Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: IMPACT OF IQOS NON-CIGARETTE TOBACCO PRODUCT ON REINFORCEMENT VALUE AND USE IN CURRENT SMOKERS

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 different types of non-cigarette tobacco products affect the way smokers use tobacco products.

If you choose to participate, you will complete three in-person visits. The first visit you will undergo a few screening procedures. You will blow into a small machine, answer a variety of questionnaires, and (if female) provide a urine sample to see if you are eligible to participate.

Participants will complete three study visits and daily electronic diaries across the two weeks of the study. If you are eligible to participate, you will try a new type of tobacco product called a heated tobacco product. The heated tobacco product heats tobacco-filled sticks, called Heatsticks, to produce a nicotine-containing vapor. You will complete a task where you choose between the heated tobacco product and a regular cigarette. Then you will receive a heated tobacco product to take home for one week. We are interested in how the heated tobacco product changes your tobacco use. After you leave the visit, you are not required to use the heated tobacco product and it is entirely up to you if and how frequently you use it.

There are some risks to participating in the study that are described in this document. Heated tobacco products are likely less harmful than combustible cigarettes for adult smokers, but we are unsure how harmful, or how safe they might be. Some of the risks include side effects from using the heated tobacco product, including cough.

There is no direct benefit for participating. Researchers hope what is learned in this study will help to determine how different types of tobacco products affect smoking behavior. You have the alternative not to participate in this study.

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. This study is being done at one site at MUSC. 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.

We are interested in how a new tobacco product, the IQOS heated tobacco product, might affect the way people use tobacco products. IQOS is a new tobacco product that was recently approved by the Food and Drug Administration (FDA) for sale in the US. IQOS electronically heats sticks of tobacco in a controlled way. You can inhale the vapor from these products similar to the way you inhale smoke from a cigarette.

IQOS is not a fully burned tobacco product, meaning it is likely less harmful than regular cigarettes because regular cigarettes are burned. However, we are unsure how harmful, or how safe, it might be. IQOS is regulated in the United States by the FDA, and is currently available for commercial sale.

This study is sponsored by a grant from the National Cancer Institute. Funds are provided to the Medical University of South Carolina for distribution by the National Cancer Institute. The investigator in charge of this study is Dr. Tracy Smith. Approximately 10 people will take part at MUSC. Portions of Dr. Smith's and her research team's salaries will be paid by this grant

B. PROCEDURES

Study IQOS

The IQOS product is made by Phillip Morris, and is available in a small number of retail locations, although the availability of IQOS is likely to grow in the future. You will sample the IQOS at the second study visit and will take home an IQOS with you to use as you wish for one week. You may not share your IQOS with anyone else.

If you agree to be in this study, the following will happen: You will undergo tests to help the study team determine if you can be in this study after you sign the consent form. If you agree to participate in the screening, you will be asked to do several things. This visit will last approximately 1 hour. If you are eligible, you will be scheduled for two more in-person visits and be asked to complete an online diary entry every day about your tobacco use from now until your last visit. Transportation can be provided via taxi service for those with unreliable transportation for both visits. Your participation in the

screening interview is voluntary, as is the rest of the study, which means that you can leave at any time if you lose interest or are uncomfortable.

Screening / Baseline Visit (Study Visit 1)

To determine if you are eligible, you will complete the following procedures:

First, if you are a woman, 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.

Then, we will ask you questions about your medical history, and your current and past smoking behavior. If you are eligible to participate, you will complete additional questionnaires about your past smoking behavior, your feelings, and your mood.

Males will provide a urine sample which we will test for exposure to nicotine and other chemicals in cigarette smoke; for females the urine sample provided for pregnancy testing will also be used to test for nicotine exposure (females will only provide urine once).

Due to COVID-19 restrictions, 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 for 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 questionnaires, you may be eligible for the study, a staff member will schedule the baseline visit to determine final eligibility and conduct the remainder of the visit.

Study Visit 2

This visit will last approximately 1 ½ hours. You will blow into the small machine again that will tell us how much you have been smoking recently. At this visit, you will try a regular cigarette and then you will try a new kind of tobacco product, called IQOS. IQOS is a heated tobacco product recently approved for sale in the United States by the FDA. After you try each product, you will answer questionnaires about them. Then you will complete a task where you choose between taking two puffs of a regular cigarette, taking two puffs of the IQOS, or not taking any puffs. You will make this choice several times in a row.

At the end of this visit, you will receive the IQOS to take home. You are not required to use the IQOS at home, and you can use it as much or as little as you wish. We ask that you do not share this product with anyone. You may smoke your usual brand cigarettes as you wish.

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

Study Visit 3

The Week 3 visit 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, mood, and about the tobacco product you took home. You will also return the IQOS and accessories. You will provide a urine sample, which we will test for exposure to nicotine and other chemicals in cigarette smoke.

Due to COVID-19 restrictions, 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 and IQOS 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.

C. RISKS AND DISCOMFORTS

1) **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.

2) **Heated Tobacco Products:** Heated tobacco products 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 heated tobacco products, and how they might be harmful, is not completely understood.

   Heated tobacco product use is not harmless, although it is generally believed that heated tobacco products contain fewer harmful chemicals than cigarettes. Specific potential known risks include:

   a. All heated tobacco products 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 IQOS after the trial is over.
   b. The most common side effect related to heated tobacco product use is cough.

c. If stored improperly (in pocket or where the device can turn on accidentally), overheating of the device may occur, which presents a minor burn risk.

3) **Concurrent Use of Heated Tobacco and Smoking**: Using heated tobacco 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 heated tobacco product use may alleviate these symptoms. Usually smokers adjust their smoking levels to find the right level of nicotine for them.

4) **Undermining Cessation**: It is possible that using a heated tobacco product could make you less likely to try to quit smoking or less successful at quitting smoking. Quitting use of all tobacco products is best for your health.

5) **Use of Heated Tobacco Products among Non-participants:** Do not share your heated tobacco product 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 product. It is especially important that you keep your product away from minors. Nicotine is addictive and could cause harm to children.

6) **Unknown Risks:** The experimental treatments may have unknown side effects. The researchers will let you know if they learn anyt**h**ing that might make you change your mind about participating in the study.

Avoiding Risks to Fetus:

In order to avoid the previously mentioned 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 AND 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.

This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless you have consented to the disclosure. More specifically, identifiable information or biospecimens will not be shared with your medical providers who are not involved in this research unless you authorize the study to disclose information to them, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must authorize the researchers to release it.
The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include: child abuse and neglect, or harm to self and others, but there could be others.
Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

E. BENEFITS

There will be no direct benefit to you from participating in this study. However, the information that we get from the study may ultimately help the Food and Drug Administration decide how best to regulate tobacco products with the goal of improving public health.

F. COSTS

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

G. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid a total of $200 for participating in the study. You will receive $25 for completing the screening/baseline session if you are eligible, and $15 if you are not eligible. You will receive $75 for completing Study Visit 2, and $50.00 for completing Study Visit 3. Due to COVID-19 restrictions, 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 $50 across both weeks). Payment for all diary entries will be made at Study Visit 3. If you complete all visits and all diary entries, you can earn up to $200 for completing this study. The payment structure is shown on the top of the next page:

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

Payments may be made in cash or using Amazon gift codes delivered directly to your email. Due to COVID-19 restrictions, cash may not be offered during your participation. You will be informed of your payment method before your visit.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

H. ALTERNATIVES

You have the alternative not to participate in this study.

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 (Dr. Smith 843-792-5164, 68 President Street, Charleston, SC 29425).

I. DISCLOSURE OF RESULTS

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

J. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of our 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. AUTHORIZATION TO USE AND DISCLOSE (RELEASE MEDICAL INFORMATION)

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

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

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

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration;

National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

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

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

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

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

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

L. SIGNIFICANT NEW FINDINGS

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

M. 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.

N. 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.

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 website will include a summary of the results. You can search this web site at any time.

P. COLLECTION OF SPECIMENS

Urine will be collected as part of this study. This urine will be used only for this study and will not be stored for future use. These urine specimens will be analyzed for nicotine and other tobacco chemicals. Your specimen will be linked back to the other data collected as part of this study, but will be destroyed when the study is over.

Q. 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 the screen 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.

I agree to participate in this study. I have been given a copy of this form for my own records.

_____ _____

Signature of Person Obtaining Consent Date *Name of Participant

_____

Signature of Participant Date

NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

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

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

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

A. The following uses do NOT require your authorization, except where required by SC law:

1. For treatment. Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.

2. To obtain payment. We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.

3. For health care operations. We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.

4. For public health activities. We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.

5. Victims of abuse, neglect, domestic violence. Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.

6. Health oversight activities. We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.

7. Judicial and administrative proceedings. Your PHI may be released in response to a subpoena or court order.

8. Law enforcement or national security purposes. Your PHI may be released as part of an investigation by law enforcement.

9. Uses and disclosures about patients who have died. We provide coroners, medical examiners and funeral directors necessary information related to an individual's death.

10. For purposes of organ donation. As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.

11. Research. We may use your PHI if the Institutional Review Board (IRB) for research reviews, approves and establishes safeguards to ensure privacy.

12. To avoid harm. In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.

13. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.

14. Marketing. We may send you information on the latest treatment, support groups and other resources affecting your health.

15. Fundraising activities. We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.

16. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.

B. You may object to the following uses of PHI:

1. Hospital directories. Unless you object, we may include your name, location, general condition and religious affiliation in our patient directory for use by clergy and visitors who ask for you by name.

2. Information shared with family, friends or others. Unless you object, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.

3. **Health plan.** You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:

You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation

1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.

2. Psychotherapy notes.

3. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:

A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to

limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date**.**

B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.

C. The Right to See and Get Copies of Your PHI. You have the right to inspect and receive a copy of your PHI (including an electronic copy), which is contained in a designated record set that may be used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a fee for copying, mailing or other costs associated with your request. We may deny your request to inspect and receive a copy in certain very limited circumstances. If you are denied access to PHI, you may request that the denial be reviewed.

D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.

E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record.

F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 369 / Charleston, SC 29425. The phone number is (843) 792-3881.

G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.

H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

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

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES
If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. **Please be assured that you will not be penalized and there will be no retaliation for voicing a**

concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.

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

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

CHANGES TO THIS NOTCE

We reserve the right to change the terms of this Notice at any time. We also reserve the right to make the revised or changed Notice effective for existing as well as future PHI. This Notice will always contain the effective date. You may view this notice and any revisions to it at: http://www.musc.edu/privacy.

EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003.
Revised September 2013.