E-cigarettes as harm reduction tools in smokers who fail to quit with traditional methods

NCT05525078

Informed Consent Document

Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: E-cigarettes as harm reduction tools in smokers who fail to quit with traditional methods

You are being asked to volunteer for a research study. Research studies are voluntary and only include people who choose to take part. The purpose of this study is to understand how e-cigarettes and nicotine replacement therapy can help people stop smoking by either switching to e-cigarettes or nicotine replacement therapy.

If you choose to participate, you will be randomly assigned to one of two groups. Some participants will be put into a group that receives an e-cigarette, and some participants will be put into a group that receives nicotine replacement therapy (in the form of patches and lozenges). If you are put into the group that receives e-cigarettes, you will choose a date on which you will try to switch completely to using e-cigarettes instead of smoking. If you are put into the group that receives nicotine replacement therapy, you will choose a date on which you will try to quit smoking completely and will use the nicotine replacement therapy to help you. Before you stop smoking, you can use your e-cigarettes or nicotine replacement therapy while continuing to smoke. We will provide you with enough e-cigarettes or nicotine replacement therapy to use for four weeks after you quit smoking cigarettes. At the end of the study, if you have quit smoking cigarettes, we encourage you to purchase more e-cigarettes or nicotine replacement therapy as needed.

Participants will complete two study visits, three phone assessments, and daily electronic diaries across the five weeks of the study. Your participation will last approximately five weeks.

E-cigarettes are likely less harmful for adult smokers than combustible cigarettes, but we are unsure how harmful, or how safe e-cigarettes might be. Side effects from using the e-cigarette are generally rare and mild, and may include: nausea, headache, heartburn, irritability, anxiety, or trouble sleeping. Nicotine replacement therapy is an US Food and Drug Administration (FDA)-approved medication for smoking cessation. Side effects from nicotine replacement therapy are mild and may include: nausea, mouth/throat irritation, hiccups, flatulence, upper respiratory tract infection, skin irritation, insomnia, dream abnormalities, headache, and vertigo.

A possible benefit of being in this study is that if you are put into the group that receives nicotine replacement therapy, you will receive nicotine replacement therapy for free. Nicotine replacement therapy is FDA-approved to help people stop smoking. If you choose not to participate in this study, there are other options to help you quit smoking, including calling 1-800-QUIT-NOW or contacting a medical provider directly.

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

A. PURPOSE OF THE RESEARCH

You are being asked to participate in this study because you are a smoker who has tried to quit smoking with FDA-approved medication in the past and you are still interested in quitting smoking. This study is sponsored by a grant from the Hollings Cancer Center. Funds are provided to the Hollings Cancer Center for distribution by the American Cancer Society. The investigator in charge of this study is Dr. Tracy Smith. This study is being done at one site. Approximately 30 people will take part at the Medical University of South Carolina. Please read this consent form carefully and take your time making your decision. 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 clearly understand.

The purpose of this study is to investigate whether e-cigarettes help smokers stop smoking by switching completely to e-cigarettes compared to nicotine replacement therapy. In this study, we use NJOY ACE e-cigarettes and NJOY ACE pods. The NJOY Ace and NJOY Ace pods have received authorization from the FDA for commercial sale, but it is not FDA approved for smoking cessation, and no e-cigarette product has been approved by FDA for smoking cessation.

B. PROCEDURES

Overall Study Design

Assessment	Visit Information	Timeline
Assessment 1 (in person)	Screening / Baseline visit. Receive e-cigarette or nicotine replacement therapy / Begin daily diaries	Day 0
Target Quit / Switch Date (no assessment)	Continue completing diaries	~Day 7
Assessment 2 (phone call)	Continue completing diaries	Day 14
Assessment 3 (phone call)	Continue completing diaries	Day 21
Assessment 4 (phone call)	Continue completing diaries	Day 28
Assessment 5 (in person)	End daily diaries	Day 35

Participants who complete this study will complete five assessments, and study participation will take about 5 weeks. Participants will complete a Screening/Baseline visit in person, three weekly assessments on the phone, and a final assessment in person. Transportation can be provided via taxi service for those with unreliable

transportation for both visits. At the baseline visit, eligible participants will be assigned to a group. Participants who are assigned to the e-cigarette group will be provided with an e-cigarette and a supply of e-liquid pods. They will choose a date on which they will stop smoking and switch completely to using their e-cigarette (Switch Date). Participants who are assigned to the nicotine replacement therapy group will receive a supply of transdermal nicotine patches and nicotine lozenges. They will choose a date on which they will quit smoking (Quit Date). During the weekly phone calls and in-person visits, participants will answer a variety of questions about their smoking, mood, and health on the phone. At the in-person visits (Assessment 1 and Assessment 5), participants will provide a breath sample.

Study Products

The nicotine patches, nicotine lozenges, e-cigarettes, and e-liquids we are using are all available in stores today. Patches are 14 mg NicoDerm brand, and lozenges are 4 mg Nicorette mini lozenges. Nicotine patches and nicotine lozenges are FDA approved for smoking cessation. The e-cigarettes are NJOY brand e-cigarette and NJOY pods. NJOY ACE pods have a nicotine concentration of 50 mg/ml (5%). The NJOY Ace and NJOY Ace pods have received authorization from the FDA for commercial sale, but it is not FDA approved for smoking cessation, and no e-cigarette product has been approved by FDA for smoking cessation.

Assessment 1 (Screening / Baseline Assessment, In-Person)

<u>If you agree to be in this study, the following will happen:</u>

Signing this consent form does not mean that you will be able to take part in this study. You will undergo tests to help the study team determine if you can be in this study. If you agree to participate in the screening, you will be asked to do several things. This visit will last about 1 hour. If you are eligible, you will be scheduled for three phone calls and an in-person visit and be asked to complete an online diary entry every day about your cigarette, nicotine replace therapy and/or e-cigarette use from now until the last visit.

<u>To determine if you are eligible, you will complete the following procedures:</u>

We will ask you questions about your medical history and your current and past smoking behavior.

If you are a woman below the age of 56, we will test your urine for pregnancy. If you are pregnant, you will not be able to be in the study.

Next, you will be asked to blow into a small machine that will tell us how much you have been smoking recently. If the test indicates you are not a regular smoker, you will be dismissed from the study.

Your participation in the screening interview is voluntary, which means that you can leave at any time if you lose interest or are uncomfortable.

To determine if you are eligible to participate in the study, we will review the information you provide to us at the Screening/Baseline visit.

If you are eligible to participate, you will complete additional questionnaires about your past smoking behavior, your feelings, and your mood.

You will be randomly assigned to one of two groups. If you are assigned to the e-cigarette group, you will receive a NJOY ACE e-cigarette and choose an e-liquid flavor. There is a 66% chance you will be assigned to the e-cigarette group.

If you are assigned to the nicotine replacement therapy group, will you receive nicotine patches and nicotine lozenges. There is a 33% chance you will be assigned to the nicotine replacement therapy group.

No matter what group are assigned to, you will choose a date within one-week of your screening visit to stop smoking. If you are assigned to the e-cigarette group, you will try to switch completely to use your assigned e-cigarette instead of smoking on the date you choose (Switch Date). Use the e-cigarette as much as you need in order to stop smoking cigarettes. If you are assigned to the nicotine replacement group, you will try to stop smoking completely on the date you choose and will use the nicotine replacement therapy we provide to you (Quit Date). We will provide you with instructions about how to use the nicotine replacement therapy, and it is important that you adhere to these instructions as much as possible. No matter which group you are assigned to, we encourage you to try using your assigned product (e-cigarettes, nicotine replacement therapy) between now and your chosen date. Trying your product before you stop smoking may help you successfully quit on your chosen date. It will also help you get used to how your product makes you feel and figure out how to use the product. Do not share the e-cigarettes or nicotine replacement products we give you with anyone else. If you are unable to stop smoking completely, continue using your assigned product and try to reduce your smoking as much as possible.

During periods of high COVID-19 transmission, we may complete some eligibility questionnaires over the phone prior to the in-person screening visit. If we determine, based on these questionnaires, that you are not eligible for the study, we will pay you for the visit, but will not require you to come to the lab to complete the remainder of the screening questionnaires. If, after completing these phone questionnaires, you are eligible for the in-person visit, a staff member will schedule the baseline visit to determine final eligibility and conduct the remainder of the visit.

Switch or Quit Date (No assessment)

Although we do not ask you to complete a phone call or an in-person assessment on your

chosen date, we will text you the day before and the day of your Switch or Quit date and remind you to stop smoking completely and use your assigned product instead.

Assessments 2-4 (Phone Calls)

These calls will last approximately 15 minutes. You will answer questions about your assigned product, your tobacco use during the prior week, and your mood.

Assessments 5 (In-person)

Assessment 5 will last approximately 30 minutes. You will blow into the small machine again that will tell us how much you have been smoking recently. You will complete several questionnaires about your smoking and mood. Assessment 5 is your last visit, but we encourage you to continue to abstain from smoking. The products we have provided to you are commercially available, and we encourage you to obtain more if they have helped you to stop smoking.

During periods of high COVID-19 transmission, we may ask you to complete some of these questionnaires in advance of this visit either by phone or electronically on your own.

Electronic Daily Tobacco Use Diaries

If you are eligible and participate, you will be asked to complete daily diaries about your smoking, e-cigarette, and/or nicotine replacement therapy use. These can be completed online and will take about 2 minutes. Each day, you will receive an alert to complete your diary entry by text message or e-mail and have several hours to complete this entry. In order to complete these diary entries and participate in this study, you need to have daily e-mail access to a personal e-mail address or a personal smartphone with internet where you can receive daily text messages. You can receive additional payment for completing these entries.

C. RISKS AND DISCOMFORTS

1) **Survey Questionnaires:** The interviews and surveys will include questions about your medical history and your mood. Answering these personal questions could make you uncomfortable.
2) **Breach of Confidentiality:** There is a risk of a loss of confidentiality of your personal information as a result of participation in this study. We will make every effort to keep your personal information confidential.
3) **E-Cigarettes:** E-cigarettes can expose users to several harmful chemicals, including nicotine. Nicotine, which is also in cigarettes, may lead to some of the same diseases as smoking. Exactly what other chemicals are in e-cigarettes, and how they might be harmful, is not completely understood. E-cigarette use is not harmless, although it is generally believed that e-cigarettes contain fewer harmful

chemicals than cigarettes. Specific potential known risks include:

a. Most but not all e-cigarettes contain nicotine. The e-cigarettes used in this study will contain nicotine. Nicotine, which is also in cigarettes, is the ingredient that leads to addiction. It is possible that this experience could lead to long-term use of e-cigarettes after the trial is over.
b. The most common side effects related to e-cigarette use are changes in taste, mucus in throat/sinus, dry mouth, dry cough, throat irritation, sore throat, mouth ulcers, dizziness, headache, and nausea.
c. Ingestion of e-liquids containing nicotine can cause poisoning and possible death, if consumed all at once. Keep your study e-cigarette and all e-liquid away from pets and children.

4) **Nicotine Replacement Therapy (NRT):** In this study you will receive two types of nicotine replacement therapy: transdermal nicotine patches and nicotine lozenges. These products are FDA-approved to be safe and effective for smoking cessation. Risks are minor and described below.
   a. Nicotine lozenge: nausea, mouth/throat irritation, hiccups, flatulence, and upper respiratory tract infection
   b. Nicotine patch: skin irritation, insomnia, dream abnormalities, headache, nausea, and vertigo.
   c. Combined patch and lozenge: the most common side effects when patch and lozenge are combined are similar to those when the medications are used separately and include disturbed sleep, skin irritation, nausea, and mouth / throat irritation.
5) **Use of E-cigarettes and Smoking Together**: Using e-cigarettes and smoking at the same time could result in receiving too much nicotine. Symptoms of getting too much nicotine include nausea, dizziness, headache, and stomachache. If you experience these symptoms, reducing your smoking or e-cigarette use may lessen these symptoms. Usually smokers adjust their smoking levels (or use of e-cigarettes) to find the right level of nicotine for them.
6) **Use of Nicotine Replacement Therapy and Smoking Together:** It was previously thought that using NRT at the same time as cigarettes could result in nicotine intoxication; i.e. nausea, dizziness, headache, stomachache, etc. An older anecdote suggested that using both NRT and smoking could result in heart attacks, but several large experimental studies since then have failed to confirm this observation. Recent research now demonstrates that starting nicotine patch prior to stopping smoking increases quit rates relative to starting patch at the time of cessation.
7) **Use of E-cigarettes among Non-participants:** Do not share your e-cigarette with anyone else. We are monitoring your safety while using this product and cannot monitor the safety of others if you decide to share your e-cigarette. It is especially important that you keep your e-cigarette away from minors. Nicotine is addictive and could cause harm to children.

8) **Craving and Withdrawal:** If you decide to change your smoking, you may experience craving and/or withdrawal. The e-cigarettes or nicotine replacement therapy that we provide can lower this risk.

Avoiding Risks to Fetus:

In order to avoid risks to a fetus, it is important that you are not pregnant during this study. Avoiding sexual activity is the only certain method to prevent pregnancy. However, if you choose to be sexually active, you should use an appropriate "double barrier" method of birth control (such as female use of a diaphragm, intrauterine device (IUD), or contraceptive sponge, in addition to male use of a condom) or the female should be using prescribed "birth control" pills, injections, or implants. If you choose to be sexually active during this study, pregnancy could still result even with the use of these birth control methods. Female participants with child-bearing potential will be tested for pregnancy at the screening visit.

D. MEDICAL RECORDS

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.

E. BENEFITS

There will be no direct benefit to you from participating in this study. However, the information that we get from the study may ultimately help us understand whether e-cigarettes can provide a benefit to adult smokers who have been unable to quit smoking.

F. COSTS

There will be no cost to you as a result of participation in this study. Normal cellular data and usage rates will apply if you use your cell phone for study procedures.

G. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid up to a total of $275 for completing all the visits and phone calls. You will receive $50 for completing Assessment 1 (the screening/baseline session) if you are eligible, and $15 if you are not eligible. You will receive $25 each for completing the Assessment 2, Assessment 3, and Assessment 4 phone calls, $50 for completing the in-person Assessment 5, and an additional $100 if you complete all visits/phone calls. Payment will be made in cash or Amazon gift codes (depending on availability) and payment for completing the phone calls will be provided at the Week 4 visit.During periods of high COVID-19 transmission , we may ask you to complete some questionnaires prior to your lab visit. These questionnaires would

normally be completed at the lab visit. If you do not complete these questionnaires prior to the visit, you will be asked to complete them at the lab visit. You must still attend your lab visit in order to earn compensation for that visit.

You can also earn up to $25 per week for completing daily electronic diaries about your tobacco use (up to $125 across all five weeks). Payment for all diary entries will be made at the Week 4 visit. If you complete all visits and all diary entries, you can earn up to $400 for completing this study. The payment structure for the diaries is shown below:

Number of diaries completed per week	Payment
6-7	$25
4-5	$10
2-3	$3
1	$1

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 cards 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 $10 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.

H. ALTERNATIVES

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

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).

I. DATA SHARING

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

J. 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.

K. SIGNIFICANT NEW FINDINGS

If there are significant new findings about the health effects of e-cigarettes or nicotine replacement therapy during the course of the study, you will be notified.

L. STUDENT PARTICIPATION

If you are an MUSC student, 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

If you are an MUSC employee, 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. 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 website will include a summary of the results. You can search this web site at any time.

O. FUTURE CONTACT

Other researchers at MUSC 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 this page and select your choice electronically:

____Yes, I agree to be contacted by this team or other researchers at MUSC about research opportunities

____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. Tracy Smith at (843) 792-5164***. 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.

If you agree to participate in this study, please sign below for paper consents or scroll to the bottom of this page to provide an electronic signature. I have been given a copy of this form for my own records.

_____ _____

Signature of Person Obtaining Consent Date *Name of Participant

_____

Signature of Participant Date

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.