Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Speech Entrainment for Aphasia Recovery (SpARc)

NCT#: 04364854

Principal Investigator: Dr. Leonardo Bonilha

Medical University of South Carolina
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SUMMARY

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. This is a research study to find out the best dose of a specific computerized aphasia treatment called Speech Entrainment Therapy (SET). Appointments will be performed online through a telehealth platform. Participants will be randomly assigned to one of four different SET treatment groups. One of these groups includes a control group. Participants who are randomized to the control group will not receive any SET. Participants will view SET through a computer program on a laptop. The purpose of SET is to improve speech fluency.

You will receive several days of language testing, a neurological exam, and complete surveys. There is an optional MRI at the 3-month or 6-month follow-up visit. We will video record you during assessments and some treatment sessions. Depending on the group to which you are randomized, you will receive SET for one hour, five days a week (Monday – Friday) for either 3 weeks, 4.5 weeks, 6 weeks, or you will not receive SET.

You may benefit from participating in this study if the therapy is effective for you, but that cannot be guaranteed. There are minimal risks to participating in this study. Risks include fatigue, stress from testing and treatment, and negative reaction to MRI if claustrophobic. You do not have to participate in this study to receive speech therapy and could opt for other forms of speech therapy (e.g., outpatient, in-home, etc.).

A. PURPOSE OF THE RESEARCH

The purpose of this study is to determine the most effective dosage of SET for patients with aphasia. You are being asked to join because you had a stroke at least six months ago and may have difficulty speaking.

The best dose will be determined by comparing three experimental doses of SET to a no-SET group. SET is an audio-visual computer therapy program that has been shown to improve language fluency in patients with aphasia. You will be asked to listen to someone speaking and speak along with them as best as you can.

This study will enroll a total number of 80 participants with non-fluent aphasia. It is also being conducted at the University of South Carolina (UofSC) and University of Utah (UoU). MUSC will enroll a total of 30 participants. This study is funded by a grant from the National Institutes of Health (NIH).

The lead investigator of this study is Dr. Leonardo Bonilha. Portions of Dr. Bonilha's and his research team's salaries will be paid by this grant.

B. PROCEDURES

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

Baseline Visit (Week 1):

We will review the study and consent form and answer any questions you may have. After you have consented, you will be asked to provide MRI/CT scans and participate in a neurological exam to confirm that you had a left hemisphere stroke. This may require access to your electronic medical record or signing a release of medical records. Presence of right hemisphere stroke or other structural neurological conditions (such as brain tumors or arteriovenous malformations) will exclude you from participation in this study.
If the imaging verifies presence of left hemisphere stroke, you will then be given a common clinical aphasia assessment to determine the presence of non-fluent aphasia. If you are found to have non-fluent aphasia and are eligible for the study, you will be randomly assigned to one of four groups, like drawing numbers from a hat.

- Group A will receive SET for 3 weeks
- Group B will receive SET for 4.5 weeks
- Group C will receive SET for 6 weeks
- Group D will not receive SET for 6 weeks

We will continue baseline language testing if time permits. It may take several days to complete the baseline assessments. Baseline language assessments include story-telling tasks, a test of your ability to process word meaning, a test of your ability to repeat words, a test that looks at your communication skills and quality of life, and a test of your cognition. We will also collect individual demographic and baseline characteristics, such as presence of post-stroke depression and fatigue. A video recording will be taken of you from your head to torso for all baseline assessments for scoring purposes.

If randomized to an SET group (A, B, C), you will be provided a telehealth therapy kit, which includes a laptop, mouse, headphones, and wifi hotspot (if required). You will be asked to sign a "technology contract" and are expected to return all loaned items upon completion of the study.

The remainder of the study timeline will depend on the group to which you are randomized. The group schedules are listed below:

Group A (SET for 3 weeks)

Weeks 2-4: You will receive SET Monday-Friday for one hour each day for 3 weeks. SET will be performed through a speech therapy app that is preloaded on the laptop loaned to you. You will be accompanied by a trained member of the research team who will instruct you how to perform the

task. You will be seated in front of a computer screen and fitted with headphones. You will then see videos of someone speaking and be asked to speak with them.

- *Week 5:* This is your 1-week follow-up. We will perform language testing over a 2-day period, depending on how long you require to complete the assessments.

- *Week 16:* This is your 3-month follow-up. We will perform language testing over a 2-day period, depending on how long you require to complete the assessments.

- *Week 28:* This is your 6-month follow-up. We will perform language testing over a 2-day period, depending on how long you require to complete the assessments.

Group B (SET for 4.5 weeks)
Weeks 2-6: You will receive SET Monday-Friday for one hour each day for 4.5 weeks. SET will be performed through a speech therapy app that is preloaded on the laptop loaned to you. You will be accompanied by a trained member of the research team who will instruct you how to perform the task. You will be seated in front of a computer screen and fitted with headphones. You will then see videos of someone speaking and be asked to speak with them. In week 6, you will have three days of SET.

- *Week 7:* This is your 1-week follow-up. We will perform language testing over a 2-day period, depending on how long you require to complete the assessments.

- *Week 18:* This is your 3-month follow-up. We will perform language testing over a 2-day period, depending on how long you require to complete the assessments.

- *Week 30:* This is your 6-month follow-up. We will perform language testing over a 2-day period, depending on how long you require to complete the assessments.

Group C (SET for 6 weeks)
Weeks 2-7: You will receive SET Monday-Friday for one hour each day for 6 weeks. SET will be performed through a speech therapy app that is preloaded on the laptop loaned to you. You will be accompanied by a trained member of the research team who will instruct you how to perform the task. You will be seated in front of a computer screen and fitted with headphones. You will then see videos of someone speaking and be asked to speak with them.

- *Week 8:* This is your 1-week follow-up. We will perform language testing over a 2-day period, depending on how long you require to complete the assessments.

- *Week 19:* This is your 3-month follow-up. We will perform language testing over a 2-day period, depending on how long you require to complete the assessments.

- *Week 31:* This is your 6-month follow-up. We will perform language testing over a 2-day period, depending on how long you require to complete the assessments.

Group D (no SET)
Weeks 2-7: You will not receive SET during this time frame.

- *Week 8:* This is your 1-week follow-up. We will perform language testing over a 2-day period, depending on how long you require to complete the assessments.

- *Week 19:* This is your 3-month follow-up. We will perform language testing over a 2-day period, depending on how long you require to complete the assessments.

- *Week 31:* This is your 6-month follow-up. We will perform language testing over a 2-day period, depending on how long you require to complete the assessments.

For all groups, if appointment conflicts arise during the SET or no-SET phase, in order to stay on the study timeline, you may be asked to schedule make-up appointments on the weekends, if agreeable. All baseline and follow-up testing will be video recorded and uploaded to an MUSC-approved cloud storage service. Research staff members at UofSC will have access to these videos for scoring. A central technology support specialist located at MUSC will be available for technology assistance for all sites during the trial and will also have access to all video recordings in order to monitor audio/visual quality.

All participants, including controls, will have the opportunity to participate in an optional research MRI. This MRI is completely voluntary and may occur at the 3- or 6-month follow-up visit. The MRI is performed on-site at MUSC, and an MRI safety screening will be performed prior to the visit to ensure safety. If you choose not to participate in a research MRI, you will still be allowed to complete the study.

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

___ *Yes, I agree to have an MRI.*
___ *No, I do not agree to have an MRI.*

C. DURATION

This study will range from a timeline of 28 weeks to 31 weeks depending on what group to which you are randomized. All testing appointments will last no longer than three hours. All SET appointments last one hour.

D. RISKS AND DISCOMFORTS

D1. *Optional MRI scanning.*
There have been no ill effects reported from exposure to the magnetism or radio waves used in this test. A known risk is that the magnet could attract certain kinds of metal; therefore, we will carefully ask you about metal within your body (including certain dyes found in tattoos). If there is any question

about potentially hazardous metal within your body, you will be excluded from participation in the optional research MRI. We will also keep the examining room locked so that no one carrying metal objects can enter while you are in the scanner. Please, inform the study staff if you have a history of claustrophobia (extreme anxiety in close spaces). This may also be a contraindication to participation in the optional research MRI.

Temporary hearing loss has been reported from the loud noise. This is why you will be asked to wear headphones and earplugs.

D2. *Patient assessment.* You may have a negative reaction to neuropsychological testing. For example, this can be caused when persons realize that their performance on a given test is far worse than they would have expected. This may cause frustration or irritability. We always make sure that ample time is allotted for neuropsychological testing, and you will be allowed breaks as needed.

D3. *SET*. You may experience fatigue during SET. Each SET session will be limited to approximately 60 minutes in effort to lessen fatigue.

D4. *Loss of confidentiality.* There is the risk of a breach of confidentiality, despite the steps that will be taken to protect your identity.

D5. *Incidental findings*. We are performing imaging solely for the research purposes described above. It is not a clinical scan intended for diagnostic or therapeutic purposes. If you want your scan to be reviewed by a physician so that the physician can look for medical issues, you can request a copy of your scan. We will provide an electronic copy at no charge.

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

CERTIFICATE OF CONFIDENTIALITY

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

Information about your study participation will not be in your MUSC medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information

released to an insurer, medical care provider, or any other person not connected with the research, you must authorize the researchers to release it.

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

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

F. BENEFITS

If you have aphasia, you may benefit from the behavioral therapy provided; however, this is not guaranteed. While behavioral aphasia therapy has been shown to provide improvements in language function following a stroke, it is not guaranteed or promised that you will personally notice any improvement. If you do not receive SET, you may still benefit from a thorough evaluation of your communication abilities.

G. COSTS

There will be no cost to you as a result of participation in this study.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid $25 at the completion of each of the following appointments: completion of baseline testing, 1 week post SET or no SET, 3 months post SET or no SET, and 6 months post SET or no SET, for a total of $100.

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.

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

If you choose not to participate in this study, you could receive other treatments for your condition. Other therapy options would include initiating or continuing traditional speech therapy in the setting of your choice, (e.g., a rehabilitation facility, outpatient clinic, or home health).

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.

K. 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 who may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:
    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

In addition to this study, you have the option of participating in an MRI. 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 portions of this study, or scroll down to the bottom of the screen and select your choice electronically:*

___ *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.*

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.

L. SIGNIFICANT NEW FINDINGS

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

M. 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.

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. CLINICAL TRIALS.GOV

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

P. 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 for paper consents, or scroll down to the bottom of the screen and select your choice electronically:*

___ *Yes, I agree to be contacted.*
___ *No, I do not agree to be contacted.*

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

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

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

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

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact ***Leonardo Bonilha, M.D., Ph.D. at 843-792-5044***. I may contact the Medical University of SC Patient and Family Care Liaison at (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.

If you wish to participate, please sign below for paper consents or scroll to the bottom of the screen to provide an electronic signature.

_____ _____

*Name of Participant *(Please print)* Signature of Person Obtaining Consent Date

_____

Signature of Participant Date

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 participant.)*

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.