ii) daily craving. Study personnel will collect these diaries at the beginning of the following test session.

You will be required to provide a breath and saliva sample at all six follow-up test sessions. These samples will provide additional information about your smoking behavior.

At the end of the final test session, study personnel will address any questions that you may have as a study participant and provide recommendations for additional cessation treatment.

C. DURATION:

Participation in the study will take about 6 months. You will be seen for 12 outpatient sessions including the clinical assessment, initial CR assessment visit, the three

treatment sessions, and seven testing sessions. All of your visits will be approximately 1-2 hours in duration. However, if you test positive for smoking or alcohol/drug use on your initial visit or on your first treatment session, that visit will need to be rescheduled, which may increase the time it takes to complete the study.

D. RISKS/DISCOMFORTS:

Interviews: The interviews that you will undergo during the course of the study 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 uncomfortable you may refuse to answer it without fear of penalty (i.e. loss of compensation or study dismissal).

Exposure to smoking cues: Exposure to cues may produce some craving for nicotine or other discomforts. However, this discomfort is usually brief and you will be in the safety of a smoke-free laboratory environment. Although previous studies do not show an increased risk of smoking craving or relapse after cue exposure, this possibility cannot be completely ruled out.

fMRI Machine: 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 the fMRI component of 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.

Confidentiality: There is a risk of loss of confidentiality of your personal information as a result of participation in this study. Please refer to the confidentiality section for a detailed description of confidentiality protections for all participants.

Pregnancy: Because of the potential risks associated with fMRI screenings while pregnant, pregnancy at the general clinical assessment or either of the fMRI sessions will be cause to be dismissed from the study. All women participating in this study must notify the staff immediately if they become pregnant during the study.

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 fMRI component of this study.

Confidentiality:

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 with the highest level of confidentiality. The information we collect will contain your 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.

E. MEDICAL RECORDS

If you are an MUSC patient you have an MUSC medical record. If you have never been an MUSC patient, an MUSC medical record will be created for the purposes of this study. Results of research tests or procedures will be included in your MUSC medical record. All information within your medical record can be viewed by individuals authorized to access the record We will make every effort to keep confidential all research information in the medical record that identifies you to the extent allowed by law.

F. 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 except if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you are an MUSC patient you have an MUSC medical record. If you have never been an MUSC patient, a MUSC medical record will be created for the purposes of this study. Results of research tests or procedures will be included in your MUSC medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law; however, there is the possibility that your research information will be disclosed.

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 or 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.

G. BENEFITS:

Many persons report that one benefit of their participation in a study on smoking addiction is that they feel like they are making a contribution to increasing knowledge about how to overcome dependence problems. Others have reported that they learn a lot about how they react to things that remind them of their smoking and that this knowledge is useful to them (i.e., they think differently about their smoking after study participation and/or they reduce their smoking behaviors). Required abstinence from smoking during certain portions of the study as well as treatment referral information provided by study staff may serve to motivate participants in future attempts to abstain from cigarette use. Some people may feel that there is no direct benefit

(other than compensation) to their participation in this study. Your participation will contribute to a research study that may prove beneficial to you and others in the future.

H. COSTS:

You will not be charged for any of the study treatments or procedures. The costs of all tests associated with this study will be covered by the study.

The researchers would like to send you text messages to remind you of your scheduled appointments. If you choose to receive text messages to remind you of your scheduled appointments, your normal message and data rates may apply. Please initial by your choice below for paper consents, or scroll down to the bottom of the screen and select your choice electronically:

_____ Yes, I agree to be contacted by text message

_____ No, I do not agree to be contacted by text message

I. PAYMENT TO PARTICIPANTS:

You will be paid for your participation as follows:

$30.00 for completing the screening assessment.
$60.00 for completing the baseline cue reactivity assessment/fMRI.
$75.00 for completing the first of three treatment sessions.
$100.00 for completing the second treatment session.
$125.00 for completing the third treatment session.
$150.00 for completing the first test/fMRI session.
$100.00 for completion of each of the test sessions (2 weeks, 4 weeks, 6 weeks, 2 months, 3 months, and 6 months following the first test session, respectively).

Therefore, the maximum compensation for participation in this research study is $1,140. Payment for study visits will be made using a pre-paid debit card, called a ClinCard. It works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be given a ClinCard at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule above. Details of the debit card system are explained on an additional sheet. If the study staff has discovered that the information you have provided to us is unreliable/inaccurate, any member of the research team will have the right to withhold payment from you even if you have participated in a portion of the study visit.

If you test positive for nicotine or alcohol/drug use on your second/third treatment session or first test session, you will lose compensation associated with that visit. However, if you remain abstinent from smoking, alcohol/drug use on all subsequent sessions (excluding the follow-ups), you will earn the lost compensation back. You can only earn back a maximum of one day of compensation during treatment.

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 and the IRS will be notified of the amount you received. NO information about your participation in this study, other than the amount of compensation you received, will be revealed to the IRS.

J. ALTERNATIVES:

The study examines the use of smoking cues to change your interest in smoking; this may lead to an effective treatment for smokers. Participants who wish to receive additional information on nicotine dependence will receive a clinical referral. Participation in this study is voluntary, and you may refuse to participate or discontinue participation at any time. If you choose not to participate, it 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.

K. 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

You will not be allowed to see or copy the information described on this Authorization as long as the research study is in progress. When the study is complete, you have a right to see and obtain a copy of the 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

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.

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;
- Health insurer or payer in order to secure payment for covered treatment;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- 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. 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. 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 for paper consents, or scroll down to the bottom of the screen and select your choice electronically:

_____ Yes, I agree to be contacted.

_____ No, I do not agree to be contacted.

R. RESULTS OF THE RESEARCH:

If for any reason, you would like your study records released to anyone other than the investigators, you will be asked to sign an additional release of information form. You will also be asked to sign a Health Insurance Portability and Accountability Act (HIPAA) Authorization to use or disclose your protected health information for research purposes.

The 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 investigators associated with this study, employees of the sponsors, and the MUSC Institutional Review Board for Human Research will have access to identifying information.

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 contact 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. 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 study staff'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. Michael Saladin at (843) 792-5306. I may contact the Medical University of SC Hospital Medical Director (843) 792-9537 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 participant in this study.

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

If you wish to participate, please sign below for paper consents or scroll to the bottom of the screen to provide an electronic signature. Please provide your email address to receive a copy of this form.

Signature of Person Obtaining Consent Date	Name of Participant
Signature of Participant Date	
Participant Email Address	

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.