“N-Acetylcysteine and Transcutaneous Vagus Nerve Stimulation for Oromotor Rehabilitation in Infants of Diabetic Mothers”

NCT04632069

11/9/2021

**Medical University of South Carolina**
**CONSENT TO BE A RESEARCH SUBJECT**

**TITLE OF RESEARCH: N-Acetylcysteine and Transcutaneous Vagus Nerve Stimulation for Oromotor Rehabilitation in Infants of Diabetic Mothers**

## 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 two therapies to help infants of diabetic mothers (IDM) learn to feed by mouth better. If you choose to have your child participate, we will use an FDA-approved antioxidant, N-acetylcysteine (NAC), and a non-invasive form of brain stimulation with a device that is FDA cleared for use in children. NAC can restore normal levels of antioxidants in the brain. Transcutaneous auricular vagus nerve stimulation (taVNS) stimulates a nerve by the ear that enhances learning motor skills like feeding. We will test whether NAC+taVNS for 2 weeks allows your infant to learn to feed better and avoid a G-tube, change the stress level in the brain and strengthen brain circuits involved with feeding on MRI scan. NAC is safe even in very sick newborns and infants and is available over-the-counter without a prescription. We have used taVNS in over 500 sessions in newborns and infants without any significant side effects. The MRI studies and heel-stick blood drawing procedure in this study have minimal risk. The alternative to this study is simply for your child to continue to receive the same feeding skills training by therapists that he or she has been receiving to learn to feed.

## PURPOSE OF THE RESEARCH

You are being asked to enroll your child in a research study. Research studies are voluntary and include only people who choose to take part. 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.

Newborns who are born premature or suffer brain injury at birth are at risk for motor problems, including feeding difficulties. Feeding skills are practiced with a therapist, who helps the infant feed safely while learning this skill. Nevertheless, many infants have to stay in the hospital learning to feed, when they are otherwise ready to go home. Some infants are not able to take all feeds by mouth and have a tube surgically placed in the stomach for direct stomach feeding (G-tube), bypassing the mouth.

We have shown that taVNS paired with bottle feeding helped 70% of infants get to full feeds by mouth in 2 weeks, if they were not infants of diabetic mothers (IDM). However,

90% IDM failed to get to full feeds with taVNS. IDM infants have been shown to have lower levels of antioxidants and more stress in their brain well after birth, which may lead to learning problems. Brain MRI in our IDM infants showed lower levels of a major antioxidant, and these low antioxidant levels were important in their failure to learn to feed.

NAC is a widely-available, safe, FDA-approved antioxidant that can restore normal levels of the major antioxidant in the brain. NAC is available in health and grocery stores without a prescription. Transcutaneous auricular vagus nerve stimulation (taVNS) uses devices that are FDA cleared for children, to deliver a very small current to the vagus nerve at the ear. When the vagus nerve is stimulated at the same time as an activity such as sucking and swallowing, circuits in the brain involved in the motor activity are strengthened, which leads to better feeding in our infants. We have observed no major side effects with taVNS in over 500 treatments in neonates during feeding.

Stress in the brain impairs learning in general. We will test whether NAC lowers the stress in your infant's brain and leads to IDM infants being able to take all feeds by mouth with taVNS.

The US Food and Drug Administration (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, and small pulsed electrical currents are then delivered to these electrodes. taVNS is a specific use of this FDA approved therapy and is just another name for TENS therapy on the ear.

This research study will be done at the Medical University of South Carolina and will include 10 infants receiving NAC + taVNS treatment. The Principal Investigator in charge of this study is Dr. Dorothea Jenkins, and the study is sponsored by the National Institutes of Health.

## B. PROCEDURES

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

### 1) Magnetic resonance imaging (MRI)

We will perform three short MRI scans of your child's brain: before starting treatment, after 3-4 days of NAC to make sure the antioxidant level is increased, and after 2 weeks of NAC+taVNS therapy to track changes in brain regions. MRI does not involve radiation, is safe in newborns, and is routinely obtained in infants after significant brain injury. MRI uses a magnet and radio waves to make diagnostic medical images of the body. Your child will be swaddled after a feeding so that they will sleep, then they will be placed on a narrow bed in an FDA-cleared vacuum swaddle device, used for clinical MRIs in infants and slid into a small tunnel approximately 6 feet in length and 25 inches in diameter.

Earmuffs will be placed to block out the loud machine-like noise. We do not use sedation for infant MRI. MRI is standard of care for infants with brain injury. This information has been shown to predict how infants' brains will develop after discharge. We will have brain experts read the MRIs and share this information with you and your child's doctors if we detect injury that was not already reported.

**2) Blood sampling: A blood sample will be obtained by heelstick** before starting the study. Then on day 3-4 with the MRI, we will obtain a blood sample before, 30 minutes, 1, 2 and 4 hours after the NAC dose. Each sample will be 1 tenth of a teaspoon. The total amount of blood drawn will be less than one teaspoon. The timing and amount of these heelsticks are similar to following blood sugar levels, which are a routine part of your infant's care. The NAC levels will be measured to make sure we are giving enough NAC.

**3) NAC** will be given at half the dose used for acetaminophen (Tylenol) overdose, diluted with sterile water, by your infant's nasogastric tube every 6hours, 1hour before a feed, for a total of 14 days. The nasogastric (n.g.) tube is already in place for feeding. We will monitor for stomach upset and vomiting.

**4) Transcutaneous Vagus Nerve Stimulation**

Four days after starting NAC, we will begin taVNS during 2 feeds a day for 14 days. We will place an electrode just inside and outside of your child's left earlobe immediately prior to an oral feeding. During the first treatment, the researcher will determine how much electrical stimulation is needed for your child to feel the tingle and register a brief 10% decrease in heart rate on the heart rate monitor. Next, we will start taVNS stimulation at slightly below this level while your child is sucking milk from the bottle or breast for up to 30 minutes of the feeding. Your child's respiration rate, heart rate, and blood oxygenation will be monitored continuously during these treatments and behavior response scores recorded, as is standard for all babies in the neonatal intensive care unit. If discomfort scores were to increase, we would hold treatments until the discomfort subsides, and then restart treatment with decreased stimulation level. The electrodes will be removed immediately after the feeding each day.

We will collect information about the feeding volume, the feeding quality, the length of time to full feeds, as well as medical conditions that may affect feeding. If feeding volumes are improving and you request that your child have more treatments, we may continue treating for another 2 weeks, for a total of 4 weeks of taVNS treatments.

**5) Development**

Preterm infants and neonates with brain injury routinely have assessments of development. We will perform 2 short, 10 minute motor developmental tests on your child while in the bassinet in the nursery for basic motor skills. Routine developmental testing of your child will be done after discharge from the hospital, every 3 months up to 24 months in the NICU follow-up clinic.

**6) Medical Records**

The researchers will check your infant's medical records to gather the following information: gestational age, ventilator support, number of drops in heart rate or pauses in breathing,

bottle feeding, infection, your and your infant's condition during labor and delivery, your infant's treatment and condition, and developmental progress.

## C. DURATION

This study consists of the treatment period of up to 18 days and the developmental follow-up period. We will give NAC for a maximum of 14 days, including 10 days with taVNS. We will perform taVNS stimulation paired with feeding for up to 2 weeks, or for a maximum of 4 weeks if progress is being made in feeding volumes. Each taVNS treatment session will last 30 minutes with a bottle or breast feed. If your child is ready for discharge before the sessions are complete, we will discontinue treatments at or just before discharge. Participation in this study will not interfere with discharge plans. Developmental follow-up will be complete after 24 months. You may request that your child's participation in this study be stopped at any time.

## D. RISKS AND DISCOMFORTS

**Risks of taVNS:**

**Potential skin discomfort, irritation.** Electrical stimulation of peripheral nerves can cause temporary, local discomfort under the electrodes. We will also monitor the skin for any redness or irritation, which should resolve quickly. In recent studies at MUSC in infants using taVNS we did not see any redness of the ear or other skin problems.

We will monitor your child for discomfort with our standard infant behavior response scales (scale 1-7), recorded by nurses several times a day. Scores greater than 3 indicate mild discomfort. We will hold the treatment until scores are less than or equal to 3. If scores are repeated greater than 3, we will decrease the taVNS stimulation. This level of discomfort is much less than with an intravenous line placement, and similar to a heel stick to obtain blood.

**Potential decrease in heart rate**: Stimulation of the vagus nerve at the ear causes a brief lowering of heart rate by about 10% or 14 beats per minute and a quick rebound to normal levels within a minute. This quick decrease in heart rate lets us know our ear electrode is in the correct place. However, we have not seen bradycardia (heart rate less than 80 beats per minute for 5 seconds) with taVNS during feeding, but we will monitor your infant's vital signs throughout the study to ensure safety.

**Risks of NAC:** NAC given by n.g. diluted with saline, is expected to be well tolerated at this dose (less than the amount used in adult Tylenol overdose). We will monitor for stomach upset and vomiting, and increase the sterile water given with NAC, if necessary.

**Risks of MRI:** There have been no ill effects reported from exposure to the magnetism or radio waves used in this test, which is standard of care in infants with brain injury. A known risk is that the magnet could attract certain kinds of metal, which babies do not

routinely have implanted. However, if your child has MRI incompatible clips, we will not perform the MRI scan, and cannot participate in the study. Therefore, we will carefully ask you about metal within your child's body. We will also keep the examining room closed so that no one carrying metal objects enters while your child is in the scanner. The MRI may show abnormalities not detected by head ultrasound. If the research team finds new abnormalities, Dr. Jenkins or the pediatric neurologists will discuss these with you and your care team.

**Risks of Blood drawing by heelstick:** Heelstick is routine method of obtaining blood in infants and is used to monitor blood sugar levels every 1-2 hours, as your baby had after birth. Risks associated with drawing blood include momentary discomfort and/or bruising. Infection, excess bleeding, or clotting is possible, but unlikely.

**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 office. Your child will not be identified directly in any publication or presentation of this research.

**Unknown Risks**: NAC and TENS stimulation of peripheral nerves are FDA approved and 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 AND/OR CERTIFICATE OF CONFIDENTIALITY

Information that your infant participated in this study and the orders for the study procedures will be in his or her MUSC medical record. Results of research tests or procedures will not be included in your 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 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 feed faster or more effectively and avoid a G-tube, but we are not sure NAC+ taVNS will have any effect on your child's feeding. 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 in IDM infants.

## G. COSTS

The study drug will be provided to you at no cost. There will be no additional cost to you for procedures required in this research study. All study-related tests and procedures will be paid for by the Sponsor. All routine clinical care that you would have undergone without participation in the study, including testing and procedures, will be billed to you/your insurance company.

One MRI is standard of care for all infants with brain injury and will be billed to your insurance if ordered by the clinical team.

## 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 feeding training. Other than practicing feeding, there are no other ways to help an infant learn to feed more effectively.

## J. DATA SHARING

Information about your infant (including his or her identifiable private information and/or any identifiable biospecimens) may have all of his or her identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

## K. DISCLOSURE OF RESULTS

If there are significant new findings during the course of the study, you will be notified in the nursery or during a routine clinic visit.

## 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.

## SIGNIFICANT NEW FINDINGS

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

## COLLECTION OF SPECIMENS

The research MRI scans will be collected to look for the effect of treatment on brain circuits and metabolism. The raw data from the scans will be stored long-term, identified by study number, to see how well these MRI changes track with your infant's development. The risk of storing these scans under the study number is small and is the same as for the loss of confidentiality, above. The National Institutes of Health requires that we share unidentified raw data with other investigators who request to use this data, but your infant's name will not be identified. We may combine this data with other MRI data from other babies, to help us understand brain development in infants of diabetic mothers better and the effects of this treatment, but we will not share your infant's name. The MRI data is important to determine if NAC works at the doses we are using. You may refuse to allow us to keep the MRI data, but your infant will not be able to participate in the study. The analysis of the MRI data, once complete, cannot be withdrawn, but will be deidentified for publication and sharing of raw data with other researchers. The MRI data obtained from your infant in this research may help in the development of a future commercial product. There are no plans to provide financial compensation to you should this occur.

- If the pediatric neurologists reading the MRIs determine that there is an important finding which you and your infant's doctors do not know about, we will tell you and your infant's doctors about this finding, and they will decide on further studies.

## FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about your infant's development and 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. Dorothea Jenkins at 843-792-2112. 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 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 and if you are consenting electronically you should scroll to the next screen to sign.*

_____ _____

Signature of Person Obtaining Consent Date *Name of Participant

Participant's Personal Representative (if applicable):

_____

Name of Personal Representative *(Please print)*

_____

Signature of Personal Representative Date

Relationship: ___ Spouse ___ Parent ___Next of Kin ___Legal Guardian* ____ DPOA for Healthcare*

**(If you are the health care agent or guardian, please provide proof of your authority to act on behalf of the patient)*

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.