Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Testing a wearable telemedicine-controllable taVNS device for NeuroCovid Recovery and Rehab

You are being asked to consent to participate in a research study because you tested positive for Coronavirus (COVID-19) and you have some continuing symptoms. Your participation is voluntary, and you can withdraw at any time. This is not a treatment study and you should be in regular contact with your primary care team.

The purpose of the research is to test out a new form of treatment where we stimulate a nerve in your ear. This is called transcutaneous (through the skin) auricular (ear) vagus nerve stimulation (taVNS) which means that you will receive stimulation through the ear. The taVNS device looks like an ear bud you would use with your smart phone or computer. We are investigating whether or not taVNS can treat neurologic or psychiatric symptoms of COVID-19 which are termed NEUROCOVID. Some symptoms you may experience are new onset anxiety, depression, vertigo, anosmia (loss of smell), headaches, fatigue, or irritability.

This study is entirely online, and you will never need to come to MUSC. You will go through a series of virtual (online) sessions. These virtual sessions will first include a screening session where you sign the consent form and participate in online assessments. Once you have agreed to participate and if you meet study criteria, you will then be sent a taVNS device and receive training on device operation. Next, you will be randomly assigned (like flipping a coin) to receive 2 weeks of either active or sham taVNS treatment. This part of the study is blinded, meaning neither you nor the study team will know what treatment you are receiving. Upon completion of the initial 2-week blinded phase of the study, you will start active taVNS treatments for an additional 2 weeks. Lastly, you will have 4 virtual assessments spread over the 8 weeks following post-taVNS treatment.

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

A. PURPOSE OF THE RESEARCH

COVID-19 is a virus that infects people. We are more aware now of how the virus attacks the lungs and gastrointestinal system. What we are now learning is that some people develop symptoms that involve the brain, and that the virus can directly enter the brain. The purpose of this research study is to investigate the brain effects of the virus and whether this new treatment, taVNS, might help treat some of these symptoms.

There is a different, more invasive form of vagus nerve stimulation called cervical vagus nerve stimulation (CVNS). This technique involves surgically implanting a wire into the neck around the vagus and connecting that to a generator placed under the skin on the chest. This invasive and expensive approach to VNS is FDA approved to treat epilepsy and chronic depression and also helps with anxiety. Transcutaneous auricular vagus nerve stimulation (taVNS) is the new non-invasive neuro-modulation approach that we are using in this study, where we stimulate this nerve through the ear. taVNS is the non-invasive approach that uses a different branch of the same vagus nerve as

does CVNS. Because taVNS is less invasive than CVNS, it is more convenient and tolerable. taVNS is non-invasive, can reduce neuro-inflammation and activate anti-inflammatory responses. The device used in this research study has been designed, developed, manufactured, quality checked, verified and validated as part of FDA Quality Systems protocols. However, it is not FDA approved for any clinical indication, although research suggests it may help with some symptoms that are now appearing in patients with NeuroCovid."

This research study is a Phase II study. Phase II studies are designed to evaluate the device's effectiveness in people with a disease and to determine the common short-term adverse effects and risks associated with the device. The study also includes evaluation of both safety and the effectiveness of the device. A grant from the National Institute of Health (NIH) is sponsoring this study. MUSC is the only enrolling site. MUSC, the study and the Principal Investigator will be paid by the grant to conduct the study. Approximately 30 people will take part in this study.

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask them to explain any words or information that you do not clearly understand. You are being asked to participate in this study because you have COVID-19 and neurocognitive symptoms. The investigator in charge of this study at MUSC is Mark George, MD.

B. PROCEDURES

As a reminder, this is not a treatment study and you are strongly encouraged to keep in regular contact with your primary care team. If you agree to be in this study, the following will happen:

Screening:

You will be informed of all study procedures and what is expected if you agree to participate. You will then sign the consent form. If you are a woman of childbearing age, we will ship you a urine pregnancy test by mail and you will perform the pregnancy test during the virtual call after the consent form is signed. During this visit, we will conduct assessments to verify that you meet study criteria.

The assessments that will be conducted will evaluate safety, mood, cognitive, and medical conditions.

If the screening procedures indicate you are qualified to participate, the MUSC study team will mail you a taVNS device.

Baseline:

These sessions will be split over a few days. The sessions will include various assessments to gauge the severity and frequency of the symptoms you are experiencing. We will send you a link to watch a training video on how to self-administer the taVNS device. During these sessions, you will receive extensive training on how to use the taVNS (ear stimulation) device. MUSC study personnel will walk you through operation of the device after you have completed watching the training video provided. You will complete tests to verify that you have adequate knowledge on how to operate the device with minimal supervision. You should not attempt to use the device if you have not a) watched the training videos, b) consulted with study staff, or c) do not feel comfortable operating the device.

Once you have successfully passed the tests on how to operate the device, the study team will instruct you on how to find the right dose. The purpose is to determine how much electrical

stimulation is needed for you to feel the taVNS (ear stimulation). We call this your perceptual threshold (PT) (the amount of stimulation that you need to be able to feel the device).

Randomized 2 weeks:

Immediately before the first session 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. For the first two weeks of treatments, you will be in your randomly assigned group. One group will receive either active taVNS (ear stimulation) or sham taVNS (ear stimulation). This part of the study is blinded meaning that neither the researcher nor you will know which type of stimulation you receive. We will not tell you which group you are in, but we can find this out if there is an emergency.

Each group will administer the intervention twice daily for six days per week for two weeks. You will complete brief assessments before and after each stimulation. We will monitor vital signs before, during and after stimulation. The stimulation will occur for 60 minutes. The two stimulation sessions each day should occur at least two hours apart. You will need to do two treatments each day, for 6 days/week. The MUSC research assistant will be online with you for at least the first three treatment sessions in order to make sure that you can do this correctly. They will only let you do this alone after they see that you are doing it correctly, and you feel comfortable. If you wish you can always have a research assistant online with you while you stimulate. The device will be recording how well it works during each session, as well as your heart rate. The MUSC research people will be monitoring this daily to make sure you are doing the treatments and that your heart is not slowing down too much.

Active Treatment 2 weeks:

For the second two weeks of treatment, everyone will receive active taVNS (ear stimulation). Like in the first two weeks you will administer the intervention twice daily for six days per week for two weeks. You will complete brief assessments before and after stimulation. We will monitor vital signs before, during and after stimulation. The stimulation will occur for 60 minutes. The two stimulation sessions should occur at least two hours apart.

After this you will ship the device back to MUSC in a prepaid shipping box.

Follow-up:

During the follow-up portion of the study, you will complete various assessments similar to those you completed while receiving stimulation. Follow-ups are completed during the 4th, 6th, 8th, and 12th week from the start of stimulation.

*NOTE: If you are a woman of childbearing potential and /or a man capable of fathering a child before, during, and/or after participation precaution should be taken. Examples of acceptable methods of birth control for participants involved in the study includes birth control pills, patch, IUD, condom, sponge, diaphragm with spermicide, or avoiding sexual activity that could cause you to become pregnant.

C. DURATION

Participation in the study will require 9 assessment visits (each lasting up to 2 hours), approximately 3 device training visits (each lasting up to 1 hour), and 48 treatments over a period of 15 weeks. Each

treatment session takes one hour. Thus, you will need to spend about 114 hours involved in the study, distributed over 15 weeks. Time spent completing assessments will vary greatly depending on how many symptoms you are experiencing. The total number of hours spent, approximately 114 hours over 15 weeks, is an estimated number.

D. RISKS AND DISCOMFORTS

We have used taVNS in several studies at MUSC in the Brain Stimulation Lab and so far, it appears safe with few side effects. We list some of these below.

Potential Skin Discomfort: You may feel local discomfort in your ear. This is likely temporary and just during the stimulation. Additionally, this often goes away after the first minute of the treatment. In extreme cases a burn may occur. Prevention of discomfort or burns requires you to notify the study team immediately, and they will stop stimulation and you will apply vitamin E cream. Tissue surrounding the ear may be sensitive, sore or feel slight numbness, and this is also temporary and will go away after stimulation is turned off.

Potential Headache, Dizziness, and Facial Pain: Ear stimulation may cause headaches or face pain, which should resolve shortly after treatment.

Safety in case of pregnancy: This protocol will not include pregnant women. If you are pregnant you cannot participate in the study. The risks of using taVNS with pregnant women are currently unknown. Please inform the research team if you are pregnant or think that you have become pregnant during the study. A urine pregnancy test will be performed before the experiment begins.

Potential decrease in heart rate: Ear stimulation may slow your heart rate. In rare cases (less than 1%) decreased blood pressure or fainting may occur. You should be sitting down during the treatment sessions in order to reduce the risk of fainting.

Potential Randomization Risk: The treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.

Questionnaire Risk: There are no anticipated risks to you. However, you may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. Also, being assessed for study entry, including the possibility that you may not meet criteria for entering the study may be distressing. If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for a one on one meeting with our team psychiatrist.

Unknown Risks: The Study team will let you know if they learn anything that might make you change your mind about participating in the study.

Loss of Confidentiality: There is a risk of a loss of confidentiality of your personal information as a result of participation in this study.

Worsening Symptoms: Please contact your primary care provider for standard of care options for symptoms you are experiencing. Please stay in regular contact with your primary care doctor for routine care and follow-up. If the symptoms you are experiencing worsen, please contact your primary care doctor immediately. As a reminder this study of taVNS is designed to be used in addition to standard of care treatments.

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 any MUSC medical record.

F. BENEFITS

The potential benefit to you is that the treatment you receive may prove to be more effective than other available treatments, although this cannot be guaranteed. As these NeuroCovid symptoms are rather new, there are no other proven treatments for NeuroCovid symptoms, although it is likely that standard treatments for specific symptoms might help. Please contact your primary care provider for standard of care options for symptoms you are experiencing. This study of taVNS is designed to be used in addition to standard of care treatments, so do not stop any treatments your doctors are prescribing. Please let the study staff know the medications and treatments you are taking.

G. COSTS

There is no cost to you for participating in this study. All of the ratings and treatments are free.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will receive compensation. There are nine rating sessions in this study and participants will receive $25 for each completed rating session. (The total amount you will receive is $225). All payments will be made through Clincards, mailed to you. Payment for study visits will be made using a pre-paid debit card, called a ClinCard. It works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be mailed a ClinCard at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule above. Details of the debit card system are explained on an additional sheet.

We will mail the first Clincard prior to your screening visit. The payment schedule is as follows: screening session, week one (1) randomization session, week two (2) randomization session, week three (3) unblinded active session, and week four (4) unblinded active session, each follow-up session (2-, 4-, 6-, 8- week post treatment). There is no payment for the treatment sessions.

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

Your alternative is to not participate in this study. We encourage you to contact your primary care provider for standard of care options for specific symptoms you are experiencing.

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.

In rare cases, the device manufacturer, Soterix, may need access to minimal PHI (such as your name, phone number and address) in the event there is a device malfunction. Well-trained MUSC staff will make every attempt to resolve any issues before putting Soterix in direct contact with you.

K. DISCLOSURE OF RESULTS

There is no plan to inform you later of the results of the study, but you can always contact the research staff and ask. If there are significant new findings during the course of the study, you will 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.

In addition to the main study, you have the option of participating in (insert the optional types of research that may be performed). Your protected health information may be used or shared with others outside of MUSC for this research as well. Please initial below if we may use/disclose your protected health information for the optional research portion/s of this study.

____Yes, you may use my protected health information for the optional research portions of this study.

____No, you may not use my protected health information for the optional research portions of this study.

M. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified.

N. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

O. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

P. CLINICAL TRIALS.GOV

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Q. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

Last Update: May 1, 2018

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The sponsor and the Food and Drug Administration (FDA) will receive copies of the research records. The investigators associated with this study, employees of the sponsor, the FDA, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event of a study related injury, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. The data collected on you to this point remains part of the study database and may not be removed. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Mark George, MD at 843-867-5142. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights

as a research subject in this study.

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

_____	_____
Signature of Person Obtaining Consent Date	*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.

The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, and MUSC Physicians Primary Care) 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." W**e collect or receive 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.**

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. 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.

5. 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.

6. 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.

7. Judicial and administrative proceedings. Your PHI may be released in response to a subpoena or court order.

8. Law enforcement or national security purposes. Your PHI may be released as part of an investigation by law enforcement.

9. Uses and disclosures about patients who have died. We provide coroners, medical examiners and funeral directors necessary information related to an individual's death.

10. 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.

11. Research. We may use your PHI if the Institutional Review Board (IRB) for research reviews, approves and establishes safeguards to ensure privacy.

12. 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.

13. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.

14. Marketing. We may send you information on the latest treatment, support groups and other resources affecting your health.

15. 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.

16. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.

B. You may object to the following uses of PHI:

1. Hospital directories. Unless you object, we may include your name, location, general condition and religious affiliation in our patient directory for use by clergy and visitors who ask for you by name.

2. Information shared with family, friends or others. Unless you object, 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. Psychotherapy notes.

3. 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 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 receive a copy of your PHI (including an electronic copy), which is contained in a designated record set that may be 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 fee for copying, mailing or other costs associated with your request. We may deny your request to inspect and receive a copy in certain very limited circumstances. If you are denied access to PHI, you may request that the denial be reviewed.

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.

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 369 / 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 Office of Civil Rights. The address will be provided at your request.

CHANGES TO THIS NOTCE

We reserve the right to change the terms of this Notice at any time. We also reserve the right to make the revised or changed Notice effective for existing as well as future PHI. This Notice will always contain the effective date. You may view this notice and any revisions to it at: http://www.musc.edu/privacy.

EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003.

Revised September 2013.