

Official Title: A Novel Therapy + E-learning Self-management Program for Stroke Survivors

NCT: 04245449

Document Date: 8/14/2019

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

TITLE OF RESEARCH:

A novel therapy + e-learning self-management program for stroke survivors

SUMMARY:

You are being asked to provide your consent (permission) to volunteer for a research study. The purpose of this study is to test a new type of stroke rehabilitation program that combines occupational therapy with a computer-based stroke education course. If you volunteer for this study, you will participate in (1) 24 occupational therapy sessions at the Medical University of South Carolina over 3 months and (2) 3 months of computer-based education. You will also participate in 4 evaluation sessions (before, in the middle, and at the end of the therapy + education program, and within 60 days after the end of the program). The risks to participation include fatigue and arm pain from the therapy program, and also loss of privacy from being a part of the computer-based educational program. Benefits may include greater overall knowledge of stroke and stroke rehabilitation. An alternative to this study is to attend outpatient occupational therapy.

A. PURPOSE OF THE RESEARCH

You are being asked to volunteer for 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 the study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand.

The purpose of this study is to determine whether it is “feasible” to combine stroke rehabilitation occupational therapy with an online stroke rehabilitation education program. In other words, we want to know if combining therapy with online learning can easily be done. You are being asked to participate in this study because you have had a stroke. The study is sponsored by the National Institutes of Health (NIH) through the Medical University of South Carolina (MUSC) Center in stroke recovery. The investigator in charge of this study is Michelle Woodbury. The study is being done at 1 site; the Medical University of South Carolina. Twelve (12) people will take part in this study.

Volunteers in this study will participate in a 3-month online educational program. This will include 24 stroke rehabilitation occupational therapy sessions at MUSC and weekly online learning activities. We will examine the “feasibility” of this program (can participants easily do the program), and knowledge about how to take care of one’s self after stroke through surveys and focus groups. We will also test arm movement skills before, during and after the 3-month program to see whether the therapy + online learning improved arm movement skills. A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Woodbury’s and her team’s salaries will be paid by this grant.



Please read this consent form carefully and take your time making your decision. As your study investigator 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 had a stroke. The study is sponsored by the National Institutes of Health (NIH) through the Medical University of South Carolina Center of Stroke Recovery Research. The investigator in charge of this study at MUSC is Michelle Woodbury. The study is being done at 1 site. Approximately 12 people will take part in this study.

B. PROCEDURES

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

1. You will have the following questions and assessments to make sure that you are eligible. These questions and assessments will take about 30-45 minutes.
 - We will ask you to tell us
 - about the type of stroke you have had
 - your age and handedness
 - any pain you have
 - any past orthopedic conditions (fracture, muscle or tendon injuries) in your arms or upper body
 - 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.
 - Fugl-Meyer Upper Extremity Assessment: this is a test of how well you can move your weaker arm into various postures, for example to bend your elbow or reach your arm over your head. It will take about 15 minutes to complete.
 - Whether you have an internet connection in your home and can access the internet on a computer, tablet and/or phone.
2. If you are eligible for the study we will then administer the following assessments of feasibility, self-confidence, social support, self-management skills, and arm movement abilities. All together these assessments will take about 1.5- 2 hours. The assessments are described in the bullet list below.
 - Short Assessment of Health Literacy - this is an 18-item test designed to assess an adult's ability to read and understand common medical terms. It will be administered by the study therapist and will require about 10 minutes to complete



- Technology Literacy self-evaluation – this is a 23-item questionnaire in which you will answer true/false to questions about your readiness to participate in an online course. Any items in which you answer “false” will be reviewed with you by the study team in efforts to provide help. This will require about 20 minutes to complete.
- Self-Efficacy (self-confidence) - will be assessed using the NIH PROMIS Self-Efficacy for Managing Daily Activities assessment. This is an 8-item assessment where you report your level of self-confidence in doing 8 daily activities such as performing household chores, lift/carry groceries and shop/run errands. This will require about 5 minutes to complete.
- Social Isolation will be assessed using the NIH PROMIS Social Isolation assessment. This is an 8-item self-report assessment indicating the frequency (never, rarely, sometimes, usually, always) you may have feelings of being left out, detached, isolated etc. This will take about 5 minutes to complete.
- Emotional Support will be assessed using the NIH PROMIS Emotional Support assessment. This 8-item assessment records your self-reported view of the frequency (never, rarely, sometimes, usually, always) with which you have emotional support from others in areas such as listening, someone to confide in, someone who understands one's problems etc. This will take about 5 minutes to complete.
- Your ability to move the arm made weak by your stroke will be measured with the Fugl-Meyer Assessment of the Upper Extremity, a 30-item assessment that indicates how well you are able to move your weaker arm into/out of various postures. This will take about 15 minutes to complete.
- Your ability to move your weaker arm quickly to do activities will be measured with the Wolf Motor Function Test (WMFT), a 15-item assessment indicating the speed at which a stroke survivor can move the weaker arm to complete functional tasks such as stacking checkers or picking up a soda can. This will take about 15 minutes to complete.
- Difficulty using the weaker arm during daily activities will be assessed with the Stroke Impact Scale – Hand subtest. This is a 5-item assessment in which you will rate how difficult it is to use your weaker arm 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.
- Arm use at home: one way that we will measure the effect of the therapy + online learning program on you is to measure how much you use your arm weaker arm during activities at home and in the community. We will fit activity-sensors to your wrists (called



“arm accelerometers”). These are small wrist bands about the size of a watch and secured with Velcro. We would like you to wear these activity-sensors for 3 days while you do regular activities in your home (e.g., cooking, cleaning) and in the community (e.g., shopping, socializing). We will arrange to have the sensors returned to us (via mail or pick-up) after the 2-day period.

2. You will be asked to attend a focus groups on the same day as the assessments describe above. A focus group is a discussion group. The purpose of the discussion will be to hear your view point on the therapy + online learning program. There will be a total of 3 focus groups – one at the beginning of the program, one immediately at the end of the 5 month program, and one about 2 months after the end of the program.
 - a. The focus group (discussion group) meeting will take about 2 hours.
 - b. The discussion group leader, Dr. Michelle Nichols, will welcome you to the group and explain the process.
 - c. The discussion group will be audio recorded. The audio recording will be transcribed (written word for word) after the discussion group is over. This is important because we do not want to miss any information.
 - d. You will be led through a discussion about how the therapy + online education program was designed and intended to work. You will be asked questions about this program.
 - i. The first discussion group will be held before you begin the program. This discussion will center on your expectations. What do you expect to happen? What do you expect will be challenging/easy with regards to the online education program? What skills for taking care of yourself do you have or need?
 - ii. The second discussion group will be held immediately after the 5-month program ends. This discussion will center on your experiences and views of the program. What did you like/not like about the program? What was hard/easy? What skills for taking care of yourself did you learn?
 - iii. The third discussion group will be held 2 months after the 5-month program ended. The discussion will be like the previous focus group but will have you reflect on the skills that you learned and have been able to continue to implement on your own.
3. You will then schedule a day to begin the therapy + online education program.
 - a. On the first day, you will join a group of 3-4 other stroke survivors at the MUSC stroke rehabilitation research center for an orientation to the online educational program. We will help you set up your computer, tablet or phone to access the course. We will show you how to, and then practice, signing in to the course and using its features. All of your online activities will be done with this group, like a “class”.



- b. Then, you will set up a therapy schedule with the study therapist. You will come to MUSC for therapy
 - i. 3 times/week for 4 weeks (month 1),
 - ii. 2 times/week for 4 weeks (month 2) and
 - iii. 1 time/week for 4 weeks (month 3)
4. You will also be expected to participate in online educational activities
 - a. 1-2 times/week for 4 weeks (month 1)
 - b. 2-3 times/week for 4 weeks (month 2)
 - c. 3 times/week for 4 weeks (months 3)
5. You will return here for another assessment session 3 more times. Each of these visits will require about 2.5 hours.
 - In the middle of the program (after 1.5 months of the program)
 - Immediately after the 3-month program is over
 - 2 months after the end of the program.

C. DURATION

Participation in the study will take about 28 visits to the research center over a period of 5 months.

D. RISKS AND DISCOMFORTS

Common adverse events occurring in approximately 20% of subjects:

- Generalized fatigue
- Arm and/or shoulder pain

Less common adverse events occurring in 5% of subjects:

- Excessive fatigue
- Excessive arm and/or shoulder pain

In addition, there is a risk of a loss of confidentiality of your personal information and embarrassment because of participation in this study.



There is a risk of loss of privacy as a result of participation in the group discussions.

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

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.

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

The potential benefit to you is that the therapy + online education program may help you gain movement skills in your weaker arm and teach you skills for taking care of yourself. However, the



benefits cannot be guaranteed. It is possible that there will be no direct benefit to you because of participating in this study.

We hope 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 stroke rehabilitation.

G. COSTS

You will be using a computer, tablet or phone to connect to the internet for the online educational activities. Therefore, normal online data use rates will apply.

H. PAYMENT TO PARTICIPANTS

You will receive \$50 for each assessment visit (4 visits), and \$20 for each therapy visit (24 visits).

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

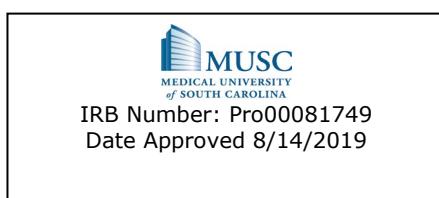
Your alternative is to not participate in this study.

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

Once the study is over, the results of this study will be compiled and published in a scientific journal and presented at scientific conferences. No identifiable private information will be included in these publications or presentations. If you would like a copy of your personal results, including all of your assessment scores, please send Dr. Woodbury or the study team a written request. Your results will be sent to you once the study has ended.



L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, Dr. Woodbury and her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

- The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw



your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

M. SIGNIFICANT NEW FINDINGS

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

N. STUDENT PARTICIPATION

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

O. EMPLOYEE PARTICIPATION

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

P. CLINICAL TRIALS.GOV

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



Q. FUTURE CONTACT

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

Yes, I agree to be contacted

No, I do not agree to be contacted

MUSC STANDARD PARAGRAPHS:

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 **Michelle Woodbury 843-792-1671**. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

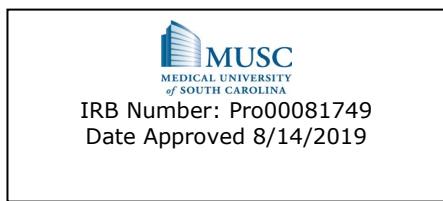


If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my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





NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

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

The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, and MUSC Physicians Primary Care) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." **We collect or receive this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.**

HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI)

A. The following uses do NOT require your authorization, except where required by SC law:

- 1. For treatment.** Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.
- 2. To obtain payment.** We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.
- 3. For health care operations.** We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.
- 4. For public health activities.** We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.
- 5. Victims of abuse, neglect, domestic violence.** Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.
- 6. Health oversight activities.** We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.
- 7. Judicial and administrative proceedings.** Your PHI may be released in response to a subpoena or court order.
- 8. Law enforcement or national security purposes.** Your PHI may be released as part of an investigation by law enforcement.
- 9. Uses and disclosures about patients who have died.** We provide coroners, medical examiners and funeral directors necessary information related to an individual's death.



IRB Number: Pro00081749
Date Approved 8/14/2019

10. For purposes of organ donation. As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.

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

12. To avoid harm. In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.

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

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

15. Fundraising activities. We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.

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

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

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

2. Information shared with family, friends or others. Unless you object, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.

3. Health plan. You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:

You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation

1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.
2. Psychotherapy notes.
3. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:

A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date.



IRB Number: Pro00081749
Date Approved 8/14/2019

B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.

C. The Right to See and Get Copies of Your PHI. You have the right to inspect and receive a copy of your PHI (including an electronic copy), which is contained in a designated record set that may be used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a fee for copying, mailing or other costs associated with your request. We may deny your request to inspect and receive a copy in certain very limited circumstances. If you are denied access to PHI, you may request that the denial be reviewed.

D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.

E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record.

F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 369 / Charleston, SC 29425. The phone number is (843) 792-3881.

G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.

H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

HEALTH INFORMATION EXCHANGES

MUSC, along with other health care providers belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of patients. As a member of these exchanges, MUSC shares certain patient health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. **Please be assured that you will not be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.**

PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES



IRB Number: Pro00081749
Date Approved 8/14/2019

If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue / MSC 332 / Charleston SC 29425. You also may send a written complaint to the Office of Civil Rights. The address will be provided at your request.

CHANGES TO THIS NOTICE

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

EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003.

Revised September 2013.



IRB Number: Pro00081749
Date Approved 8/14/2019