Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: STARS (Smoking Treatment And Remote Sampling) Study

SUMMARY

You are being asked to volunteer for a research study. Research studies are voluntary and only include people who choose to take part. This is a research study to find out if a medication to help stop or reduce smoking, either varenicline tartrate (sometimes called Chantix) or nicotine replacement products (patches or lozenges), is effective when mailed to smokers, as a one-time sample.

If you agree to participate, you will be randomly assigned to one of three groups. You have a 50% chance of being assigned to a group that will receive varenicline, a 25% chance of being assigned to a group that receives the nicotine patches and lozenges, and a 25% chance of being assigned to a group that receives neither medication. If you are assigned to a group that receives free samples, they will be mailed to you free of charge. There is no requirement to use them; it is completely up to you. There is no requirement to quit in this study either; that is also up to you. There may be a direct benefit to you if you are assigned to either of the groups that receive medications, but that cannot be guaranteed. It is hoped that what is learned from the study will benefit individuals who want to quit smoking in future.

The study lasts for six months and will involve six total surveys. As part of participation, we ask that you complete daily diaries (about 1 minute each) for the first 4 weeks of the study.

Both varenicline and nicotine replacement products are well-established medications that help smokers quit. Side effects from taking varenicline might include insomnia, headache, or nausea. Some individuals report changes in mood. Most smokers who use varenicline do not experience these symptoms. Side effects from using nicotine replacement products can include nausea or headache, but these are rare. You have already been screened for our study, and we believe it will be safe for you.

If you are interested in learning more about this study, please continue reading below. If you choose not to participate, you can receive this same treatment from your doctor, through prescription (varenicline), or at local stores (nicotine patches and lozenges). Alternate methods to learn more about your smoking or quitting are to talk to your physician or to call the National Cancer Institute's Quitline (1-877-448-7848).

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time deciding whether you want to participate as a volunteer in this research study. As your study investigator or study staff member discusses this consent form with you, please ask him/her to explain any words or information that you do not understand.

Dr. Matthew Carpenter, from the Medical University of South Carolina, is the Principal Investigator of this study. The purpose of this study is to learn what happens when people are given a free sample of medication to help stop or reduce smoking, either nicotine replacement products or varenicline. We will look at quit attempts, changes in

smoking, and attitude towards these medications, in both smokers who want to quit and those who do not.

Smoking causes a number of deaths and diseases, including heart disease and cancer. All smokers are advised to quit. Varenicline tartrate (sometimes called Chantix or Varenicline), is a prescription medication for smoking cessation. The supply we will use is either approved by the US Food and Drug Administration (FDA), Chantix, or one of two generic formulations authorized by the FDA: 1) Apo-Varenicline, or 2) PAR varenicline. FDA authorized means that the FDA has given temporary permission for APO-varenicline, and full permission/approval for PAR varenicline, to distribute generic varenicline in the United States. Many studies show that varenicline can help smokers quit smoking. Varenicline is a prescription medication, which usually means that you have to see your doctor to get it. This study examines a different way to deliver varenicline, directly to you for a few weeks, and without need to see your doctor. We call this method "varenicline sampling." We have already determined that you are eligible for this study, and therefore eligible to receive the varenicline sample. Varenicline is used to treat nicotine addiction. It both reduces cravings for and decreases the pleasurable effects of cigarettes and other tobacco products. Smokers who use varenicline generally reduce their desire to smoke cigarettes.

Another group will receive samples of nicotine replacement products, both patches and lozenges. These are also approved by the FDA to help stop or reduce smoking, and are available at many stores, without a prescription. Many studies show that they can help smokers quit. Nicotine patches and lozenges can be used together or individually. They also reduce cravings for cigarettes.

You are being asked to participate in this study because you are a current smoker. People invited to participate in this study must be at least 18 years old, healthy and, if female, cannot be pregnant or breastfeeding. A total of up to 720 individuals may be asked to participate. Participation in the study will last six months and will include follow up surveys and daily diaries completed via telephone/email.

The study is sponsored by the National Cancer Institute, and being led at the Medical University of South Carolina, but study recruitment is based state-wide, throughout South Carolina.

B. PROCEDURES

Overall Study Design:

1. 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.
2. Consent and Eligibility check – when consent is returned, you will be contacted via phone to complete an additional questionnaire which will assess your eligibility to continue in this study.
3. Pregnancy testing – If you are female and under 56 years old, a pregnancy test will be mailed to you after consent. All females under 56 must take a pregnancy test to confirm study eligibility.
4. Initial Phone Call and Randomization – Next you will be called for the first contact in the study, your final eligibility will be determined at this phone call. If you are eligible, you will be placed into one of the three groups, like drawing numbers from a hat. For those in the medication groups, we will mail you a 1-month supply of medication with instructions on use, but it is up to you if you want to use them.

5. Online Assessments – Participants in all groups will complete online assessments starting two weeks after the first phone call. You will also be asked to complete a smoking breathalyzer test during each of these assessments.
6. Daily diaries – Starting at 1st phone call and continued through the 4th week of participation. You will receive a daily prompt for each diary, via text message or email, which will give you access to an online, secure survey. It will take about 1 minute to complete each diary.

Procedures:

If you agree to be in this study, the following will happen. Once your consent form has been signed, we will ask you a few more questions to determine your final eligibility. If you are a female age 55 or below, we will send you a pregnancy test in the mail, and you will be asked to take this. Once you receive the package in the mail, you will be required to take the test and fill out a secure online survey verifying your test results.

Once we have determined your final eligibility to be in our study, you will first be asked to complete some questions about your smoking. After that, you will be randomly assigned to one of three groups.

If you are assigned to the varenicline group, a medication sample will be provided to you free of charge for the first 4 weeks of the study (the sampling period) and sent via mail. Varenicline is a well-established medication to help stop or smoking that reduces withdrawal and reduces the effects of nicotine in the event of smoking. Studies show that varenicline is among the best medications to help smokers quit. There are some known side effects, presented below. We will also provide you within information for the South Carolina Quitline and a letter that you can take to your doctor, if you wish, to discuss options for getting more varenicline after the sampling period is over.

If you are assigned to the nicotine products group, samples of both nicotine patches and lozenges will be provided to you free of charge for 4 weeks. These are well-established products that help smokers quit, especially when used together, though they can also be used individually. If you choose to get more, you can do so through any local grocery or pharmacy store. For both medication groups, using a medication is your choice, not a study requirement. After the 4-week sampling period, you will be contacted for assessment only at Contacts # 4-6, as noted above.

If you are assigned to the *Assessment Only Group*: You will not be provided with medication, but you will be given information about the South Carolina Quitline and other information to help you quit. We still encourage you to quit smoking, but this is up to you.

For all groups, we will contact you on the schedule noted below. All participants will be contacted 5 times over the next 6 months. One of these, Week 0, will be via phone, and all other follow-ups will be sent via email. The first phone call will be the longest contact (approximately 30 minutes). Each follow-up survey will be shorter, approximately 15 minutes each.

Survey #	1	2	3	4	5	6
Timing, at week:	0	2	4	8	12	24

Survey questions will include assessment of your current smoking patterns, your confidence to refrain from smoking, feelings of tobacco withdrawal you may experience, your desire to quit and urge to smoke, any attempts to quit and strategies you may have used to help you quit, as well as your opinions about quit strategies. These surveys will be sent via email, and your responses will be entered directly into our secure database (which only study personnel can access). Though we encourage all smokers to quit, you are not required to do so within this study. It is your choice. It is also your choice whether you use medications to help you quit smoking, either provided by us (medication groups) or not (all groups). You are free to use whatever methods you want to help you quit smoking.

Smoking Breathalyzer. Participants in all groups will receive a small device, sent in the mail, and offered free of charge. After each of the five follow-up assessments above (Contact #2-6), you will be asked to breathe into this device to record the level of carbon monoxide that you have been exposed to recently (which is a measure of smoking). The device can be used repeatedly but should not be shared with others. It is yours to keep after the study is over.

Diaries During Sampling Period: Participants in all groups will be asked to complete a very brief (about 1 minute) diary, each day for the first four weeks of the study. You will receive a prompt via SMS text or email to complete this diary each day during this period, which will give you access to an online, secure survey. You will have up to 6 hours to complete each daily diary. These diary questions will ask about your smoking the prior day. You will be reimbursed for completion of these diaries (see below).

C. DURATION

Participation in the study will take place over a period of 6 months in the form of 6 contacts.

D. RISKS AND DISCOMFORTS

Varenicline: In this study, varenicline will be given orally (by mouth). The dose that we are providing is a bit lower than what is usually used, though you can use up to the standard dose if you choose. Two studies have examined varenicline at this lower dose and found it to be effective for helping to stop or reduce smoking, and with fewer side effects. Nonetheless, some side effects are still possible. When using varenicline, it is usually best to slowly increase your dosage over a few days. If you were to stop and re-start immediately at a higher dose (without this slow increase), there may be an increased risk for nausea.

The more common side effects of varenicline include insomnia (~15%), nausea (~12%), headaches (~15%), and abnormal dreams (~7%). You might also experience depressed mood, agitation, or changes in behavior (~5%) if using varenicline. 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. 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. If at any point in this study you feel you are experiencing any of these symptoms, you can contact the study office and we will have a physician discuss this with you.

Although very rare (<1%), reports of serious skin reactions, including rash, swelling, redness, and peeling of the skin have been reported with varenicline. Some of these skin reactions can become life-threatening. Stop taking your study medication and get medical help right away if you have any of the following symptoms:

- Ø Swelling of the face, mouth (tongue, lips, and gums), throat or neck; trouble breathing
- Ø Rash with peeling skin
- Ø Blisters in your mouth

If you have cardiovascular disease (heart or blood vessel problems), taking varenicline may increase your risk of certain cardiovascular adverse events. Contact the study team if you experience new or worsening symptoms of cardiovascular disease while taking varenicline, for example:

- Ø Shortness of breath or trouble breathing
- Ø New or worsening chest pain
- Ø New or worsening pain in legs when walking

If any of the above symptoms occur, you should stop taking study medication and immediately report any such symptoms to the study staff. We will also be asking you questions during our follow-up surveys about these symptoms.

In July 2021, a voluntary recall of certain lots of Chantix® was issued because of higher than acceptable levels of impurities. All recalled medication was removed from the supply at that time. The pharmacy at MUSC and study team will monitor our drug supply and any new recalls to ensure you are not being given recalled drug. However, there are also two generic version of varenicline (same formulation; one called Apo-varenicline and the other PAR-varenicline) that are approved and available for use in Canada, which has been recently been authorized (APO) or approved (PAR) for use in the United States by the FDA. Until Chantix becomes available again in the US, we will be offering either of these two generic options.

Nicotine Products

Risks include the side effects you may experience if you use the nicotine patch and lozenge. The most common side effects for the patch include redness or irritation (itching) on skin; it is also possible to feel mild nausea, headache, heartburn, or trouble sleeping. Most of these are mild and go away over time. Few smokers (<5%) have to stop using these products because of side effects. Using nicotine replacement therapy (of which two common types are nicotine lozenges and patches) and smoking at the same time might be harmful, but most studies suggest this is not true. You will be screened for all precautions with regard to using these products. Also, some smokers are concerned about getting addicted to nicotine products. Since we are only giving you small samples, this is unlikely (less than 5% of smokers have difficulty when stopping the lozenge and patch).

If you are provided with the patch and lozenge, you have the option to use either one, both, or neither. If you use both, this is generally ok. A number of studies have shown that combined use of patch and lozenge is safe and effective. If you do use both together, the most common side effect would be nausea or headache. If you experience either, you can cut down, or use only one product (or neither). Very rare risks of NRT could include mouth problems, persistent indigestion, severe sort throat, irregular heartbeat or palpitations. Signs of nicotine overdose include nausea, vomiting, dizziness, diarrhea, weakness and rapid heartbeat.

Treatment Randomization: You will be assigned to a treatment program by chance. The treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.

Loss of Confidentiality: Another risk within this study, for all participants, is the potential for loss of confidentiality. We make every effort to ensure your privacy, including safe protection of your personal information.

In order to ensure confidentiality, all participant information will be identified with a number and kept under lock and key. We never present findings from any one individual; all of your responses will be summarized within your assigned group.

Pregnancy: We do not know if the study drug will affect mother's milk or an unborn fetus. Therefore, breast-feeding and pregnant women are not allowed to take part in the study. If you are pregnant or become pregnant, there may be risks to the embryo or fetus that are unknown at this time. Women who can become pregnant must take a pregnancy test before the start of the study. Please inform study staff if you become pregnant while enrolled in our study. Acceptable forms of birth control include:

- oral contraceptives (birth control)
- contraceptive patch
- barrier (diaphragm or condom)
- intrauterine contraceptive system
- levonorgestrel implant
- medroxyprogesterone acetate contraceptive injection
- complete abstinence from sexual intercourse
- hormonal vaginal contraceptive ring

Other Risks: If you decide to change your smoking, you may experience craving and/or withdrawal. The medications that we provide, if you receive them, can lower this risk. There is also the potential for psychological risks, in that some of our questions (particularly around mood) might be sensitive or difficult to answer.

Unknown Risks: The experimental treatments may have unknown side effects. The researchers will let you know if they learn anything 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

Some, but not all, participants will get varenicline or nicotine patches and lozenges, which we believe might help them quit. That means that the benefits are not guaranteed.

In addition, your participation will aid researchers in evaluating new methods of how varenicline affects smoking behavior. If at the end of the study you would like information about quitting smoking, then information will be provided to you**.**

G. COSTS

There will be no direct cost to you for your participation.

Normal cellular data and usage rates apply if you choose to use your cell phone for study procedures. Please indicate below if you would like to receive text messages for this study by checking one of the options below:

___ Yes, I would like to be contacted via text message for this study.

___ NO, please do not contact me via text message for this study, contact me through email and phone calls only.

H. PAYMENT TO PARTICIPANTS

You will be reimbursed for your participation in this study in gift codes to Amazon, that will be sent out via email, as detailed below. If you complete each follow-up questionnaire within five days (120 hours) of receiving the link, you will be compensated the amount specified in the chart below. In addition, in order to earn the additional $20 payment for completing the breathalyzer sample, you will need to complete the sample within 72 hours of completing the questionnaire.

Contact #	1	2	3	4	5	6
Week:	0	2	4	8	12	24
Payment:	$10	$10 +$20 for breathalyzer sample	$30 +$20 for breathalyzer sample	$20 +$20 for breathalyzer sample	$30 +$20 for breathalyzer sample	$40 +$20 for breathalyzer sample

At the first contact, if you are not eligible, you will still be compensated $10 for your time in gift cards.

In addition to the payment for contacts above, participants in all groups can earn up to $60 more in gift cards for diary completion. These payments will be based on the percentage of diaries you complete, per the chart on the top of the next page:

Diaries Completed During First Two Weeks	Diary Payment, Sent at Week 2 (after first two weeks of sampling period)
13-14	$30
12	$25
7-11	$20
5-6	$15
1-4	$10
0	0
The above will be repeated for the second two weeks of the sampling period (days 15-28), for a total of up to $60 ($30 more; second payment sent at Week 4).	

The maximum that someone in this study can earn if they complete all aspects of the study is $300 ($240 for surveys + $60 for diary completion).

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.

Referrals
You are invited to participate in the recruitment of other subjects for this study. If you choose to participate, we will provide you with information that you may give to other people (e.g. friends, acquaintances) who you think would be eligible and interested in this study. These individuals will not be identified unless they contact the study staff themselves. If any of the cards results in successful study recruitment, you will receive $25 for each referred individual who enrolls in the study. Participation in the recruitment process is completely voluntary and if you elect not to participate, your participation in this study will not be affected in any way.

I. ALTERNATIVES

If you choose not to participate in this study, you could receive this same treatment from your doctor, through prescription (varenicline), or at local stores (nicotine patches and lozenges). You can also get other over-the-counter treatments for smoking from your doctor, or at local stores. Alternate methods to learn more about your smoking or quitting are to talk to your physician or to call the National Cancer Institute's Quitline (1-877-448-7848). You do have the alternative not to participate in this study. You may also call the toll-free number at the end of this consent to obtain information about smoking. **Before signing this form, if you have any questions about this study, or are interested in other alternative call 1-800-375-0516.**

J. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

K. DISCLOSURE OF RESULTS

If you wish to be informed of the study outcomes, at the end of the trial, let our staff know and will be happy to share with you. We do not share individual results with anyone.

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. SIGNIFICANT NEW FINDINGS

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

N. STUDENT PARTICIPATION

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

O. EMPLOYEE PARTICIPATION

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

P. CLINICAL TRIALS.GOV

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

Q. FUTURE CONTACT

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

____Yes, I agree to be contacted

____No, I do not agree to be contacted

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. Matthew Carpenter. I may contact the Medical University of SC Hospital Medical Director (843) 792-9537 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. If you wish to participate, you should sign below.

_____ _____

Signature of Participant Date Signature of Researcher Date

_____

Printed Name of Participant

Please sign, date, and print your name above if you wish to participate, and return one copy to our research office. Keep the other copy for yourself.

The Notice of Privacy Practice below is for you to review and keep for your records. We are required to give you this notice but are happy to discuss it with you if you have any questions.

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.