Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Priming Upper Extremity Motor Practice with Aerobic Exercise (Pump-Ex): A feasibility and pilot study

SUMMARY

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this research study is to test the methods and procedures of combining aerobic exercise and an upper extremity rehabilitation program, called Duck Duck Punch , for chronic stroke survivors. Additionally, this study will also examine the effect of combining aerobic exercise and Duck Duck Punch on upper extremity function and the effect of aerobic exercise and Duck Duck Punch on the nervous system in chronic stroke survivors.

If you agree to participate, you will undergo screening that includes completion of questionnaires, exercise testing, and tests of your arm that was most affected by your stroke. If you are eligible, you will attend a rehabilitation program that combines aerobic exercise and upper extremity rehabilitation. You will complete a total of eighteen sessions (three times weekly for six weeks) of fifteen minutes of aerobic exercise on a stationary bike followed by Duck Duck Punch. At the beginning, midpoint, and end of the study you will undergo tests involving a type of brain stimulation that uses electrical and magnetic impulses and blood sampling. These tests will occur before and after your fifteen-minute session of aerobic exercise and Duck Duck Punch session. There will be a total of twenty-three visits (screening and assessment and intervention visits combined) that are expected to last between one and two hours each. It is expected that it will take approximately eight weeks to complete all visits. There are risks associated with this study which include muscle or joint soreness or pain from the rehabilitation program, headaches from brain stimulation, and pain from blood sampling. Your alternative is not to participate in this study.

This is a clinical trial and any benefits cannot be guaranteed. You may see improvements, worsening, or no change in upper extremity function following the aerobic exercise and Duck Duck Punch intervention. There are risks and discomforts associated with non-invasive brain stimulation, blood sampling, exercise, Duck Duck Punch, and loss of confidentiality. If you are interested in learning more about this study, please continue to read below.

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. This is a pilot study which means that we are testing the methods and procedures involved with combining aerobic exercise and Duck Duck Punch before testing the intervention on a larger scale. The purpose of this study includes an evaluation of the safety and effectiveness of combining aerobic exercise and Duck Duck Punch. Duck Duck Punch is approved by the Food and Drug Administration for physical rehabilitation for adults. 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. You are being asked to participate in this study because you have experienced a stroke. The investigator in

charge of this study is Ryan Ross, Ph.D. The study is being done at MUSC. Approximately 10 people will take part in this study.

B. PROCEDURES

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

Screening and Assessment Procedures

You will have the following screening and testing to make sure that you are eligible. These assessments will take place over the course of two visits lasting approximately one hour each. Visit 1 will consist of the A, B, C and D and Visit 2 will consist of E.

A. **Patient Health Questionnaire:** This is a brief questionnaire that will ask you about your feelings, mood, and emotions over the previous two weeks.

B. **Montreal Cognitive Assessment:** This is a test of your ability to remember things and organize your thoughts. It will take you about 10 minutes to complete.

C. Screening for safety to receive brain stimulation. You will be asked several questions relating to any metal you may have in your body, any previous history of seizures, any previous brain surgery, any history of headaches, child bearing potential, and medication use.

D. **Clinical Assessments:** You may be asked a series of questions or to perform several standardized tests similar to those performed in general outpatient physical therapy. These include tests to measure upper extremity function and tests to assess physical function as well as other dimensions of health-related quality of life: emotion, communication, memory and thinking, and social and role function.

1. **Fugl-Meyer Upper Extremity Assessment:** This is a test of how well you can move your arm that was most affected by your stroke into various positions. For example, bending your elbow or reaching your arm over your head. It will take about 15 minutes to complete. This assessment will be videotaped to allow another reviewer to score your assessment to ensure accuracy.
2. **Wolf Motor Function Test:** This is a test of how quickly you can use your hand and arm that was most affected by your stroke to do various functional tasks such as picking up a soda can or folding a towel. It will take about 20 minutes to complete.
3. **Stroke Impact Scale:** This is an evaluation that will ask you to rate how difficult it is to use your hand and arm that was most affected by your stroke to do different activities at home such as turn a doorknob or manipulate coins. This evaluation will take about 10 minutes for you to complete.
4. **International Physical Activity Questionnaire:** This brief survey of your physical activity habits over the last 7 days. We will ask you about your

activity related to your job, transportation, at home, recreation, and leisure. This will take about 10 minutes to complete.

5. **NeuroCom Balance Master™ Test:** This is brief test of your balance. You will be asked to stand on a force plate in a big machine. You will be harnessed in, so you will not be able to fall. During the test you will be asked keep your eyes open or closed, and the floor or walls may move. We will warn you before anything starts to move. The goal will be to stand as still as you can. This test will take about 15 minutes for you to complete.

E. **Exercise Tolerance Testing:** We will test your ability to exercise at different intensities while pedaling a stationary bike. We will not ask you to exercise or go faster than feels comfortable and safe for you. Your blood pressure will be monitored prior to, during, and at completion of the exercise testing session. If necessary, the test will be stopped because of excessive blood pressure changes such as a drop in maximum blood pressure, or increase in blood pressure between heart beats or inappropriate slow heart rate. Your heart rate will be determined from the electrocardiogram (EKG). An EKG machine measures heart function using small metal tabs attached to specific body parts. The EKG machine records the electrical impulses of the heart. Your maximal heart rate will be recorded as the highest heart rate achieved during the exercise tolerance test.

For the test, you will first sit quietly for two minutes. Then you will begin pedaling at a relatively light intensity. Every 3 minutes the intensity of pedaling will increase until maximal effort is achieved.

If screening and test results show that you are eligible for the study, you will be scheduled for one additional baseline assessment visit (Visit 3 – F, G, H), eighteen intervention visits (Visits 4 – 21; aerobic exercise + Duck Duck Punch), and two post-intervention assessment visits (Visits 22, 23).

F. **Transcranial Magnetic Stimulation (TMS):** TMS is form of non-invasive brain stimulation. Prior to beginning the aerobic exercise + Duck Duck Punch intervention you will be asked to undergo an evaluation using TMS that stimulates the brain in order to get a small muscle in the hand or arm to twitch. A small stimulus that feels like a slight pinch, or tap, will be given to the brain using a handheld stimulator. The stimulator will be moved around until the best position is located to give a twitch of an arm or hand muscle. This will be measured by electromyography (EMG) by several small electrodes that will be placed on various muscles on either the arm or hand.

G. **Muscle activity testing:** We will make several measurements to provide objective information regarding the activity of muscles while they are at rest and stimulated by TMS. Muscle activity will be measured by electromyography (EMG). EMG allows us to measure the electrical activity of a muscle in response to TMS. This will allow us to develop a better understanding of how the brain is influenced by aerobic exercise and/or Duck Duck Punch. Small gel pads attached to wires will be placed on a small muscle at the base of your thumb to measure muscle activity.

H. **Paired associative stimulation (PAS):** Prior to beginning your aerobic exercise + Duck Duck Punch intervention you will undergo PAS testing. PAS testing uses both of the TMS and EMG procedures that were described. The PAS procedure includes TMS and stimulation of a nerve in your wrist. An electrical stimulator and gel pads attached to wires will be used to perform the electrical stimulation. During this procedure you will feel a light stimulation of a nerve in your wrist and at approximately the same time you will receive TMS at a predetermined spot. The stimulation to your nerve will feel like a small tingling or brush against your skin. You may also recognize that some of the muscles in your hand or arm twitch. Both the TMS and nerve stimulation and last for less than a second. You will receive a total of 200 TMS and nerve stimuli over about 14 minutes.

Intervention procedures

Intervention procedures will take place three days per week for six weeks (Visits 4 -21). Each visit will take approximately one to two hours. You will experience all of the following procedures during your intervention visits.

I. **Duck Duck Punch:** Each session you will be asked to perform approximately 200 arm movements while playing Duck Duck Punch. Duck Duck Punch is an interactive video game in which you will use your arm that was most affected by your stroke to reach forward and "punch" the virtual ducks that you see on the screen. During the session, study personnel will monitor your fatigue and pain levels.

J. **Transcranial Magnetic Stimulation (TMS):** On three separate occasions (Visits 5, 13, and 20) you will undergo a TMS assessment. Before and after your Duck Duck Punch session you will be asked to undergo an evaluation using TMS that stimulates the brain in order to get a small muscle in the hand or arm to contract.

K. **Aerobic exercise:** Every other weekday (Monday, Wednesday, Friday) you will be asked to ride a recumbent stationary bike before you complete your Duck Duck Punch session. On these visits you will perform 15 minutes of high intensity aerobic exercise. The intensity will be defined as a percentage of your heart rate reserve. Heart rate reserve is equal to the highest heart you achieve in the exercise tolerance test minus your heart rate at rest. Your heart rate will be monitored continuously throughout the exercise session and your blood pressure, and rate of perceived exertion (RPE) will be monitored before, every five minutes during exercise, and five minutes after exercise.

L. **Blood Draw:** On three separate occasions (Visits 4, 12, and 21) you will have a blood sample taken before and after your aerobic exercise session. In each of these sessions, a nurse will place a catheter in a superficial vein in your forearm. A catheter is a flexible needle that will stay in your arm while you exercise. This will allow us to obtain small blood samples before and immediately after you complete your bout of exercise. Each visit will require two samples. Each sample will require slightly less than 2 teaspoons of blood and it is expected that the total amount of blood drawn for all three sessions will be approximately 12 teaspoons. We hope collecting these samples will provide us with a better understanding of the influence of aerobic exercise on an important marker present in blood.

Post-intervention procedures

Following the intervention you will attend two post-intervention visits (Visit 22 and 23). On visit 22 the Clinical Assessments described in (D) will be performed. On Visit 23 TMS, EMG, and PAS as described in (F, G, H) will be performed.

C. DURATION

Participation in the study will take about 23 visits over a period of 8 weeks. Each visit will take up to two hours.

D. RISKS AND DISCOMFORTS

There is a risk of a loss of confidentiality of your personal information as a result of participation in this study. Researchers will take appropriate steps to minimize these risks and protect any information collected about you. The data from your questionnaires, interviews, and testing results will be de-identified once they have been collected and before they are stored in a database. Assessment videos will be downloaded from cameras promptly and stored on a secure database identifiable only by subject code.

Screening: This activity will involve answering a few questions that could cause you to become upset, emotionally distressed, or embarrassed. To reduce this risk, screening will occur in a private office with only study personnel present.

NeuroCom Balance Master™ Test: You will wear a safety harness so that you cannot fall if you lose your balance. Occasionally, participants report dizziness or nausea, if you begin to feel this, tell the assessor and we will end the assessment.

Duck Duck Punch: Repetitive movement performed while playing Duck Duck Punch may cause fatigue and/or shoulder pain. To reduce this risk the study personnel will assess your fatigue and pain levels at each session. If necessary, the amount of Duck Duck Punch performed may be reduced.

Aerobic Exercise: The physical activity involved with these sessions may contribute to temporary muscle soreness or fatigue. These are normal responses to exercise and generally disappear within 1-2 days. Adequate rest will be incorporated between experimental sessions. During each exercise session you will be encouraged to complete the 15-minute bout without stopping, however we will monitor your vital signs (heart rate and blood pressure) before, during, and after exercise to ensure that you are responding appropriately to exercise. If an abnormal response is detected then exercise will be terminated immediately. Despite these safety measures, as with any exercise activity, there is a risk that you may experience an injury. There is also a slight risk of skin irritation from the use of the blood pressure cuff and heart rate monitor strap. To reduce this risk, study personnel will perform visual inspection of your skin periodically. Your risks from participating in this study are no greater than the risks during conventional physical rehabilitation services. The same precautions and safety guidelines will be taken as those that are provided in patient care rehabilitation settings.

Transcranial Magnetic Stimulation (TMS): There is a very low risk of a seizure during or after TMS. The risk of seizure induction by this protocol has been thoroughly assessed and the TMS parameters have been chosen to be well within published safety guidelines for the conduct of TMS studies in human subjects. You will be receiving much less stimuli than the maximum suggested and all parameters (frequency, intensity, type of stimulation) are within the published safety guidelines. If you have a history of seizure, you will not be allowed to participate in this portion of the study. Additionally, if you are a woman of child bearing potential you will not be allowed to participate in this portion of the study. Headaches and complaints of short-term hearing difficulties have also been reported following TMS. Headaches are temporary and manageable with common over-the-counter pain remedies and you will wear foam earplugs for protection during TMS sessions. To reduce the risk of an adverse event, you will be required to pass a TMS screen and will be continuously monitored for any abnormal responses to TMS. Additionally, the TMS device is equipped with an automatic shut-off switch in case the coil delivering the stimulation begins to overheat.

Muscle Activity Testing: There is a slight risk of skin irritation with the use of surface EMG electrodes and tape. To reduce this risk, study personnel will perform visual inspection of your skin periodically.

Paired Associative Stimulation (PAS): The risks associated with PAS are the same as the risks for TMS, however some irritation of the skin at the site the peripheral nerve stimulation may occur.

Blood Draw: A nurse will perform all blood sample collections. Risks associated with drawing blood from your arm include momentary discomfort, pain, and/or bruising. Infection, excess bleeding, clotting, or fainting is possible, although unlikely. To reduce this risk, only a nurse will be permitted to perform blood samples collections. Proper anti-septic procedures will be followed in order to minimize the risk of infection at the site of the puncture of the vein.

Unknown Risks: The experimental treatments may have unknown side effects. The researchers will let you know if they learn anything during the course of the study that might make you change your mind about participating in the study.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform Dr. Ross or the person reviewing this consent with you, before enrolling in this or any other research study or project. Throughout the study, the researchers will notify you of any new information that may become available.

E. MEDICAL RECORDS

Information about your study participation will not be in your medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record.

F. BENEFITS

The potential benefit to you is that combining aerobic exercise and Duck Duck Punch may improve arm motor skills although this cannot be guaranteed. It is possible that there will be no direct benefit to you from participating in this study. However, it is hoped that the information gained from the study will help in the treatment of future patients with conditions like yours and will help the researcher learn more about the effect of combining aerobic exercise with upper extremity rehabilitation in chronic stroke survivors.

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 per visit for participation in this study. Total compensation for the study is up to $575. 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 given 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

Your alternative is to not participate in this study.

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. DISCLOSURE OF RESULTS

Results of this research will be used for the purposes described in this study and will not be disclosed to you as a subject.

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 FDA approves the drug or device 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. STUDENT PARTICIPATION

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

O. EMPLOYEE PARTICIPATION

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

P. COLLECTION OF SPECIMENS

Blood specimens will be collected as part of the study procedures. The specimens collected will be used to assess an important molecule called brain-derived neurotrophic factor. Blood samples will not be linked to your identity and stored at MUSC. The PI and SCTR Research Laboratory staff will have access to the specimens and associated data. The specimens will be stored only for the purposes of this study. Specimens will not be stored for future use. The results of specimen analysis will only be published as a group and will in no way be linked to your identity. Additionally, research results will not be added to your medical record.

Q. RESTORE

We would like to include data collected in this study and from other stroke related studies you may participate in with the Registry for Stroke Recovery (RESTORE-Pro00037803). RESTORE provides MUSC's stroke recovery research community with a database containing information on research participants including stroke type, disability status, and demographics to assist in recruitment. By

including data from this study in RESTORE, MUSC researchers will have access to a more complete database with key elements of physical function characteristics for more targeted recruitment efforts in the future. Additionally, this could reduce the burden placed on subjects by reducing the duplicative efforts of collecting common data and assessments requested by multiple studies and storing them in one centralized and secure location.

If you consent to participate in RESTORE your data from this study, including your personal health information, will be included in the registry. You will be asked to sign a Release of Study Records Form to share data from other stroke related studies in which you have participated. If you authorize this release your information from those studies will become part of the RESTORE registry study.

R. FUTURE CONTACT

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

____Yes, I agree to be contacted

____No, I do not agree to be contacted

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

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

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. The data collected on you to this point remains part of the study database and may not be removed. Your

decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

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

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Ryan Ross at (843)-792-3477. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.
I agree to participate in this study. I have been given a copy of this form for my own records.

_____ _____
Signature of Person Obtaining Consent Date *Name of Participant

_____
Signature of Participant Date

MUSC
Medical University of South Carolina

NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESSS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

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.