NCT 04471207
13 April 2021

Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Intelligent Biometrics to Optimize Prolonged Exposure Treatment for PTSD - Clinical Trial

You are being asked to participate in a research study. Participation is voluntary. The purpose of this study is to examine a new technology system (small camera and device) that connects to an application and to determine if it will improve the effectiveness of *Prolonged Exposure* (PE) therapy – a form of talk therapy that includes the retelling of one's trauma - for posttraumatic stress disorder (PTSD) in veterans and civilians. An application, or 'app' is a software program that is downloadable to a cellular telephone.

This study will include an initial appointment where you will complete questionnaires and interviews in a private room in our research offices, or through telehealth to determine if you are eligible to participate. This appointment will take approximately 3 hours. If you are eligible and decide to enroll in the study, you will complete up to 10 sessions of PE therapy over the course of up to 10 weeks. The PE sessions will occur twice a week for about five weeks and each session will last about two hours. You will be asked to complete 'homework' assignments outside of the office as part of the PE therapy. For example, you may be asked to engage in a stressful activity, such as watching a suspenseful video clip, drive to a busy intersection or listen to war reenactments. In addition, you will be asked to wear a small device or technological system during your out-of-office homework assignments and in various portions of your study participation. This device includes a small camera, Bluetooth earpiece and discrete monitors that will measure your heart rate and moisture on your skin. This system will connect to a cell phone with a specific application that will monitor how you are responding to the exercise. You will be randomly selected (like drawing out of a hat) to have your study "coach" virtually guide you through out-of-office assignments using the technology system, or to conduct the assignments on your own while wearing the system. You have the option to complete visits in our research offices or through telehealth.

There are risks of participating in the study that are described in this document. Significant risks include loss of confidentiality. It is possible that you might feel some discomfort talking about your trauma experiences in therapy and completing the assignments. You may also feel some discomfort or boredom answering questions included in this study. You may skip any questions that you are not comfortable answering.

All participants in this study will receive psychological assessment as well as evidence-based treatment for PTSD (~10 sessions of PE) delivered by a trained clinician. Information on other relevant treatment, services and community resources will be provided and may be helpful but cannot be guaranteed. If you do not choose to participant, you will be provided with community and VA treatment referrals for PTSD (VA PTSD clinic, MUSC providers that treat PTSD).

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. Please ask questions at any time during the study. Feel free to ask study staff to explain any words or information in this

consent form that you do not clearly understand. You are being asked to participate in this study because you are l between 18-75 years of age, are fluent in English, and you may have posttraumatic stress disorder (PTSD). The purpose of this study is to examine the safety and effectiveness of a new technology system (small camera, Bluetooth earpiece and monitors for heart rate) that connects to an application on a cell phone to understand how this might improve *Prolonged Exposure* (PE) therapy for PTSD in veterans and civilians. The study is sponsored by from a grant from the National Institute on Mental Health (NIMH). The investigator in charge of the study is Dr. Sudie Back at the Medical University of South Carolina (MUSC). This study is being conducted at MUSC. Approximately 40 people will take part in this study.

B. PROCEDURES

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

1. Baseline visit

a. You will be asked to answer some questions about yourself such as your age, health, exposure to traumatic events, PTSD symptoms, medications, use of alcohol and drugs, mood, and sleep, to determine if you are eligible to participate.

b. If you have recently started taking a prescription medication, you may be asked to wait 4 weeks until you participate in the study so that the effects of the medication will be stable and will not affect the study results.

c. If full eligibility criteria are met and you choose to complete the treatment portion of the study (described below), you will be randomly assigned to one of two groups. This means that you have a random chance (like drawing out of a hat) of being in either group. Neither the researchers nor you will make the choice to which group you are assigned. The two groups are Group A (wearing the technological system during out-of-office homework assignments without guidance) and Group B (wearing the technological system during out-of-office homework assignments with guidance). A trained study therapist will be assigned to you, and your therapy sessions and out-of-office homework assignments will be recorded. The recordings will be stored in a secure encrypted system only available to study personnel.

2. In-Service with Zeriscope

a. All eligible participants will be provided a technology package that includes a cell phone, electronic tablet (for telehealth participants), complete Zeriscope technology system, training materials, device cleaning supplies and masks. Note that the cell phone, tablet and all electronic devices are provided specifically for the purpose of this research and for the use of the mobile application and wearables the study team is testing. This equipment will not be able to work for other purposes; and you will be required to return all equipment at the end of the treatment phase. You will be provided prepaid shipping labels to return the system. You will not acquire cellular or data charges for any of this equipment.

b. After you receive the technology package, an 'In-Service' call will be scheduled with Zeriscope to review the use of the equipment and to get you comfortable with the technology.

3. Treatment visits

a. You will be asked to complete up to 10, 90-minute sessions of Prolonged Exposure (PE) therapy. PE is a highly effective cognitive-behavioral therapy for PTSD. At each therapy session, you will be asked questions about any changes in your health, mood, medications, and behaviors.

b. You will meet with a study therapist (either in person or through telehealth visits) for the PE therapy sessions. Therapy sessions will be audio recorded and therapy will involve:

   i. In Session 1 your study therapist will explain the rationale for PE, review your trauma history, teach you a relaxation skill, and introduce you to the wearable technological system.

   ii. In Session 2 your study therapist will introduce you to out-of-office therapy assignments, provide any additional instruction on how to use the technological system, and conduct a short in-session practice of the system.

   iii. Sessions 3-9 will continue the out-of-office assignments. During these sessions, you will also be asked to talk about the trauma memory with your therapist to help you process and heal from the event(s).

   iv. In Session 10, you and your therapist will review the progress made in therapy, and discuss any potential next steps depending on your symptoms and preferences. At this last visit, you will be asked to answer questions about your thoughts, feelings and experiences with the treatment and technology system.

c. The device you will be asked to wear during the out-of-office homework assignments and in various therapy sessions consists of a small camera (about the size of a pencil eraser), Bluetooth earpiece with microphone, and discrete monitors to measure and record your heart rate and the moisture and temperature of your skin (skin conductance). In addition, this device will connect to an application on a password protected cell phone that will monitor and record the above listed information as well as your reported subjective units of stress (SUDS). Further, it will video- and audio-record the assignment.

   i. If you are randomly selected to have your study coach virtually guide you through the first three out-of-office assignments, your study coach will connect with you remotely through the technological system. Your study coach will be able to see a live video stream and speak with you through an audio device in order to guide you through the assignment. They will also be able to see your current heart rate level and skin conductance in real-time. Further, this information may be reviewed with you by your study therapist at your next in-office appointment. You will be asked to wear the device during all your out-of-office assignments.

   ii. If you are randomly selected to wear the device without being guided through the out-of-office assignments, you will not receive the real-time or in-office feedback

described above. You will be asked to wear the device during all your out-of-office assignments.

4. **Follow-up visit**

    a. Approximately one month after the treatment phase, you will be asked to complete one follow-up appointment and asked to answer some questions about your PTSD symptoms, health, mood, and sleep (similar to your baseline appointment).

5. **Withdrawal from the research study**

    a. 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 talk with 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 investigator's instructions. If your participation is ended for medical reasons, you will be referred to a doctor or other health professional for care.

C. DURATION

Participation in the study will take about 12 visits (i.e., 1 baseline visit, 10 therapy sessions, 1 follow-up visit) over a period of approximately 3 months.

D. RISKS AND DISCOMFORTS

Interviews and Surveys: The questions that will be asked may be sensitive in nature and may 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.

Physical Discomfort: You may experience some physical discomfort from wearing the device. We will instruct you on how to appropriately wear the device and have you practice wearing it in the office. We will also provide written and illustrated instructions for how to wear and use the device during out-of-office assignments to make sure it is as comfortable as possible.

Risk of Loss of Confidentiality: There is a chance that your personal information may inadvertently not be kept confidential. Some answers you give during the research visits (like whether you use illegal drugs) may put you at risk if other people find out. To keep what you say private, your study records will use a code number instead of your name. We will protect your records to the extent allowed by law by keeping all your materials in locked file cabinets only accessible by research staff, and all computer files will be secure password-protected files that are only accessed by approved research staff. Your research records will be kept separate from your clinic records and will not be a part of your medical record. Only research staff will have access to your private information. Further, there is the possibility that your personal information/identity may not be kept confidential while you are completing your out-of-office assignments.

Limits of Confidentiality:
Suspected or known abuse or neglect of a child, disabled or elder abuse, or threatened violence to self or others may be reported to appropriate authorities.

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.

F. BENEFITS

While there is no guarantee of specific benefit to participants in this study, other potential benefits include a thorough psychological assessment, 10 sessions of evidence-based treatment for PTSD provided by a trained clinician, referrals to appropriate treatment services and community resources.

G. COSTS

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

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid $50 for the baseline visit and $50 for the follow-up visit. You will also receive $30 for each of the 10 treatment visits. The total compensation available to you is $400. Payment for study visits will be made using a Visa gift card or a pre-paid debit card, called a ClinCard. MUSC manages all ClinCards. It works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted as long as you do not exceed the balance available on the card. 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. Your ClinCard will come with information on how to use the card, a phone number to call to set a PIN and a phone number to call to check the card balance. Please be sure to review all the information that comes with the ClinCard. If your card is lost or stolen, notify the study staff at 843-577-5011 x5188.

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

If you choose not to participate in this study, you could receive other treatments for your condition. The standard therapy for your condition is PE without the use of a technological system. Your alternative is

to seek treatment from provided community or VA resources (e.g. PE without use of a technological system).

Withdrawal from the Study
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 talk with 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 investigator's instructions. If your participation is ended for medical reasons, you will be referred to a doctor or other health professional for care. You will be responsible for the cost of these services.

J. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all 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

Study data will not be shared with participants to maintain confidentiality.

L. PHOTOGRAPHS, VOICE AND/OR VIDEO RECORDING

As part of the treatment protocol, you will be asked to record and listen to your therapy sessions. In addition, your out of office therapy assignments will be recorded through the wearable device as part of your treatment. This could pose a risk to confidentiality and although we will take every step possible to ensure that all recordings are stored securely and any risks minimized, however there is a risk is that you could be identified, including information regarding alcohol and drug use, or other criminal behavior. To minimize any risk, all recordings will be kept in a locked file cabinet or on a secure and encrypted server and only the project staff and Principal Investigator will have access to the recordings. They will be destroyed after the study has been completed.

M. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study therapist and the 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 therapy team and the research team may 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 and 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.

N. SIGNIFICANT NEW FINDINGS

If there are 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 a 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. 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.

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, or scroll 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.

You have the option of receiving appointment reminders through text messages on your personal cell phone, if you have one. Should you elect to receive text messages, normal cellular data usage and rates will apply. Please indicate your choice below, or scroll to the bottom of the screen and select your choice electronically:

____**Yes**, I agree to be contacted via text message.

____**No**, I do not agree to be contacted via text message.

CONSENT

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, the sponsor, 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 that you are injured as a result of participation in this study, 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 therapist 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 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. Sudie Back at 843-792-9383.** 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.
Please sign below for paper consents or scroll to the bottom of the screen to provide an electronic signature.

Signature of Person Obtaining Consent Date

_____

*Name of Participant (printed) Date

_____

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.