Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

The effects of time restricted feeding on AGE-RAGE signaling in women at high risk for breast cancer

(TREC: Time Restricted Eating on Cancer Risk study)

Principal Investigator: Harsha Karanchi, MD

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 learn about time restricted feeding (TRF) and breast cancer risk markers in post-menopausal women with prediabetes. Time restricted feeding involves changing the daily eating period for consumption of meals and snacks.

If you agree to participate, you will have an initial in-person visit for blood sample collection, 24-hour urine collection, vital signs, and questionnaires about your sleep, eating and exercise habits. You will be instructed to take a photo of all food consumed and send via text message throughout the study. A continuous glucose monitor (CGM) will be worn for 14 days. You will return the CGM by mail. After 14 days, you will be randomly assigned to either the time restricted feeding group with a daily eating period of 8 hours or the control group with a daily eating period of greater than or equal to 12 hours. You will eat according to your assigned group for 12 weeks. You will not be asked to change diet quality, quantity, caloric content or physical activity. During the study you will have 8 phone or video visits with a psychologist or dietician to help facilitate the eating pattern and 1 phone or video visit with the study coordinator. At the end of the study, you will wear the CGM for two weeks and then have an in-person visit and repeat the procedures done at the first visit. The length of the study is 14 weeks.

You may experience an improvement in your pre-diabetes. However, these benefits cannot be guaranteed. Risks and discomforts of time restricted feeding (TRF) may include increased sensation of hunger, headache, nausea, dizziness, fatigue. These risks and discomforts are not permanent and may come and go, can be related to dehydration and can be minimized by drinking water. These discomforts will most likely improve as your body adapts to the eating schedule.

This study is voluntary and the alternative is to not participate in the study.

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. 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.

Post-menopausal women with pre-diabetes are at high risk for breast cancer. Prolonged nighttime fasting duration may be associated with reduced breast cancer risk. Earlier studies have identified breast cancer risk markers with potential to be modified favorably by time restricted eating pattern. We will study the effect of a time restricted eating pattern on breast cancer risk markers in blood and urine.

You are being asked to join this research study as you are post-menopausal (no menstrual periods for greater than one year) and have pre-diabetes which means that your lab results show that your blood sugar level is higher than it should be but not high enough to diagnose diabetes.

The study is sponsored by National Institute of Health (NIH). The investigator in charge of this study at the Medical University of South Carolina (MUSC) is Dr. Harsha Karanchi. A grant from NIH will sponsor this study. Portions of Dr. Karanchi and his research team's salaries will be paid by this grant. Approximately 60 people will take part in this study at MUSC.

B. PROCEDURES

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

The researchers will check your medical records to gather information about your medical history and lab results.

Visit 1, Enrollment will last about 2 ½ hours and the following will occur:

•Fasting blood samples will be drawn (no food, drink or caffeine except for water for 12 hours prior to appointment and no exercise or alcohol for 2 days prior to appointment). Approximately 5 tablespoons of blood will be drawn to check your general health and for research purposes.

•24-hour urine, you will collect all your urine for 24 hours in a provided container and bring to your appointment. You will receive instructions for urine collection prior to this visit and a urine container will be mailed to you.

•Blood pressure, pulse, weight, height, and waist circumference will be checked.

•You will complete questionnaires about your eating, sleep and exercise habits.

•A Freestyle Libre Pro continuous glucose sensor (CGM) will be inserted on your upper arm. The sensor is about the size of a quarter and has adhesive to stick to your skin. It has a tiny filament that goes beneath the skin to measure interstitial glucose. Interstitial glucose is the glucose level in the fluid around your body's cells. This sensor will record your glucose every 15 minutes but will not display the value to you. You will be asked to remove the sensor after 14 days and return the sensor to the site in a self -addressed stamped envelope provided to you. You will be given instructions about wearing and removing the sensor.

•You will receive daily text messages on your personal cellular phone with a unique link to upload photos of each meal, snack and beverage consumed that day. You will upload the photo at the time of the food or beverage intake. If you didn't take a photo, you can enter a description of the food or beverage

Week 0-2: At the end of the 14 days, you will be randomly assigned to one of two groups. This means that you have a 50/50 chance (like flipping a coin) of being in either group. You will randomly be assigned to either the Time Restricted Feeding group or the control group.

At the end of the 14 days, if you have not sent sufficient photos or descriptions of food intake, you will be excluded from randomization into the intervention period, and cannot continue in the study.

If you are assigned to the Time Restricted Feeding group, you will self- select a daily eight hour eating window that ends before 8:00 PM each day. You are encouraged to drink water at any time. You will continue the time restricted feeding for twelve weeks. There is no restriction on the food you eat during the eight hours. You will be allowed to eat outside the 8-hour window up to 2 days/week to allow social commitments deemed necessary by you.

If you are assigned to the control group, you will continue a daily eating period of greater than or equal to 12 hours. There is no restriction on the food you eat.

In both groups, you may consume caffeine (without additional nutritional content such as cream, sugar, or artificial sweeteners) outside the eating window as needed, and record with the text message system.

You will receive daily text messages with a request to upload photos and/or descriptions of each meal, snack and beverage consumed.

Weeks 3 (after group assignment), 4, 5, 6, 8, 10, 12 and 14: You will have visits with a psychologist or dietician through a phone call or a virtual visit. These visits will take approximately 10 – 30 minutes.

Week 12: You will be given a CGM sensor kit and instructions on inserting a new sensor. A virtual visit or phone call will occur for you to place the CGM sensor on your arm. This will take about 20 minutes.

You will continue to receive daily text messages with the request to upload photos and/or descriptions of each meal, snack and beverage consumed. Study staff may call you throughout the study to encourage eating during your eating group times. You may receive text messages with study reminders.

Visit 2, Week 14 will last about 2 hours and the following will occur:

•Fasting blood samples will be drawn (no food, caffeine or drink except for water for 12 hours prior to appointment and no exercise or alcohol for 2 days prior to appointment). Approximately 5 tablespoons of blood will be drawn to check your general health and for research purposes.

•24-hour urine, you will collect all your urine for 24 hours in a provided container and bring to your appointment. The container will be given to you at visit 1.

•Blood pressure, pulse, weight, and waist circumference will be checked.

•You will complete questionnaires about your eating, sleep and exercise habits.

•CGM will be removed from your arm

Study staff may call you throughout the study to encourage eating during your eating group times.

You may be withdrawn from the study if there are any concerns regarding your safety. You may withdraw from the study by contacting the study the staff.

C. DURATION

Participation in the study will take about 11 visits (2 in person visits and 9 video/telephone visits) over a period of fourteen weeks.

D. RISKS AND DISCOMFORTS

Time restricted feeding risks and discomforts may include increased sensation of hunger, headache, nausea, dizziness, fatigue.

Blood drawing risks include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting is possible, although unlikely.

CGM sensor risk may include mild pain associated with sensor insertion, infection, redness,

bleeding and reaction to adhesive such as swelling, rash, itching, and bruising. If you experience any symptoms of infection or adhesive reaction, remove the sensor and contact the study team.

Confidentiality risks include a loss of confidentiality of your personal information as a result of participation in this study. Study staff will take measures to keep and protect your privacy and confidentiality. You will be assigned a unique computer-generated ID. Your study records will be kept in a secure area. The collected data will be stored electronically at MUSC using encryption. The text message platform acts as a pass-through, no data are stored with the platform. Only your phone number is used to send a text message. The text message data will be stored electronically at MUSC using encryption.

E. MEDICAL RECORDS AND CERTIFICATE OF CONFIDENTIALITY

If you are an MUSC patient you have an MUSC medical record. If you have never been an MUSC patient, a MUSC medical record will be created for the purposes of this study. Results of research tests or procedures will be included in your MUSC medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law; however, there is the possibility that your research information will be disclosed.

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 except if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you are an MUSC patient you have an MUSC medical record. If you have never been an MUSC patient, a MUSC medical record will be created for the purposes of this study. Results of research tests or procedures will be included in your MUSC medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law; however, there is the possibility that your research information will be disclosed.

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 or 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

You may experience an improvement in your pre-diabetes. However, these benefits cannot be guaranteed.

It is hoped that information gained from the study will help researchers learn more about lifestyle changes that modify breast cancer risk markers.

G. COSTS

You will be responsible for all text message/data rates charged by your cellular phone provider.

All routine clinical care that you would have undergone without participation in the study, including testing and procedures, will be billed to you/your insurance company. All study-related tests and procedures will be paid for by the Sponsor.

Some insurance plans will not pay for these services for people taking part in research studies. You will be responsible for any charges that your insurance does not cover including co-payments and deductibles.

H. PAYMENT TO PARTICIPANT

In return for your time and effort, you will be paid $100 for participation in this study. If you do not complete the study, you will receive $50 for Visit 1 and $50 for Visit 2.

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. 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.

J. DISCLOSURE OF RESULTS

Your study results will be sent to you at the conclusion of the study. However, if any of your lab results show abnormalities that may require follow-up or treatment, you will be notified when the study team receives the results.

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 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.

L. SIGNIFICANT NEW FINDINGS

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

M. 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.

N. 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.

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 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.

P. COLLECTION OF SPECIMENS

Blood and urine samples will be sent to the MUSC lab to check your general health including labs to check electrolytes, kidney function, liver function, cholesterol and prediabetes status. Blood and urine samples will be used for research purposes to analyze for markers of breast cancer risk and inflammation.

As part of this study, we will store blood and urine specimens collected from you for future research. These specimens will be stored for a minimum of 2 years. This future research may be conducted by Dr. Karanchi or by other researchers who obtain IRB approval for their research. This research will not involve genetic studies. The specimens will be de-identified/anonymized. This will protect your confidentiality and anonymity; it will also have other consequences:

1. It will be impossible to withdraw these samples from any future research project. Your sample cannot be destroyed if it has been de-identified and can no longer be traced back to you.
2. Results of any future research will not be given to you or your doctor.
3. Even though your name and other personal identifiers will not be connected to the sample, other information about you might still be connected. For instance, information about your race, ethnicity, sex, your medical history, and so forth might be available to investigators studying your specimen. Such information might be important for research or public health. It is possible that this information (including genetic information) might come to be associated with your racial or ethnic group.
4. The specimens obtained from you in this research will not be used in the development of a future commercial product.

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

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 Dr. Harsha Karanchi at 843-792-2529. 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 Participant Date	Printed Name of Participant

_____

Signature of Person Obtaining Consent 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.