Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Combining taVNS with early CIMT to improve health outcomes of infants
Principal Investigator: Dorothea Jenkins, MD
NCT# 05101707

SUMMARY

You are being asked to enroll your infant in a research study. Research studies are voluntary and include only people who choose to take part. The purpose of the research is to test an experimental therapy to help young children who have weak arm movements improve their motor skills with the weaker arm.

If you choose to have your child participate, we will use constraint-induced movement therapy (CIMT) for 4 weeks with a non-invasive form of nerve stimulation using a device that is cleared by the US Food and Drug Administration (FDA) for children. Transcutaneous auricular vagus nerve stimulation (taVNS) stimulates a nerve by the ear that may enhance learning motor skills. CIMT involves placing a mitt constraint on the stronger arm and hand while encouraging your child to use the weaker arm and hand during intensive therapy sessions. Pairing CIMT and taVNS may improve your child's motor skills more than with therapy alone. The sessions in this study will take 2 hours a day, 5 days a week for 4 weeks (40 hours total CIMT), with 3 month follow-up, for a total of 4 months study participation. While your child may become distracted or tired during these therapy sessions, we do not expect any other risks or discomfort. We have used taVNS safely in over 500 sessions in newborns and infants. The alternative to this study is for your child to continue to receive the same skills training they are currently receiving by occupational therapists.

A. PURPOSE OF THE RESEARCH

We will test whether the experimental treatment of taVNS paired with 40 hours of CIMT allows your infant to move his or her weaker arm and hand better and strengthen the circuits in the brain involved with movement. You are being asked to allow your infant to join the study because he or she has motor problems with one arm and or hand and is 6 to 18 months of age, a time when we think we can improve brain circuits for better motor functioning.

Newborns who are born premature or suffer brain injury at birth are at risk for motor problems. The common motor skills of reaching and grasping that infants have to learn can be weaker on one side of the body, depending on the site of the brain injury. These skills are practiced with an occupational therapist, to help the infant strengthen these skills. Even with the high intensity therapy program of CIMT, it takes between 40-120 hours total treatment time for most infants to improve their motor skills.

The purpose of this study is to evaluate the safety and effectiveness of taVNS to improve motor skills when paired with the minimal amount of CIMT. A course of daily vagal nerve stimulation has been shown to be safe and to help the brain learn motor tasks in adults and in our study of infants with brain injury or prematurity, without side effects. Nerve stimulation has also been used in neonates to decrease pain and improve motor function after nerve injury at birth.

With electrodes on your child's left ear, the transcutaneous electrical nerve stimulator device will deliver short treatments of small electric pulses while he or she is undergoing CIMT with a therapist. These devices are FDA approved for pain management on muscles, and FDA-cleared and widely available for purchase online without a prescription for home use in adults and children. We will use this FDA-approved technology to stimulate the vagus nerve and brain pathways involved in motor control.

The FDA has approved transcutaneous electrical nerve stimulation (TENS) therapy for pain management. TENS requires placing electrodes directly on the skin of a specific part of your body. Small pulsed electrical currents are then delivered to these electrodes, which stimulate the underlying muscles and nerves. taVNS is a specific use of this FDA approved therapy, and is just another name for TENS therapy on the ear. We think it may have different effects than TENS on muscles, because we can stimulate a large nerve, called the vagus nerve, in the ear. This nerve connects to the brain and is important in many functions. In animals with brain injury, stimulation of the vagus nerve combined with specific motor training helps repair the motor areas of the brain. In adults and infants, taVNS improves motor function, when paired with a motor task. Using taVNS in infants to improve motor skills is experimental, even though the TENS device is cleared by the FDA.

This research study will be done at The Medical University of South Carolina and will include up to 10 infants receiving the experimental therapy of taVNS and CIMT. The Principal Investigator in charge of this study is Dr. Dorothea Jenkins. A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Jenkins and his/her research team's salaries will be paid by this grant.

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 him/her to explain any words or information that you do not clearly understand.

B. PROCEDURES

If you agree for your child to participate in this study, the following will happen:

1) Medical Records

The researchers will check your medical records to gather the following information: gestational age at birth, ventilator support, head ultrasound and MRI results, bottle feeding, infection, your and your child's condition during labor and delivery, your child's treatment and conditions, and developmental progress.

2) Transcutaneous Vagus Nerve Stimulation

Your child will receive taVNS treatment during the CIMT treatment session.

To treat with taVNS, we will place electrodes just inside and outside your child's left earlobe immediately prior to the CIMT session. During the first treatment, the researcher will determine how much electrical stimulation is needed for your child to feel a slight tingle. Next, the researcher will start of series of short treatment sessions while your child is actively engaged by the therapist in CIMT play-based therapy. During daily treatment, short brain stimulation pulses will be on for 2 minutes, and off for half a minute, and cycled repeatedly over the entire session, along with CIMT. We will monitor your child's heart rate and record their discomfort level with a standard infant behavior response scale before, during, and after the CIMT and taVNS treatments. If discomfort scores were to increase, we would hold treatments until the discomfort subsides. We will decrease stimulation level if discomfort recurs. The electrodes will be removed immediately after the CIMT session.

3) CIMT therapy sessions

In this study we will treat young infants and toddlers with CIMT and apply taVNS during the CIMT sessions. The CIMT therapy delivered in this study is not experimental.

For CIMT we apply a custom-made hand splint for your infant's stronger hand and place a soft mitt on this splint. The constraint mitt will only be worn during the therapy sessions which will be for 2 hours, 5 sessions per week for 4 consecutive weeks. This schedule gives the shortest CIMT treatment that has been shown to be effective (40 hours total). The therapist will keep daily therapy logs and ask you to report on your

infant's activities and progress at each session. Progress will be measured with arm and hand skills tests. The therapist will review targeted therapy goals at each session with you. Therapist and parents will also develop a practical written plan to maintain gains made during the CIMT program. The plan will involve motor skills and functional activities appropriate for the infant's age at discharge from the program.

We will videotape random weekly session (20% sessions) and score how well the therapist provides the CIMT treatment while delivering taVNS. We will store these videotapes for teaching purposes and future research.

4) Development

Preterm infants and neonates with brain injury routinely have assessments of development. In this study we will test fine and gross motor function and whether we are meeting your infant's individual treatment goals. We will perform the developmental tests before and at the end of 40hours of CIMT+taVNS treatment, and 3 months after completing the treatment in Occupational therapy clinic at MUSC or in your home.

C. DURATION

Each treatment session will last 2 hours daily for 5 days a week, for a total active treatment period of 1 month. With the 3 months of developmental follow-up, participation in this study will take a total of 4 months. Participation in this study will not interfere with routine therapy plans.

D. RISKS AND DISCOMFORTS

Potential Risks of taVNS

Potential skin discomfort, irritation. Electrical stimulation of peripheral nerves can cause temporary, local discomfort under the electrodes. In recent studies at MUSC in infants using taVNS there were no episodes of transient redness of the ear, and no other skin problems. We will monitor the skin for any redness or irritation, which should resolve quickly. If the skin under the probe shows redness that persists, we will switch ears (use the right ear) during the next session with lower stimulation. We will monitor your child for discomfort and decrese the microcurrent if he or she experience irritability with taVNS.

Potential decrease in heart rate: We expect stimulation of the vagus nerve to result in a brief decrease in your child's heart rate that quickly rebounds within a minute. With this brief heart rate change we know the electrodes are in good position.

Loss of confidentiality: There is a risk of a loss of confidentiality of your child's personal information and your labor and delivery personal information as a result of participation in this study. To keep this risk small, we will use a code to identify your child's records, and keep them in a locked cabinet and office. Your child will not be identified directly in any publication or presentation of this research.

Unknown Risks: TENS stimulation of peripheral nerves is FDA approved and is considered very safe. Although taVNS is essentially TENS on your child's ear, it is still an experimental procedure that has not been approved by the FDA to improve motor function during feeding. Therefore, there may be risks and discomforts that we are not aware of. The Principal Investigator will let you know if she learns anything that might make you change your mind about participating in the study.

E. MEDICAL RECORDS

Your infant is an MUSC patient and they have an MUSC medical record. Participation in this research study and results of research tests or procedures will be included in your infant's MUSC medical record. All information within your infant's medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify your infant to the extent allowed by law.

F. BENEFITS

The potential benefit to your child from participating in this study is learning to move their arm and hand faster or more effectively, but we are not sure taVNS paired with CIMT will have any effect on your child's movement. However, the information gained from the study may help researchers learn about how to better stimulate brain function in infants and also whether and how to use taVNS to help with recovery from preterm birth or brain injury.

G. COSTS

You will not be charged for the study procedures. All other usual costs of your child's care will be billed to your insurance.

H. Payment to Participants

You will not be paid for participating in this study.

I. ALTERNATIVES

If you choose not to participate in this study, your child will receive the usual occupational therapy services during one hour per week. taVNS is not available other than in this research study. CIMT therapy is not readily available for young infants but may be available with a local therapist. There are no other therapies to combine with CIMT to help an infant learn to move more effectively.

J. DATA SHARING

Information about your infant (including their identifiable private information and/or any identifiable records) may have all of your infant's 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.

The CIMT videotapes will be stored for future use and may include identifiable information. After we score the videotapes, if you do not wish for them to be used for teaching purposes, in presentations of this research, or for future research, you may have them destroyed by written request to Dr. Coker-Bolt or Jenkins.

K. DISCLOSURE OF RESULTS

Results of the overall research study will be disclosed to you at the end of the study by email.

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. SIGNIFICANT NEW FINDINGS

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

N. CLINICAL TRIALS.GOV

A description of this clinical trial is 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.

O. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. If consenting on paper, please initial by your choice below, and if consenting electronically scroll to the next screen and indicate your choice by selecting 'yes' or 'no' and then initial the statement confirming your choice in the space that follows.

____Yes, I agree to be contacted

____No, I do not agree to be contacted

GENERAL INFORMATION:

Results of this research will be used for the purposes described in this study. This information may be published, but your child will not be identified. Information that is obtained concerning this research that can be identified with your child 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 that your child is injured as a result of participation in this study, you should immediately take your child 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 your child is in a research study. They will call your child's study doctor who will make arrangements for your child's treatment. If the study sponsor does not pay for your

child's treatment, the Medical University Hospital and the physicians who render treatment to your child 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 your child.

Your child's participation in this study is voluntary. Your child 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 your child decides to do this. Your child's decision not to take part in the study will not affect your child's current or future medical care or any benefits to which your child is entitled.

The investigators and/or the sponsor may stop your child's participation in this study at any time if they decide it is in your child's best interest. They may also do this if your child does 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 child's participation in this study or study related injury, I may contact Dr Jenkins (843- 792-2112). I may contact the Medical University of SC Hospital Medical Director (843-792-9537) concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input about my child's rights as a research subject in this study, 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 for my child to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below if consenting on paper. If you are consenting electronically you should scroll to the next screen to sign.

_____

**Printed Name of Participant Date*

_____

Signature of Person Obtaining Consent Date

_____

Signature of Parent/Legal Guardian Date

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.