Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Topical treatment for superficial disseminated actinic porokeratosis: A Single-blinded Comparison Between Lovastatin/Cholesterol and Lovastatin

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 is to treat disseminated superficial actinic porokeratosis (DSAP) with cholesterol/lovastatin or lovastatin alone. The goal of treatment is to decrease DSAP lesions after 12 weeks of treatment. Moreover, we will compare which treatment is best.

If you agree to participate in this study, you will be asked to apply twice daily the topical 2% cholesterol/2% lovastatin ointment or 2% lovastatin alone. The study is single-blinded and randomized, meaning you will not be told of which treatment you receive, and the decision of which treatment you will receive will be completely random. You have a 50% chance of receiving either treatment.

Enrollment in the study will occur in one of two ways: 1. You will be enrolled after an in-person standard of care visit, during which the study team members will enroll you in-person. 2. You will be enrolled via a virtual visit by study team members.

All subjects will be required pay for the cost of the 3-month supply of medication. For residents of South Carolina, the cost of the medication is approximately $85. For residents of states other than South Carolina, the cost is approximately $110. If you are a woman of child-bearing age, you will also be required to purchase a home pregnancy test which may cost up to $15. Costs involved with study participation are described in more detail in the cost section of the consent.

If you are able to be enrolled in the study in-person, you will also agree to close up photographs and clinical photographs taken of your DSAP at the initial visit. If you enroll virtually, you must provide close up photographs to the study team via email. At weeks 4, 8, and 12, all subjects will complete a virtual check-in visit. You will take a picture (using phone camera/digital camera) of your lesions/skin markings with a measuring instrument. This will allow us to document the size of the lesions. Physical exam, photographs, and a review of your medical records will occur in the study. Each visit will take approximately 15 minutes. Total study length will be 12 weeks. Changes in size, appearance, and pain will be monitored throughout the study.

You may directly benefit from this study as we expect DSAP will decrease in size after treatment. There are risks to participation that are described in this document, such as minor allergic irritation and local irritation. In the rare chance of significant medication absorption through your skin into your blood, signs and symptoms of muscle damage may occur including muscle soreness, twitches, and cramping. In extremely rare cases, weakness and elevated muscle proteins may occur. There is a possible increased risk of allergic reaction in the combination treatment group since there are two ingredients instead of one that you might develop an allergy to. There is a risk of loss of confidentiality, but every effort will be made to protect your privacy and health information. There is a risk of emotional discomfort with taking the questionnaires provided in the study.

If you choose not to participate in the study, your decision will not affect your medical care. Your alternative is to not participate and receive the standard of care treatment of conservative management, such as local cryotherapy (freezing the lesions), 5-FU cream, and surgery.

A. PURPOSE OF THE RESEARCH

You are being asked to join this research study because you have disseminated superficial actinic porokeratosis (DSAP). We believe using topical cholesterol/lovastatin and lovastatin alone are helpful to treat patients with DSAP.

We are asking for your participation to determine if there is a difference between the two treatments in how well they work or how safe they are. Currently, cholesterol and lovastatin are not approved by the Food and Drug Administration (FDA) to be used for porokeratosis. These drugs are considered to be investigational for the purposes for the study.

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. You are being asked to participate in this study because you have DSAP. The study is sponsored by the MUSC Department of Dermatology and Dermatological Surgery. The investigator in charge of this study at MUSC is Dr. Dirk Elston. The study is being done at MUSC only. Approximately 50 people will take part in this study.

B. PROCEDURES

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

1. You must have a confirmed diagnosis of DSAP by a licensed medical professional.
2. You must thoroughly read and sign the informed consent after asking any necessary question to clarify any lack of understanding. If you enroll virtually, signature of the informed consent form must be completed during the initial virtual visit, prior to beginning the study procedures. Virtual enrollment will occur via a secure platform approved by MUSC, called REDCap. We will send you the REDCap link the day of your enrollment visit.
3. Once enrolled in the study, you will be added to a patient list and this list will be shared amongst study team members alone. Patient visits and collected data will be recorded in documents stored in drives in computers created specifically for this research study. This information will be shared between study investigators and coordinators for the purpose of collecting and analyzing data. They are secured through MUSC's network and will only be accessible by named study personnel.
4. You will have a physical exam and medical history taken. You will be asked about current pregnancy or plans to become pregnant, as you cannot be pregnant to participate in this study. Subjects with child-bearing potential not currently on approved contraception will complete a urine pregnancy test to rule out pregnancy before being approved for the study. If you prefer to use a home pregnancy test, you must submit to the investigators a picture of the test with the date, name, the date the test was performed, and a signature to complement the integrity of the tests results. Only pregnancy tests with an explicitly negative result will be considered as acceptable.
5. Subjects with child-bearing potential will need to prevent pregnancy with an oral

contraceptive, intrauterine device (IUD), or implanted contraceptive. Any other type of pregnancy prevention is unacceptable for this study.

6. If you are shown to be eligible for the study, you will be randomly assigned to one of two groups. This means you have a 50/50 chance (like flipping a coin) of being in either group. Neither the researchers nor you will make the choice to which group you are assigned. The two groups are Group A (cholesterol/lovastatin) and Group B (lovastatin only). This study will be single blinded, meaning you will not be aware which group you are in but the investigators will.
7. Individual prescriptions will be called in and ordered at either Tidewater Pharmacy or Chemistry Rx by a study team member. Your assigned pharmacy will call you directly to coordinate medication payment and medication delivery to your address.
8. Group A will apply cholesterol/lovastatin 2 times a day for a total of 12 weeks. Group B will receive lovastatin alone, according to the same schedule.
9. Study visit timeline: you are expected to attend virtual visits for follow-up and photographs at week 4, week 8, week 12 (12 weeks). Visits will be approximately 15 minutes. A typical virtual-visit will have you attend the visit using your computer or cell phone and discussing your treatment with a doctor or his/her research team who you will see on your screen and will be talking to you.
10. Baseline and follow up clinical photographs will be taken of your DSAP. If the area imaged is close to your face, your eyes will be covered to protect your identity. If you do not want your eyes to be covered, you will be asked to sign a separate photograph release form. You will be asked to take photographs of your lesions and share them on MyChart or email. The anticipated measurement time is 5 minutes. If you are sharing photos via email, they must be deidentified photos of your legs or arms.
11. If you are actively taking approved forms of long-term contraception (oral contraceptives, implantable intrauterine devices, or other hormone eluting implants), you will be allowed to participate as long as they have no plan to become pregnant during the course of the study. If this applies to you, a negative urine pregnancy test result is required for enrollment. If you prefer to use a home pregnancy test, you must submit to the investigators a picture of the test with the date, name, the date the test was performed, and a signature to complement the integrity of the tests results. Only pregnancy tests with an explicitly negative result will be considered as acceptable.
12. Three Patient Quality of Life and disease questionnaires will be used at each visit (initial, weeks 4, 8, and 12) to ask you how you are currently doing with your treatment and if there are any changes with your quality of life due to this treatment.
13. If you wish to discontinue treatment, notify Alan Snyder at snydeala@musc.edu or Dr. Dirk Elston at elstond@musc.edu as soon as possible.

Event	Screening Baseline	Week4	Week 8	Week 12

Informed consent	X			
Eligibility Assessment	X			
Demographics	X			
Physical Examination	X			
Clinical photograph	X	X	X	X
Dermoscopic photograph (close up photograph)	X			
Safety	X	X	X	X
Questionnaires	X	X	X	X

C. DURATION

Participation in the study will take 4 visits over a period of 12 weeks.

D. RISKS AND DISCOMFORTS

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.

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.

These topical ointments result in minimal systemic absorption. In the rare chance of significant medication absorption through the skin into your blood, muscle damage may result, causing muscle soreness, fasciculations, cramping, and in extremely rare cases, muscle breakdown and weakness. Elevated muscle proteins due to muscle breakdown may also occur. However, the vast majority of cases are resolved with proper hydration and simple discontinuation of the medication. Possible cutaneous adverse events are local irritation or allergic reaction to the components of the ointment. There is a risk of a loss of confidentiality of your personal information as a result of participation in this study that will be mitigated at all costs by the study team members.

Since this study is randomized, 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. The lovastatin/cholesterol combined group has increased risk of an allergic reaction compared to the lovastatin group due to the fact that there is two compounds in the ointment as opposed to one (the allergic risk of the individuals compounds are equal). Otherwise, it is believed that both groups are comparable risk.

We do not know if the study drugs will affect embryos or an unborn fetus. Therefore, 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.

Unless you cannot have children because of surgery or other medical reasons, you must be using an effective form of birth control before you start the study. You must also agree to continue to use an effective form of birth control for 3 month/s after taking the study drug.

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

Information about your study participation will not be in your medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record.

All medical history, study related information, and collected data will be stored securely in a study-specific medical record. This will be stored in a secured drive accessible to study team members. Clinical and close up photographs will be included in your study-related medical record. All information within your medical record can be viewed by study team 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 extend allowed by the law.

F. BENEFITS

The possible benefit to you is that the treatment you receive may be more effective than the other study treatment or than other available treatments for your DSAP, although this cannot be guaranteed. All benefits are not guaranteed.

G. COSTS

The 3-month supply of the study drug will cost approximately $85 or $110, depending on which state you live in. If you live in South Carolina (SC) or near Charleston, SC, the cost of your medication will be approximately $85 and you can pick up your prescription in-person or have it sent to your residence by Tidewater Pharmacy (421 Johnnie Dodds Blvd, Mt. Pleasant, SC 29464; (843) 375-

6310). Tidewater Pharmacy is only capable of performing in-person medication pick-up or medication delivery within South Carolina.

If you are unable to be dispensed the medication from Tidewater Pharmacy or do not currently live in the state of South Carolina, your medication will cost approximately $110 and you can have the medication sent to your residence by Chemistry Rx Pharmacy (829 Spruce St #100, Philadelphia, PA 19107; (855) 861-0862). The difference in costs between pharmacies is due to differences in shipping costs and pharmacy fees.

All subjects are responsible for the cost of the drug.

If you are a woman of childbearing age, you will also be required to purchase a home pregnancy test, which may cost up to $15 at your local pharmacy. All costs associated with physician time will be waived by the physician. No costs will be incurred or associated with any of the virtual visits for both enrollment groups (in-person or virtually.) All routine clinical care that you have undergone without participation in this study will be billed to you/your insurance company, such as your medication or a pregnancy test. All study-related tests and procedures will be not paid for by the Sponsor.

If a subject is injured during the study, they will be responsible for the associated charges. Payments for the medication must be paid in full to Tidewater Pharmacy for the drug without a payment schedule. Patients are responsible for the costs of the pregnancy test as well. If the study subject withdraws from the research study or is removed from the study by the investigators, there will be no refund of any cost provided by the study team.

Some insurance plans will not pay for these services for people taking part in research studies and it is unlikely your insurance company will cover the cost of the drug or pregnancy test. Your involvement in this study will not affect your health insurance coverage. You will be responsible for any charges that your insurance does not cover including co-payments and deductibles.

H. PAYMENT TO PARTICIPANTS

You will not be paid for participating in this study.

I. ALTERNATIVES

If you choose not to participate in this study, you could receive other treatments for you condition. The standard therapies for your condition include cryotherapy (freezing lesions using cold substance), surgery, light therapy, lasers (burning skin to promote new skin formation), and 5-fluorouracil.

J. DATA SHARING

Information about you (including your identifiable private information, photographs, 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

Results from the study will be shared with you if you would like.

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

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

Significant new findings that may relate to the subject's willingness to continue participation, such as new risk information, will be provided to the subject. Significant new findings may include an unexpected adverse event or an adverse event occurring at greater frequency or severity than previously stated in the consent process.

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 to the bottom of the screen and select your choice electronically:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

O. CLINICAL TRIALS.GOV

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

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. Dirk Elston at elston@musc.edu or Alan Snyder at 910-619-5832**. 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

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.

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[**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.