Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Development and Testing of an Electronic Visit for COPD Early Detection and Smoking Cessation (RCT)

Concise 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 evaluate the benefits of an electronic visit (e-visit) for smoking cessation and early detection of chronic obstructive pulmonary disease (COPD).

If you agree to participate, you will be randomly assigned to receive either the smoking cessation e-visit or not. Approximately 80 participants will be invited to complete the e-visit and the remaining 40 participants will not receive an e-visit invitation. An additional five participants will be enrolled at the beginning of the study and will all be assigned to the smoking cessation e-visit condition. These initial participants will be asked to provide additional feedback regarding their experiences using each e-visit in order to improve the e-visits for future participants. The e-visit will look similar to an online questionnaire. It will ask you questions about your smoking history, your motivation to quit, preferences for medications for quitting smoking, and respiratory symptoms. All information you provide in the e-visit will be reviewed by an MUSC clinician. You may receive a smoking cessation medication as an outcome of the e-visit, but you are not required to take a medication for quitting smoking as part of this study. Although the e-visit may lead to a recommendation for a medication, any prescribed medications will be recommended under standard care. If you are assigned to the e-visit condition, you will be invited to complete a follow-up e-visit one-month after your initial e-visit. This follow-up e-visit will ask you about recent tobacco use, whether you have taken medication to help you quit, whether you have experienced any medication side effects, and whether you require additional cessation treatment. If you are assigned to the e-visit condition and indicate respiratory symptoms during the initial e-visit, you will also be invited to complete a lung functioning test at home (i.e., spirometry). The research team will mail you the home spirometry device and will ask that you upload a video of yourself completing a lung functioning test via the device within an additional e-visit. If you are assigned to the group that does not receive an e-visit invitation, you will receive information about the state quitline, education about the importance of quitting smoking, and a recommendation to contact your primary care physician to schedule a medical visit to discuss quitting smoking.

You will be asked to complete electronic questionnaire measures throughout the study period. You will be asked to complete these questionnaires today, one-month from today, and three-months from today. Questionnaires will assess cigarette smoking, cessation treatment utilization, and your experiences using the e-visit if assigned to that group. Participation in this study will take about 12 weeks, beginning today. You will also be asked to provide an expired air sample that will be used to determine smoking status.

Participation in this study may help you to quit smoking, but that cannot be guaranteed. The greatest risks of this study include frustration, side effects that you may experience if you are prescribed a cessation medication and decide to take that medication, and potential loss of confidentiality.

If you are interested in learning more about this study, please continue to read below.

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 document carefully and take your time deciding whether you would like to participate. The purpose of this study is to evaluate the benefits of an electronic visit (e-visit) for smoking cessation and for COPD early diagnosis. You are being asked to participate in this study because you were identified as being a current smoker during your initial screening. The investigator in charge of this study is Dr. Jennifer Dahne. The study is sponsored by a grant from the Health Resources and Services Administration (HRSA). Portions of Dr. Dahne's and her research team's salaries may be paid by this grant. The study is being done at one site. Approximately 125 people will take part in this phase of the study, all at the Medical University of South Carolina (MUSC).

B. PROCEDURES

Study participation is voluntary. You will note whether you agree to be in this study at the end of this form, which will occur prior to any study procedures. You have already completed preliminary screening for eligibility. Agreeing to be in this study will allow the research team access to information you provided during your screening to be used for research purposes.

If you agree to participate in this project, the following will happen:

1. If you are one of the first five participants enrolled in the study, you will be enrolled in the experimental (i.e., e-visit) condition and will be asked to provide feedback to the research team as you complete each e-visit. If you are enrolled as part of this group, you will be informed by the research staff prior to consent. All other study procedures outlined below will be the same as if you were randomly assigned to the experimental condition.
2. Approximately 40 participants will be assigned to Group A (the *control condition*). If you are randomly assigned to Group A, you will receive information about the state quitline, education about the importance of quitting smoking, and a recommendation that you contact your primary care physician to schedule a medical visit to discuss quitting smoking.
3. Approximately 80 participants will be assigned to Group B (the *experimental condition*). If you are randomly assigned to Group B, you will receive an invitation to complete an electronic visit (e-visit) focused on cigarette smoking, quitting smoking, and respiratory symptoms (see Concise Summary above for description of the e-visit). If you are assigned to Group B, you will also be invited to complete a follow-up e-visit one-month after your initial e-visit. If you are assigned to Group B and self-report respiratory symptoms during the initial e-visit, you will be invited to complete a home spirometry test and will be provided with instructions regarding how to complete that test. The research team will mail you the home spirometry device and will ask that you upload a video of yourself completing a lung functioning test via the device within an additional e-visit. The research team will also provide you with a referral for in-person spirometry testing. Information that you provide during the e-visit may be used for research purposes. Costs related to in person spirometry testing will be paid for by the study for appointments completed by the time of your 3-month assessment. Although the medical order for spirometry testing may remain active following the 3-month assessment, any testing completed after the date of your 3-month assessment will not be paid for by the study.

4. You will be asked to complete questionnaire measures throughout the study period. You will be asked to complete these questionnaires today, one-month from today, and three-months from today. In total, you will be asked to complete questionnaires three separate times throughout the study period. You will be emailed a link to complete these questionnaires via MUSC's REDCap (MUSC secure server where research information is stored) system and we request that you complete the questionnaires within 24 hours of receiving the link. You will be compensated for completion of the questionnaires if they are completed within 72 hours of receiving the link. Questionnaires will assess cigarette smoking, cessation treatment utilization, and your experiences using the e-visit if assigned to Group B. If you agree to participate in this study, you will complete your first set of questionnaire measures immediately after reviewing this form.
5. In addition to questionnaires, one-month from today and three-months from today you will be asked to provide a biological sample that will be used to determine smoking status. This biological indicator is expired air carbon monoxide. The research team will mail you a device that will be used to capture expired air carbon monoxide and will provide you with instructions regarding how to use the device during a scheduled video chat.
6. The research team will access your electronic medical record for a period up to 12-months following completion of your 3-month study follow-up assessment (i.e., 15-months from the date of consent). Information that the research team will capture from your medical record will include: 1) whether you received a referral to complete in-person spirometry, 2) whether you attended an in-person appointment for spirometry, 3) results of any in-person spirometry tests, and 4) whether you received an obstructive lung disease (i.e., COPD, asthma) diagnosis in the time since study enrollment.

C. DURATION

Active participation in this study will take about 12 weeks, beginning today. Participation includes completion of online assessments three times throughout the study duration and providing an expired air sample two times throughout the study duration. Each set of assessments should take between 15 and 20 minutes to complete. Providing the expired air sample should take between 5 and 10 minutes to complete.

D. RISKS AND DISCOMFORTS

1. **Frustration:** You will complete questionnaires throughout the duration of this study. The questions that will be asked may be sensitive in nature and make you feel uncomfortable. You may be asked personal questions that you find distressing. You may refuse to answer any question(s) that you do not wish to answer. Similarly, if randomized to Group B, you may become frustrated while using the e-visit. To reduce this risk, we invite you to contact us via phone or e-mail to troubleshoot difficulties with the e-visit.

2. **Smoking Cessation Medications:** You may receive a smoking cessation medication as an outcome of completing the e-visit (if assigned to Group B) or if you contact your doctor to discuss quitting smoking. You may experience side effects if you utilize these medications. These symptoms tend to be mild and go away over time. Few smokers (<5%) have to stop using these medications because of the side effects. Serious side effects from these products are very rare (less than 1%). The side effects for each medication are as follows:

Varenicline (brand name = Chantix): Some people have new or worse mental health problems, such as changes in behavior or thinking, aggression, hostility, agitation, depressed mood, or suicidal thoughts or actions while taking or after stopping varenicline. These are more likely if you have ever had depression or other mental health problems. The most common side effects of varenicline include nausea, sleep problems (trouble sleeping or vivid, unusual, or strange dreams), constipation, gas, and/or vomiting. Some people have had seizures during treatment with varenicline. New or worse heart or blood vessel problems can also occur. Tell your healthcare provider if you have heart or blood vessel problems or experience any symptoms while taking the drug. Sleepwalking can happen with varenicline, and can sometimes lead to harmful behavior. Stop taking varenicline and tell your healthcare provider if you start sleepwalking.

Bupropion (brand name = Zyban): Potential side effects of bupropion include agitation, dry mouth, insomnia, headache, dizziness, nausea, stomach pain, constipation, tremor, insomnia, weight loss/gain, changes in appetite, ringing in your ears, loss of interest in sex, sore throat, muscle pain, itching/skin rash, increased sweating, and increased urination.

Nicotine Replacement Therapy: Potential side effects of nicotine replacement therapy, including nicotine patch, gum, and/or lozenge, include mild nausea, headache, trouble sleeping, or skin redness/irritation.

If you are provided with a smoking cessation medication, you are not required to take that medication as part of your participation in this study. If you do decide to take the medication, you can discontinue use of the medication at any time. To decrease these risks, our research team is available to you by telephone and/or e-mail should you have any questions/concerns.

3. **Risks During Pregnancy:** Not enough research has been done to determine whether use of varenicline is safe during pregnancy. If you are a woman of childbearing potential and are prescribed varenicline as a result of the e-visit, you will be mailed a pregnancy test. We ask that you complete this pregnancy test and verify that you are not pregnant prior to taking varenicline. If you become pregnant at any time during this study, we request that you inform study investigators as soon as possible.

4. **Confidentiality:** There is a risk of a loss of confidentiality of your personal information as a result of participation in this study. Efforts will be taken to ensure that all information you provide throughout the course of this study is kept confidential. In order to ensure confidentiality, all participant information will be identified with a number and kept under lock and key or on a secure MUSC server accessible only to our study team. Your information may be shared with representatives of the Medical University of South Carolina or governmental authorities if you or someone else is in danger or if we are required to do so by law.

5. **Randomization:** One treatment method may provide to be more or less effective than the other treatment method provided via this study. To prevent against risks related to randomization, you are free to discontinue study participation at any time, either prior to or following randomization.

6. **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.

E. MEDICAL RECORDS

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.

F. BENEFITS

There will be no guaranteed direct benefit to you from participating in this study. The potential benefit to you is that the treatment you receive may prove to be more effective than other available treatments for smoking cessation, although this cannot be guaranteed. It is hoped that the information gained from the study will help in the treatment of future smokers.

G. COSTS

You will not be charged for participation in the study. If you use your mobile phone for completion of study assessments, normal data rates and usage will apply. Costs related to in person spirometry testing will be paid for by the study for appointments completed by the time of your 3-month assessment. Although the medical order for spirometry testing may remain active following the 3-month assessment, any testing completed after the date of your 3-month assessment will not be paid for by the study.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be compensated via electronic gift cards (e.g., Amazon), which will be emailed to you for your participation in this study. You will receive a $30 electronic gift card for completion of the baseline assessment questionnaire. After completing each follow-up questionnaire within 72 hours of being emailed the link, you will be compensated $30. You will be compensated $30 for each completed carbon monoxide recording. You will be compensated an additional $100 for completion of all three sets of questionnaires and both expired air samples. **Total compensation is $250 for completion of all aspects of the study.**

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

Treatment as usual, including smoking cessation medications, is available outside of the context of this research study. You may also receive smoking cessation treatment from your primary care physician or from other treatment resources (e.g., the state smoking cessation quitline, 1-800-QUIT-NOW) outside of the context of this study.

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at MUSC. If you decide to withdraw, we ask that you contact Dr. Dahne to let her know that you are withdrawing from the study.

J. DATA SHARING

Information about you (including your identifiable private information) 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

Clinically relevant research results, including individual research results, will not be disclosed to you as a part of this study.

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

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

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

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

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:
    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

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

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

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

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

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. 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.

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. Jennifer Dahne (843-876-2280, dahne@musc.edu). 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." W**e 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.

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**.**

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
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 NOTCE
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.