Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: **Hybrid Type 1 Effectiveness-Implementation Trial of a Proactive Smoking Cessation Electronic Visit for Scalable Delivery via Primary Care**

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 an electronic visit (e-visit) for smoking cessation.

If you agree to participate, you will be randomly assigned (like flipping a coin) to one of two groups, the e-visit group or the treatment as usual group.

If you are randomized to the e-visit group, you'll be asked to complete a separate online questionnaire that asks about your smoking history, motivation to quit, and preferences for medications for quitting smoking. All information you provide in the e-visit will be reviewed by an MUSC physician. You may receive a prescription for a smoking cessation medication as an outcome of the e-visit, but you are not required to take the medication. This medication will be electronically prescribed to your pharmacy of record and billed in the same way as any other medications that you normally receive (e.g., to your insurance if you are insured).

You will also be invited to complete a follow-up e-visit one-month after you enroll in the study. This follow-up e-visit will ask you about recent tobacco use, recent cessation medication use, and your interest in receiving additional cessation medication.

If you are assigned to the treatment as usual group, you will not receive the e-visit questionnaire but you will receive information about the state quitline, education about the importance of quitting smoking, and a recommendation to contact your doctor to discuss quitting smoking.

All participants will be asked to complete electronic questionnaires and provide breath samples using a personal Bluetooth Carbon Monoxide (CO, an indicator of recent smoking) monitor throughout the study period. You will be asked to complete these questionnaires today, one-month from today, three-months from today, and six-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 24 weeks, beginning today.

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 smoking cessation medication, and potential loss of confidentiality.

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 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 an electronic

visit (e-visit) for smoking cessation. 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 National Institutes of Health. Portions of Dr. Dahne's and her research team's salaries may be paid by this grant. The study is being done at the Medical University of South Carolina (MUSC). Approximately 672 people will take part in the study.

B. PROCEDURES

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

1. The research team will be able to access the information you provided during your screening to be used for research purposes.
2. If you're one of the first 5 participants, you will be assigned to the e-visit group. The remaining 667 participants will be randomly assigned (like flipping a coin) into one of two groups. The group that you are randomized to will be based on the primary care clinic where you were last treated. You will not have the opportunity to choose which group you receive.
3. If you are randomly assigned to the treatment as usual group, 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.
4. If you are randomly assigned to the e-visit group, you will receive an invitation to complete an electronic visit (e-visit) focused on cigarette smoking and quitting smoking. You will also be invited to complete a follow-up e-visit one-month after you enroll in the study. Information that you provide during the e-visit may be used for research purposes. You may receive a prescription for a smoking cessation medication as part of the e-visit. That medication will be electronically prescribed (e-prescribed) to your preferred pharmacy and billed in the same way that other medication you receive are billed (e.g., to your insurance). If you are not insured or if your insurance does not cover the medication you are prescribed, there may be an out of pocket cost to you for the medication. You are not required to obtain the medication from your pharmacy or to take the medication as part of your participation in this study. If you are a female of childbearing potential, you will be mailed a pregnancy test and required to complete it following today's appointment. If you are pregnant, you will not receive a recommendation for varenicline (Brand name = Chantix).
5. Both the treatment as usual group and the e-visit group will be asked to complete questionnaire measures throughout the study period. You will be asked to complete these questionnaires today, one-month from today, three-months from today, and six-months from today. In total, you will be asked to complete questionnaires four separate times throughout the study period. Each set of questionnaires should take no more than 20 minutes to complete. 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 the e-visit group. If you agree to participate in this study, you will complete your first set of questionnaire measures immediately after reviewing this form.

6. In addition to questionnaires, one-month, three-months and six-months from today, both the treatment as usual group and the e-visit group will be asked to provide a breath sample that will be used to determine recent cigarette use. Breath samples should take no more than 5 minutes to complete. In order to provide breath samples, the research team will mail you a personal carbon monoxide (CO) monitor that connects to your smartphone with Bluetooth. You will also be provided with instructions regarding how to use the device and provide the breath samples.
7. If you are assigned to the e-visit group, after completing all study procedures, you may be invited to participate in an interview with a member of the research team. The purpose of these interviews is to understand your experiences in the study and using the e-visit. Interviews will be 30-45 minutes in length and will take place either via a phone or video call or in person.

C. DURATION

Participation in this study will take about 24 weeks, beginning today. Participation includes completion of online assessments four times throughout the study duration, including assessments that you will complete today.

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 the e-visit group, 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 prescription for a smoking cessation medication as an outcome of completing the e-visit (if assigned to the e-visit group) 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. 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 delusions, hallucinations, psychosis, concentration disturbances, paranoia, confusion, risk of seizure, 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, lozenge, and/or inhaler include mild nausea, headache, trouble sleeping, or skin redness/irritation.

If you are provided with a prescription for 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:** We do not know if medications that may be prescribed to you as part of this study will affect mother's milk or an unborn fetus. If you are pregnant or becomes pregnant, there may be risks to the embryo or fetus that are unknown at this time. Pregnancy testing will be required of all study participants of childbearing potential, not only those in the e-visit condition. 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 prove 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.

E. MEDICAL RECORDS AND/OR 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. Documentation of your participation in this study will be included in the medical record and results of research tests or procedures may 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.

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.

E. BENEFITS

There will be no guaranteed direct benefit to you from participating in this study. If you are randomized to the e-visit group you may benefit from being smoke free. 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.

F. COSTS

There will be no additional cost to you for procedures required in this research study. 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. If you receive a prescription for a medication as part of your participation, the cost of this medication may vary depending on whether or not you have health insurance and what your health insurance covers. If you cannot afford the medication, you are not required to obtain the medication from your pharmacy as part of your participation in this study. 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.

G. 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 $20 electronic gift card for completion of the baseline assessment questionnaire. After completing each follow-up questionnaire within 72 hours of receiving the link, you will be compensated $20. You will also be compensated $20 for each breath sample you provide within 72 hours of receiving the link. If you complete all sets of questionnaires and breath samples, you'll receive an additional $100. If you're in the e-visit group, you may be invited to participate in a post-study interview with a member of our research team. If you are invited and complete the interview at the end of the study, you will be compensated an additional $20. **Total compensation is $240 for completion of all aspects of the study. If you're in the e-visit**

group and complete the post-study interview and all other aspects of the study, total compensation is $260.

	Baseline	Month 1	Month 3	Month 6	Bonus
Surveys	$20	$20	$20	$20	$100 for completing all surveys and breath samples
Breath Sample	N/A	$20	$20	$20	
Post study interview (e-visit group only)					$20

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.

H. 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 the principal investigator, Dr. Dahne, to let her know that you are withdrawing from the study.

I. 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.

J. DISCLOSURE OF RESULTS

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

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. 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.

M. EMPLOYEE PARTICIPATION

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

N. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below for paper consents, or scroll down and select your choice electronically:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

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

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

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

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

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact 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.

Please sign below for paper consents or scroll to the bottom of the screen to provide an electronic signature.

_____

Signature of Person Obtaining Consent Date

_____

*Name of Participant

_____

Signature of Participant Date

MUSC Medical University of South Carolina

NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

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

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

OUR PLEDGE REGARDING YOUR HEALTH INFORMATION
MUSC is committed to protecting the privacy of health information we create and obtain about you. This Notice tells you about the ways in which we may use and disclose health information about you. It also describes your rights and certain obligations we have regarding the use and disclosure of your health information. We are required by law to: (i) make sure your health information is protected; (ii) give you this Notice describing our legal duties and privacy practices with respect to your health information; and (iii) follow the terms of the Notice that is currently in effect.

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

A. The following uses do NOT require your authorization, except where required by SC law:
1. For treatment. Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.
2. To obtain payment. We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.
3. For health care operations. We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.
4. Business Associates. Your medical information could be disclosed to people or companies outside our Health System who provide services. These companies typically are required to sign special confidentiality agreements before accessing your information. They are also subject to fines by the federal government if they use/disclosure your information in a way that is not allowed by law.
5. For public health activities. We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.
6. Victims of abuse, neglect, domestic violence. Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.
7. Health oversight activities. We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.
8. Judicial and administrative proceedings. Your PHI may be released in response to a subpoena or court order.
9. Law enforcement or national security purposes. Your PHI may be released as part of an investigation by law enforcement or for continuum of care when in the custody of law enforcement.
10. Military and Veterans. If you are a member of the U.S. or foreign armed forces, we may release your medical information as required by military command authorities.
11. Uses and disclosures about patients who have died. We may provide medical information to coroners, medical examiners and funeral directors so they may carry out their duties.
12. For purposes of organ donation. As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.
13. Research. We may use and disclosure your medical information for research purposes. Most research projects are subject to Institutional Review Board (IRB) approval. The law allows some research to be done using your medical information without requiring your written approval.
14. To avoid harm. In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.
15. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.
16. Marketing. We may send you information on the latest treatment, support groups, reunions, and other resources affecting your health.
17. Fundraising activities. We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.
18. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.
19. Disaster Relief Efforts. We may disclose your medical information to an entity assisting in disaster relief efforts so that your family can be notified about your condition.
Note: incidental uses and disclosures of PHI sometimes occur and are not considered to be a violation of your rights. Incidental uses or disclosures are by-products of otherwise permitted uses or disclosures which are limited in nature and cannot be reasonably prevented.

B. You may object to the following uses of PHI:
1. Inpatient hospital directories. Unless you tell us not to, we may include your name, location, general condition and religious affiliation in our patient directory so your family, friends and clergy can visit you and know how you are doing.

2. Information shared with family, friends or others. Unless you tell us not to, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.
3. Health plan. You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:
You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation.
1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.
2. Mental Health Records unless permitted under an exception in section A.
3. Substance Use Disorder Treatment records unless permitted under an exception in section A.
4. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:
A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date**.**
B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI and/or appointment reminders in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.
C. The Right to See and Get Copies of Your PHI. You have the right to inspect and/or receive a copy (an electronic or paper copy) of your medical and billing records or any other of our records used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a cost-based fee. MUSC will act on a request for access or provide a copy usually within 30 days of receipt of the request. We may deny your request in limited circumstances. If you are denied access to your records, you may request that the denial be reviewed by a licensed health care professional. Additionally, we may use and disclose information through our secure patient portal which may allow you to view and communicate with certain health care providers in a secure manner. For more information see our https://mychart.musc.edu/mychart/
D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.
E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record. Notification will be provided within 60 days.
F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 349 / Charleston, SC 29425. The phone number is (843) 792-3881.
G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.
H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

HEALTH INFORMATION EXCHANGES

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

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

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

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

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

CHANGES TO THIS NOTICE

We reserve the right to change the terms of this Notice at any time. The changes will apply to all existing PHI we have about you.. This Notice will always contain the effective date and may be reviewed at http://academicdepartments.musc.edu/musc/about/compliance/privacy.html

EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003 and was last revised on August 2018.