Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Aim 2: Integrated Early Intervention for Alcohol Use Disorder and Posttraumatic Stress Disorder Following Sexual Assault

NCT04582695

- 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 conduct a five-week therapy for alcohol use and posttraumatic stress symptoms among women who have experienced a recent sexual assault.
- The purpose of the study is to test an investigational therapy that may help to reduce alcohol use and posttraumatic stress symptoms for who have recently experienced a SA. The therapy involves writing about the sexual assault and learning coping skills to manage cravings.
- The initial visit may take up to three hours. At this visit, participants will complete clinical interviews and self-report surveys. Next, participants will be assigned by chance to complete the investigational therapy or complete a similar therapy. Both involve five to seven 60-minute sessions of talk therapy. After the final therapy session, participants will complete a post-treatment visit to complete assessments that will be up to two hours. Finally, participants will complete a one-month, three-month, and six-month follow-up visit to complete assessments that will be up to two hours. A saliva test strip will be collected during the therapy study visits, post-treatment visits, and follow -up visits. A urine test kit will be collected during the first therapy visit, post-treatment visit, and follow-up visits.Total study duration is up to 32 weeks.
- Participants will be sent messages on their smartphones to complete an online questionnaire two times per day about drinking and mood.
- There is a risk of loss of confidentiality, but the researchers will keep the research information in a protected and secure location. There is also risk of emotional distress when talking or writing about experiences of sexual assault. If you choose not to participate, you can continue to receive services at the National Crime Victims Research and Treatment Center and Medical University of South Carolina.
- Your alternative is to receive routine treatments for sexual assault, posttraumatic stress disorder, or substance use which include participating in support groups, trauma-focused individual therapy, and therapy for substance use disorders.
- Given investigational nature of study, benefits cannot be guaranteed but it is hoped that information gained in study will help to inform treatment for alcohol use and posttraumatic stress following sexual assault.

A. PURPOSE OF RESEARCH:

The purpose of this study is to examine an intervention for alcohol use and posttraumatic stress symptoms. The intervention includes components of Written Exposure Therapy, which is a five-session treatment for posttraumatic stress disorder, and Cognitive Behavioral Therapy for substance use disorder. The therapy is five to seven, 60-minute sessions that involve writing about the details of the sexual assault, related thoughts and feelings for 30 minutes each session. The therapy also involves learning coping skills to manage cravings for alcohol use. Coping skills include breathing skills, problem-solving, and managing situations that increase risk to use alcohol. The intervention will be compared to Written Exposure Therapy only, which involves 40-minute sessions that involve writing about the sexual assault for 30 minutes. Most current therapies address alcohol use or posttraumatic stress symptoms, but do not treat these symptoms at the same time. The purpose of this study is to test a therapy that addresses both alcohol use and posttraumatic stress symptoms at the same time for recent survivors of sexual assault.

Please read this consent form carefully and take your time making your decision. As your study staff discusses this consent form with you please ask him/her to explain any information that you do not clearly understand. You are being asked to participate in this study because you have recently experienced a sexual assault. The investigator in charge of this study at MUSC is Christine Hahn, Ph.D. The study is being done at 1 site with a total of 54 participants.

B. PROCEDURES

If you agree to participate in this project, the following will happen:

1. Baseline Visit: You will be seen via teleconference or in-person for a screening visit to see if you qualify for the study. This visit will include surveys that you answer, and a clinical interview that will include questions about mental health symptoms, substance use, and trauma history. The clinical interview will last approximately one to two hours. Self-report measures will be used to collect information about pregnancy. The visit will be approximately two to three hours.

After staff has reviewed all the information collected, you will be informed at the end of the baseline visit of your eligibility status. If you are not found eligible and/or do not wish to continue in the study, additional community resources will be made available to you upon request.

If you are eligible and choose to participate you will be randomly assigned to one of two groups. 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 to which group you are assigned. One group will receive the Written Exposure Therapy with Cognitive Behavioral Therapy for substance use disorders and the other group will receive the Written Exposure Therapy.

2. Treatment Visits: Over the next five to seven weeks, you will receive 40 to 60-minute, individual sessions of Integrated Written Exposure Therapy for Alcohol Use Disorders and Posttraumatic Stress Disorder via teleconference or in-person. These therapies will be delivered at least once per week by a study therapist at MUSC. These sessions will involve writing about the sexual assault that you experienced and individual counselling to help with reducing substance use. You will have the option to attend more than one therapy session per week. After the baseline visit, you will be mailed saliva

test strips and a urine test kit to test for alcohol in your system. At these visits you will utilize a saliva test strip prior to each session to test for alcohol in your system and complete self-report questionnaires. Please note that prior to the first session you will also be asked to utilize a urine test kit. The therapy sessions will be audio recorded.

Participants must be in a private location and have access to internet while completing video teleconferencing or complete the visits in-person. Vidyo or doxy.me, online video programs, will be used for online video calls. A link will be sent to participants' email to complete self-report questionnaires online via a secured platform. Breathalyzer test will not be collected. Participants will upload picture(s) of their written therapy assignment to a secure online platform at the end of the session.

Optional Daily Assessments

During the course of the treatment visits you may be sent a text messages on your smart phone prompting you to complete a brief online questionnaire about drinking and mood. One message will be scheduled during the morning. One message will be sent at a random time during the day. If you do not have a cell phone, we can provide you with a phone for the duration of the study. The phone should be used only for completing study questionnaires. The cell phone needs to be returned to study staff at the completion of the study.

Please initial by your choice below for paper consents, or scroll down to the bottom of the screen and select your choice electronically:

_____Please initial if you agree to receive text messages on your phone to complete online questionnaires.

_____Please initial if you disagree to receive text messages on your phone to complete online questionnaires.

3. Post-Treatment Visit: After the final therapy session you will be asked to complete self-report questionnaires, urine test kit, and saliva test strip to test for alcohol in your system. The follow-up visit will last approximately 2 hours. It can be scheduled on the same day as your final therapy session or on a different day.

Participants must be in a private location and have access to internet to complete teleconferencing visits or complete the visit in-person. Vidyo or doxy.me, online video programs, will be used for online video calls. A link will be sent to participants' email to complete self-report questionnaires online via a secured platform.

4. Follow-Up Visits: At 1-month, 3-months, and 6-months after your final therapy session, you will complete self-report questionnaires, urine test kit, and saliva test strip to test for alcohol in your system. The follow-up visits will last approximately 2 hours.

Participants must be in a private location and have access to internet to complete teleconferencing visits or complete the visits in-person. Vidyo or doxy.me, online video programs, will be used for online video calls. A link will be sent to participants' email to complete self-report questionnaires online via a secured platform.

In addition, a phone call will occur during months 2, 4, and 5 of the six-month follow-up phase to assess daily alcohol use during the past 30 days.

You may withdraw from the study at any time. If you decide to stop participating in the study, you are encouraged to talk to study staff first so that you can discuss follow-up care. You may be withdrawn from the study without your consent if the researchers believe it is in your best interest of if you fail to follow study procedures.

C. DURATION

Participation in the study will include 10 to 12 visits over a period of up to 32 weeks.

D. RISKS AND DISCOMFORTS

The risks from participating in this study are discomfort when writing about your sexual assault during treatment. You can stop participation at any time if you become too distressed. Second, whereas unlikely, there is a small risk to loss of confidentiality when collecting personal information. However, all personal information including results from saliva and urine tests, and audio-recordings will be kept safe and separate from identifying information, and transcriptions of recordings will not include identifying information. Only the investigators and appropriate study staff will have access to personal information and recordings. All recordings will be destroyed at completion of this study.

If you disclose intention to harm yourself or other people the study staff will have to make a mandated report. A mandated report is made to authorities to report risk of harm when it is legally required.

If you were to find yourself needing help with distress as a direct result of our study procedures, you should contact the Principal Investigator, Dr. Christine Hahn (843-792-3386). She is a clinical psychologist and can direct you to counseling services for any project related distress, or will provide you with a referral, if needed. You may also call the National Suicide Prevention Lifeline (1-800-273-8255) if you are feeling extremely distress.

If you are or become pregnant and report use of illegal drugs, it is a law that the South Carolina Department of Social Services (DSS) must be notified. You and your family will be evaluated by the agency. You could be ordered to mandatory drug treatment, lose custody of your children, or be jailed.

You will be assigned to the study therapy by chance. The study therapy you receive may prove to be less effective than the other study therapy or other available treatments.

If you receive the group that receives Written Exposure Therapy only, your condition will go without learning coping skills for alcohol use for five to six weeks.

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

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

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

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

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

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

F. BENEFITS

Given the investigational nature of this study, benefit cannot be guaranteed or promised. It is hoped that the information gained from the study will help in the treatment of future patients with conditions like yours/will help the researcher learn more about strategies that help decrease distress after a sexual assault.

G. COSTS

If you choose to receive text messages from the study staff, normal cellular data usage rates will apply.

Please initial by your choice below for paper consents, or scroll down to the bottom of the screen and select your choice electronically:

_____Please initial if you agree to receive text messages.

_____Please initial if you disagree to receive text messages.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid up to $472 total for participation in this study.

Study Visits: You will be paid up to $365 for attending all study visits. If you do not complete the study, you will receive $50 for the initial visit, $20 for each of the five study visits, $10 for each of the optional sixth and seventh study visits, $10 for attending all five study visits, $20 for the post-treatment visit, $40 for the one-month follow-up visit, $50 for the three-month follow-up visit, and $75 for the six-month follow-up visit. Visits will be compensated with Amazon gift cards or ClinCards. ClinCards are pre-paid debit cards that work like bank debit cards and can be used to purchase goods or services everywhere Debit MasterCard is accepted. You may be given a ClinCard at the beginning of the study, and each time you receive payment for participation in this study, the money will be added to the card. Details of the debit card system are explained on an additional sheet.

Daily Online Questions: You can be paid up to $107 for completing all daily online questions. If you participate in the daily online questions sent to your phone, you will be compensated $1 for each assessment that is completed during the 5-week treatment phase. You will receive an extra $5 each week that a minimum of 80% of assessments are completed..

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

This study involves an investigational counseling. You have the option to decline to participate in this study. Alternative support services after sexual assault are available including individual therapy for posttraumatic stress disorder or substance use disorder, and support groups.

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.

Language Data from this study will be submitted to the National Institute on Alcohol Abuse and Alcoholism Database (NIAAADA) at the National Institutes of Health (NIH). NIAAADA is a large database where deidentified study data from many NIAAA studies is stored and managed. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your deidentified study data helps researchers learn new and important things about alcohol problems more quickly than before. During and after the study, the study researchers will send deidentified study data about your health and behavior to the NIAAADA. Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity. You may not benefit directly from allowing your study data to be shared with NIAAADA. The study data provided to NIAAADA may help researchers around the world learn more about alcohol problems and how to help others who have problems with alcohol. NIAAA will also report to Congress and on its website about the different studies using NIAAADA data. You will not be contacted directly about the study data you contributed to NIAAADA.

You may decide now or later that you do not want your study data to be added to the NIAAADA. You can still participate in this research study even if you decide that you do not want your data to be added to the NIAAADA. If you know now that you do not want your data in the NIAAADA, please tell the study researcher before the end of your visit today. If you decide any time after today that you do not want your data to be added to the NIAAADA, call or email the study staff who conducted this study, and they will tell NIAAADA to stop sharing your study data. Once your data is part of the NIAAADA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NIAAADA, this is available on-line at https://nda.nih.gov/niaaa.

The National Institute of Health uses Global Unique Identifiers (GUIDs) to link people across research studies. The GUID, or Global Unique Identifier, is an alphanumeric code and used as an identifier for a research participant. The GUID provides a secure mechanism to link research participants within and across research project datasets. Identifying information including name, sex, date of birth, and place of birth is used to create a GUID. The GUID itself is not personally identifiable information or protected health information.

_____Please initial if you agree to have your data submitted to National Institute on Alcohol Abuse and Alcoholism Database (NIAAADA).

_____Please initial if you disagree to have your data submitted to National Institute on Alcohol Abuse and Alcoholism Database (NIAAADA).

K. DISCLOSURE OF RESULTS

If there are significant new findings during the course of the study, you will be not be notified.

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

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

- The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

M. 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.

N. 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:

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

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 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.

If you are patient receiving care from the Grady Health System and you have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.

We will give you emergency care if you are injured by this research. However, **Grady Health System** has not set aside funds to pay for this care or to compensate you if a mishap occurs. If you believe you have been injured by this research, you should contact Dr. Christine Hahn (843-792-3386).

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 ***Christine Hahn, PhD at 843-792-3386***. 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

_____

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.