Grant Title: Development and Feasibility Testing of an Integrated PTSD and Adherence Intervention Cognitive Processing Therapy-Lifesteps (CPT-L) to Improve HIV Outcomes

Grant Number: NCT05275842

Title of Document: CPT-L Consent Form

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Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Development and Feasibility Testing of an Integrated PTSD and Adherence Intervention Cognitive Processing Therapy-Lifesteps (CPT-L) to Improve HIV Outcomes (Aim 2)

SUMMARY

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who chose to take part in them. The purpose of this study is to explore patient experiences with the use of a new treatment program designed to help people with HIV and PTSD take their medications as prescribed and improve the quality of their life.

If you are eligible and agree to join this study, you will be placed in one of two study groups. If you are put to Group A (Cognitive Processing Therapy – (CPT) with Lifesteps – (L)), you will be asked to attend 12 program sessions (twice a week for 6 weeks, 90-minute sessions) with a therapist. If you are put in Group B, you will receive one (Lifesteps – (L) educational session (60 minutes) including the standard treatment that someone with a history of HIV and PTSD symptoms would receive at a local HIV care clinic. You can attend Group A and Group B sessions via the internet or in person at the MUSC Ryan White clinic. Session will be audio recorded; however, your identity and privacy will be protected. (CPT) uses education and cognitive training to help individuals identify thoughts and feelings about their trauma and give them tools to help them change unhelpful beliefs. Lifesteps (L) includes education on the need for people with HIV to take their medications as prescribed and what could happen if you do not, as well as gives you tools to help motivate and remind you to take your medications on time. You have a 50/50 chance (like a coin toss) of being put in each group. People in both groups will complete a similar set of surveys, which are expected to take 45-60 minutes to complete at the first- and 6-week visit, and then again at a 3-month follow-up visit.

You may or may not personally benefit from being in this study. Those people put in Group A may learn useful additional information and extra coping skills than those in Group B. The program is provided at no-cost to you, and you may learn useful information and coping skills while being in the study. The potential risks associated from being in this study include: a loss of privacy from the collection and electronic storage of data, and possible emotional distress and fatigue from answering questions about your overall health and well-being. The researchers will make every effort to protect your identity. You can also stop the study at any time.

It is hoped the information that we get from this study will help us better design treatment programs for people living with HIV and PTSD. You will receive study compensation for your time. Your ability to receive care and the quality of care that you would normally receive at a HIV care clinic is not affected by your decision to join or not join this study. Your alternative is to not participate. Mental health treatments are available to you whether or not you agree to join in the research. Referral to mental health agencies outside of the agencies can be provided.

A. PURPOSE OF THE RESEARCH

The purpose of this study is to explore patient experiences with the use of a new treatment program (Cognitive Processing Therapy – (CPT), and Lifesteps – (L)) that is designed help people with HIV and PTSD take their medications as prescribed. Cognitive Processing Therapy (CPT) uses education and cognitive training to help individuals identify thoughts and feelings about their trauma and gives them tools to help them change unhelpful beliefs. Lifesteps (L) includes education on the need for people with HIV to take their medications as prescribed and what could happen if you do not, as well as gives you tools to help motivate and remind you to take your medications on time.

You are being asked to participate in this study because you are a patient of a local HIV care clinic and have a history of trauma exposure. 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 words or information that you do not clearly understand.

The investigator in charge of this study is Cristina López, PhD at MUSC College of Nursing. The study is being done at MUSC. This research and portions of Dr. Lopez's and her research team's salary are supported by a grant from the National Institutes of Health. Approximately 60 people will take part in this study, 30 volunteers in Group A and another 30 volunteers in Group B.

B. PROCEDURES

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

A. To see if you are eligible to join the study, you will be asked to complete a series of surveys about your past trauma exposure, coping strategies, mood, and health behaviors and have a clinical interview. Your medical record will also be reviewed to confirm your eligibility to join the study. This initial visit will be approximately 90 minutes - two hours. If you are eligible, and still agree to join, you will then be randomly placed by a computer into either Group A or Group B. You have a 50/50 chance (like a coin toss) of being place in either group.

<u>Group A</u>
If you are put in Group A, you will participate in a 12-week Cognitive Processing Therapy-Lifesteps (CPT-L) treatment program. The CPT-L program will be delivered twice a week for 6 weeks. Each session last about 90-minutes. You may attend these sessions either in-person or over the internet if you have an internet ready device with audio.

<u>Group B</u>
If you are put in Group B, you will complete one Lifesteps education session. This session lasts about 60 minutes. You may attend this session either in-person or over the internet if you have an internet ready device with audio.

All Groups (A and B)
While you are in the study:

1. All study sessions will be audio recorded, so that the researchers can assess your quality of care. The therapist will tell you when they are starting and stopping the audio recording. No identifying information about you will be linked with these audio recordings.

2. You will receive a text at baseline, week 4, and week 8 of participation requesting a photo of your medication adherence (e.g., pharmacy refill, remainder of pills, injection appointment) and as well as your self-rated medication adherence.

3. You will be asked again to do the same surveys that you did at the first visit at 6 weeks and after another 3 months.

4. You will also be asked to have an end of study interview with the researchers. In this interview you will be asked about your thoughts about the treatment you received during the study and for suggestions on how to improve and integrate services for people with trauma at HIV care clinics. This interview will last about 20 minutes and will be audio recorded.

5. Your HIV care clinic will provide the research team with information about your attendance to clinic appointments as well as results of laboratory tests that are already conducted as part of your health visit. Your medical chart will be reviewed to collect diagnoses, lab results, and clinic attendance. If you have not had labs at MUSC you may be asked to sign a release of information form to collect this test result from the HIV care site where the lab was done.

Participation is voluntary and you can stop your participation at any time during the study. If you decide to stop, this will not affect your access to services or the quality of care that you receive at the HIV care clinic or at the Medical University of South Carolina.

C. DURATION

Participation in the study will take place over 3 months. Participants in Group A will have twelve 90-minute treatment sessions twice a week for 6 weeks. Participants in Group B will have one 60-minute treatment session at the beginning of the study. All participants will be asked to complete a set of surveys upon enrollment, at 6-weeks, and at 3-months. These surveys will take about 45-60 minutes to do. Participants will also be asked to take part in an end of study interview with the researchers. This interview will take about 20 minutes.

D. RISKS AND DISCOMFORTS

The possible risks from being in this study include:

Emotional discomfort – you may find some of the questions the researchers about your health and feelings to be upsetting or you may feel uncomfortable answering them. If you do not wish to answer a question, you can skip it and go on to the next question.

Fatigue or tiredness – you may experience fatigue or tiredness while answering some of the surveys or when in a session. You may rest and/or stop your participation in all parts of the study at any time.

Loss of privacy – there is a risk of loss of confidentiality of your personal information as a result of study participation. MUSC and the researchers will take every precaution to help safeguard and keep your information safe and protected.

Randomization - You are being assigned to study group by chance. Those people assigned to Group A may learn useful additional information and extra coping skills than those in Group B.

E. MEDICAL RECORDS

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 your HIV care medical record.

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 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 HIV care medical record. This means that neither your research participation nor any of your research results will be included in any 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.

G. BENEFITS

There may or may not be any direct benefit to you from participating in this study. While we cannot guarantee direct benefit, you may learn new information and coping skills. The larger benefits of the study are that you will be contributing to the improvement of trauma and PTSD treatment for populations that have not been able to currently access effective treatments at HIV care clinics.

H. COSTS

Treatment received under this study is provided to you at no cost. However, if you choose to join the study and receive text messages from the study staff, you will incur your normal cellular data usage rates.

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.

I. PAYMENT TO PARTICIPANTS

All participants will receive up to $245 for full participation and completion of this study. All payments will be made in the form of a gift card.

Group A
If you are placed in Group A, you will receive $50 for completing the first set of assessments, the PTSD Diagnostic Interview, and for enrolling in the study. You will receive $40 for attending the first session then $60 for the completion of the 6-week surveys and the 20-minute exit interview (i.e., post-intervention surveys). You will also receive up to $20 for submitting self-reported adherence photos. You will additionally receive $75 for completing the 3 month follow up surveys.

Group B
If you are placed in Group B, you will receive $50 for completing the first set of assessments, the PTSD Diagnostic Interview, and for enrolling in the study. You will receive $40 for attending the first session then $60 for 6-week survey and 20-minute exit interview. You will also receive up to $20 for submitting self-reported adherence photos. You will additionally receive $75 for completing the 3 month follow up surveys.

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.

J. ALTERNATIVES

Your alternative is to not participate in this study. If you do not want to participate in this research study, but you are interested in trauma treatment, you can ask the researchers for a referral to an outside mental health agency to receive trauma treatment. Referrals for mental health treatment will vary depending on individual preferences and insurance coverage.

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.

L. DISCLOSURE OF RESULTS

The researchers will share the overall results of this study with you. Your individual research results will not be disclosed.

M. 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 your HIV care clinic may use or disclose (release) for this research study includes information in your medical record, medical history (e.g., date of diagnosis), lab tests (e.g., viral load) 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 who 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. 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:

Please initial by your choice below for paper consents or scroll to the bottom of the screen to select your choice electronically.

____Yes, I agree to be contacted

____No, I do not agree to be contacted

R. ADDITIONAL INFORMATION

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.

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.

S. 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 Cristina López, Ph.D. at 843-876-1034. 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 Participant Date

_____ _____

Signature of Person Obtaining Consent 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.