**Medical University of South Carolina**

**CONSENT TO BE A RESEARCH SUBJECT**

**TITLE OF RESEARCH:** A PHASE 1B TRIAL OF TARLOXITINIB AND SOTORASIB IN PATIENTS WITH KRAS G12C MUTATIONS

## SUMMARY

You are being asked to volunteer for a research study because you have been diagnosed with lung cancer that has a specific genetic mutation, or variant, called KRAS G12C. Research studies are voluntary and include only people who choose to take part. The purpose of the study is to determine the safety and effectiveness of two study drugs used together for the treatment of your cancer. The drugs are named tarloxotinib and sotorasib. The Food and Drug Administration (FDA) has approved sotorasib for treatment of your type of lung cancer. Tarloxotinib, or the combination of Tarloxotinib and sotorasib, is not FDA approved. It is considered an investigational drug and drug combination, as it has not been approved for the treatment of lung cancer.

Tarloxotinib is thought to work by turning off certain signals in the cancer cells telling them to grow or multiply. This is called epidermal growth factor (EGFR) inhibition. Sotorasib is thought to work in subjects with KRAS G12C mutations by targeting this genetic variant to stop cancer cell growth.

Some subjects being considered for this study may have previously received an FDA-approved treatment for their lung cancer with what is called anti-PD-L1 therapy, a certain type of immunotherapy, which works with your immune system to recognize cancer cells and target them for destruction. Some subjects have benefitted from receiving this type of therapy and lived longer than subjects who have not received immunotherapy. Talk to your study doctor before agreeing to take part in this study if you did not receive anti-PD-(L)1 therapy previously, and if you should be considered for this therapy before participating in this study.

If you choose to take part in this study, you will be seen at MUSC once a week for study treatments, and at least once every three months after you complete the study treatments. This will continue until after the last subject that is enrolled on the study has their first study visit. You will be given sotorasib in tablet form to take daily and you will receive an intravenous (through a vein) infusion of tarloxotinib at each of your weekly visits. This will last approximately 1 hour. Your vital signs and heart rhythm will be monitored while you are receiving the infusion. You will also undergo procedures such as laboratory blood and urine tests. Imaging of your cancer with x-rays by having CT, MRI or PET-CT scans will occur every eight weeks to assess changes in your cancer. Your physician will also talk with you regarding how you are feeling and if you have any questions or concerns. You may be in this study for as long as you are tolerating the study medications and if your study doctor believes you are benefitting from study treatment.

Participation in this study may improve your physical well-being, but that cannot be guaranteed. The greatest risks of this study include side effects such as changes in liver function, changes in kidney function, diarrhea, fatigue (feeling tired), nausea (feeling sick to your stomach), irregular heart rhythm, hypertension (high blood pressure), fluid buildup around the heart, muscle weakness, and lung infection. These side effects and others will be detailed in the risk section of this informed consent.

You do not have to take part in this study to be treated for your cancer. Alternative treatments include taking other medications that may be approved for your cancer, taking part in a different study if one is available, receiving no treatment, or receiving comfort care, also called palliative care.

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

## A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. You may discuss your decision with your friends and family. You can also discuss it with your health care team. Ask the study doctor or study staff to explain any words or information that you do not clearly understand.

The purpose of the study is to determine the safety and effectiveness of two study drugs, tarloxotinib and sotorasib, used together for the treatment of your cancer. The study is sponsored by MUSC.

The Food and Drug Administration (FDA) has approved sotorasib for treatment of your type of lung cancer. Tarloxotinib, or the combination of Tarloxotinib and sotorasib, is not FDA approved. It is considered an investigational drug and drug combination, as it has not been approved for the treatment of lung cancer.

Tarloxotinib is thought to work by turning off certain signals in the cancer cells telling them to grow or multiply. This is called epidermal growth factor (EGFR) inhibition. Sotorasib is thought to work in subjects with KRAS G12C mutations by targeting this genetic variant to stop cancer cell growth.

The investigator in charge of this study at MUSC is Dr. Mariam Alexander. The study is being sponsored by Rain Therapeutics and the sponsor is paying MUSC and Dr Alexander to conduct the study. The study is only being performed at MUSC. As few as 6 subjects and as many as 18 subjects will be enrolled in a safety lead-in cohort, or group, depending on how well subjects tolerate study treatment. An expansion cohort of up to 12 additional subjects will be enrolled to evaluate the safety of the combination of tarloxotinib and sotorasib. Therefore, up to 30 subjects could be enrolled in total.

## B. PROCEDURES

***Before you begin the study:***

If you agree to be in the study, you will need to have the following exams, tests and procedures to find out if you are eligible. These exams, tests and procedures are part of regular cancer care and may be done even if you do not join this study. If you have had some of them recently, they may not need to be repeated. This will be up to the study doctor. It may take about 8 hours to complete all the tests below:

- History and physical exam. The study doctor will ask you what medications you are taking.
- Vital signs (blood pressure, heart rate, temperature, respiration rate)
- ECG 12-lead. This is where small electrodes are placed on your chest so to that the electrical activity of your heart can be assessed.
- About 2 teaspoons of blood will be taken to look at your blood cell counts, the health of your kidneys and liver, to look at the level of cancer activity in your body and your electrolyte balance. Electrolytes are minerals in your blood that help maintain your body's blood chemistry, muscle action and other bodily functions.
- A urine sample will be collected in order to check your kidney function. If you are a female capable of becoming pregnant, you will have also have a pregnancy test performed.
- Radiographic scans or imaging using Computed Tomography (CT) scan (a series of images taken with x-rays), positron emission tomography (PET) scan or magnetic resonance imaging (MRI) of the chest, pelvis and abdomen. These scans will give a detailed picture of the areas of the body taken from different angles. The procedures for these are described below.

The CT scanner is a doughnut-shaped machine. During the procedure, a technologist will take you into the CT scan room where you will lie down on the participant table (usually on your back) inside of the CT machine. You should get comfortable because it is very important not to move during certain parts of the test. During this scan, you will be asked to hold your breath so that the pictures will not be blurred. The machine will make some noise, and the table will move during the scan. You may also receive signals from the technologist or from the machine about your breathing. If you have any discomfort during the test or after the injection, be sure to tell the technologist.

During an MRI you will be placed on a narrow bed and then slid into a small tunnel approximately 6 feet in length and 25 inches in diameter. You will hear a loud machine-like noise.

Before or during the CT or MRI, you may be given an injection of a contrast liquid in your vein to allow the radiologist to obtain clearer images of your organs.

A PET-CT Scan is a diagnostic tool used to detect cancer and find out the cancer's stage (a way of describing where the cancer is located, if or where it has spread, and whether it is affecting the functions of other organs in the body). Before the scan, you will receive a radioactive substance through a vein in your arm, through a solution you drink, or in a gas you inhale. Your body needs time to absorb the substance, so you will need to wait about an hour before the scan begins. Then, the scan will be performed, which will last about 45 minutes. This involves lying on a narrow table

attached to a PETCT machine, which looks like a large doughnut like a standard CT scanner. The table glides slowly into the machine so that the scan can be conducted. You will be asked to lie still during the scan. You may be asked to hold your breath for several seconds at a time. You will hear buzzing and clicking noises during the test.

During a bone scan the doctor will inject (through an IV in your vein) a radioactive substance. About three hours later, a machine measures how much radiation has been taken into the bones. The test does not hurt. You may have to stay still in a certain position for about 30 minutes to get a good picture.

If the exams, tests and procedures show that you can be in the study, you will be registered to the study and will begin study participation. If you do not qualify for the study, your study doctor will discuss other treatment options with you.

***During the study:***

The study is divided into intervals called “cycles.” These cycles are made up of 28 days each. During these cycles, you will be given the study drugs depending on your involvement with the study and how many subjects have been enrolled. Different dose levels will be tested based on how subjects have been safely tolerating the medications. Your study doctor will inform you about your dose level you will be planned to receive.

You will continue to see your regular doctor and will continue your other therapy as they have prescribed.

Your study doctor will review all the current medications you are taking before you join the study and advise you of any medications that should be stopped to minimize any unnecessary stomach discomfort or avoid possible unsafe drug interactions. If the study doctor decides that the current dose level is not well tolerated by the participants, the dose level could decrease for the whole study or the study could stop completely. You will be asked to write on a study drug diary to keep track of when you take the oral sotorasib. You will be asked to also include any symptoms or side effects that you may have. You will fill out this diary form each day. If you forget and miss a dose, you should take the dose as soon as possible. If the next dose is due in less than 8 hours, you should skip the missed dose and take the next dose as scheduled. You should write any missed or skipped doses in your drug diary. If you vomit after taking the medication, you should not take another dose at that time. At your next scheduled dose, take your normal dose. Write your symptom of vomiting on the study drug diary and discuss this information with the study doctor.

***Cycle 1 and Cycle 2:***

After you are registered to the study you will come into clinic for your Day 1 study visit and to receive your study medication. Your study visits will occur once every week. You will have the following standard of care exams, tests, and procedures. If you have had some of them recently, they may not need to be repeated. This will be up to the study doctor. It may take about 6 hours to complete all the tests below:

- History and physical exam. The study doctor will ask you what medications you are taking. (This is completed on Day 1 of each cycle)
- Vital signs (blood pressure, heart rate, temperature, respiration rate, and weight)
- ECG 12-lead. This is where small electrodes are placed on your chest so to that the electrical activity of your heart can be assessed. You will be monitored before your infusion and after your infusion for several hours to make sure there are no complications.
- About 2 teaspoons of blood will be taken to look at your blood cell counts, the health of your kidneys and liver, to look at the level of cancer activity in your body and your electrolyte balance. Electrolytes are minerals in your blood that help maintain your body's blood chemistry, muscle action and other bodily functions.
- All female subjects will be advised to take contraception throughout their time on study and will undergo pregnancy tests at each visit
- Potassium supplementation will be given on a case-by-case basis. You should not take potassium supplements unless instructed to do so by your doctor. This will be discussed before each Tarlox infusion, if needed.

***Cycle 3 and beyond:***

You will have the following standard of care exams, tests, and procedures. It may take about 5 hours to complete all the tests below:

- History and physical exam. The study doctor will ask you what medications you are taking. (This is completed on Day 1 of each cycle)
- Vital signs (blood pressure, heart rate, temperature, respiration rate)
- ECG 12-lead. This is where small electrodes are placed on your chest so to that the electrical activity of your heart can be assessed. You will be monitored before your infusion and after your infusion for up to 2 hours to make sure there are no complications.
- About 2 teaspoons of blood will be taken to look at your blood cell counts, the health of your kidneys and liver, to look at the level of cancer activity in your body and your electrolyte balance. Electrolytes are minerals in your blood that help maintain your body's blood chemistry, muscle action and other bodily functions.
- Radiographic scans or imaging using Computed Tomography (CT) scan (a series of images taken with x-rays), positron emission tomography (PET) scan or magnetic resonance imaging. (You will only undergo imaging to assess the status of your cancer every 8 weeks)

***End of Treatment:***

You will have the following standard of care exams, tests and procedures. It may take about 3 hours to complete all the tests below:

- History and physical exam. The study doctor will ask you what medications you are taking.
- Vital signs (blood pressure, heart rate, temperature, respiration rate)
- ECG 12-lead
- About 2 teaspoons of blood will be taken to look at your blood cell counts, the health of your kidneys and liver, to look at the level of cancer activity in your body and your electrolyte

balance. Electrolytes are minerals in your blood that help maintain your body's blood chemistry, muscle action and other bodily functions.

▪ Radiographic scans or imaging using Computed Tomography (CT) scan (a series of images taken with x-rays), positron emission tomography (PET) scan or magnetic resonance imaging

**Withdrawal**

You are free to withdraw from this study at any time. If you decide to withdraw from this study you should notify the research team by speaking with them in clinic, by phone and/or in writing immediately, at the below address. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, your safety and welfare are at risk, or the study sponsor decides to stop the study. The contact information for the study doctor is:

Mariam Alexander, MD PhD
Medical University of South Carolina
86 Jonathan Lucas St Charleston, SC 29425
Phone: 843-792-9300

If you experience any of the side effects listed in the Risks and Discomforts section or if you become ill during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make the decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and well-being, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

If you withdraw or are removed from the study, the researcher may ask you to return to the clinic for a final close-out visit or evaluation. You could be removed from the study if the doctor believes that you are no longer benefitting from the study, or if you are not following the study's directions.

## C. DURATION

You can continue participating in this study if you are tolerating the study medications and if your study doctor believes it is safe to continue. You can continue the study if your disease worsens. You may be removed from the study if you discontinue treatment for other reasons.

## D. RISKS AND DISCOMFORTS

While on this study, you are at risk for the side effects listed below. Not everyone will have these side effects. You may have none or several. Most people do not experience all the side effects listed. A side effect may get worse while on study drug, or more side effects may develop as the longer you stay on study. This depends on your general health and the amount of the study drug you receive (the dose). Many side effects are inconvenient but not damaging to your health. They are almost always reversible and usually go away shortly after you stop taking study drugs. However, some side effects are serious medical conditions that in rare cases, may cause your death or cause your condition to worsen. The study doctor will closely monitor and treat/prevent the side effects that you

might have through the study period. Other drugs and procedures may be given to make side effects less serious and less uncomfortable. There may be side effects which are unknown at this time.

## Sotorasib

Less than 30% of subjects reported these events:
- Diarrhea
- Fatigue

Less than 20% of subjects reported these events:
- Changes in liver function
- Changes in kidney function
- Nausea
- Dizziness
- Cough
- Abdominal pain
- Back pain
- Headache
- Decreased appetite
- Decrease in red blood cells

Less than 10% of subjects reported these events:
- Constipation
- Insomnia
- Pneumonia
- Pleural effusion
- Blood alkaline phosphatase increased
- Swelling or inflammation in stomach or intestines
- Small intestinal obstruction
- Pain or swelling in joints and/or extremities
- Skin Rash
- fever

## Tarloxotinib

Less than 50% of subjects reported these events:
- Irregular heart rhythm (prolonged QT segment)

Less than 10% of subjects reported these events:
- Hypertension
- Fluid around the heart
- Muscular weakness
- Lung infection
- Pneumonitis
- Diarrhea

- Pruritus
- Skin Rash
- Pain in extremity
- Bone pain
- Decrease in blood cells
- Changes in liver function
- Excess fluid in lungs
- Intestinal obstruction
- Blood clot in lungs
- Blood build up around the heart
- Abdominal swelling
- General Pain

**Blood Draw**
Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting is possible, although unlikely.

**ECG**
The ECG procedure may cause some mild discomfort during the placement and removal of the leads to and from the skin. You may also experience some local irritation, redness, or burning in the areas where the leads are attached.

**Pregnancy**
We do not know if the study drug will affect mother's milk or an unborn fetus. Therefore, breastfeeding and pregnant women are not allowed to take part in the study. If you are pregnant or become pregnant, there may be risks to the embryo or fetus that are unknown at this time. Women who can become pregnant must take a pregnancy test before the start of the study.

You should not father a child while on this study as the treatment may indirectly affect an unborn child. If you are sexually active and are at risk of causing a pregnancy, you and your female partner(s) must use a method to avoid pregnancy that works well or you must not have sex.

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 6 months after taking the study drug.

**X-Ray**
While X-rays are linked to a slightly increased risk of cancer, there is an extremely low risk of short term side effects. Exposure to high radiation levels can have a range of effects, such as vomiting, bleeding, fainting, hair loss, and the loss of skin and hair.

**CT Scan**
CT scans use X-rays, which produce ionizing radiation. Research shows that this kind of radiation may damage your DNA and lead to cancer. But the risk is still very small -- your chances of developing a fatal cancer because of a CT scan are about 1 in 2,000. But radiation's effect adds up

over your lifetime. So your risk increases with every CT scan you get. Talk to your doctor about the procedure's potential dangers and benefits, and ask why the CT scan is necessary.

**PET scan**
For your PET scan, a radioactive drug (tracer) will be injected into a vein. Because the amount of radiation you're exposed to in the tracer is small, the risk of negative effects from the radiation is low. But the tracer might:

- Expose your unborn baby to radiation if you are pregnant
- Expose your child to radiation if you are breastfeeding
- Cause an allergic reaction, although this is rare

**Loss of confidentiality**
There is a risk of loss of confidentiality since medical records will be reviewed during this study. MUSC and its study team members will take every effort to ensure that your information is kept confidential during this study. Unknown risks The experimental study drug may have unknown side effects. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

## E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

If you are an MUSC patient, you have an MUSC medical record. If you have never been an MUSC patient, a MUSC medical record will be created for the purposes of this study. Results of research tests or procedures may be included in your MUSC medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law.

## F. BENEFITS

Participation in this study may improve your physical well-being, but that cannot be guaranteed. There may be no benefit to you in taking part in this study. Your participation may provide valuable information and data that may benefit other subjects in the future with your type of cancer or other cancers.

## G. COSTS

The cost of routine medical care for your cancer is billable to you or your insurance provider. Because sotorasib is FDA approved for treatment of your cancer, you or your insurance will be responsible for covering the medication's cost. Financial support may be available to help you pay for this medication if you are unable to afford it.

Tarloxotinib will be provided at no cost to you.

## H. PAYMENT TO PARTICIPANTS

You will not be paid for participating in this study.

## I. ALTERNATIVES

Alternative treatments include taking other medications that may be approved for your cancer, taking part in a different study if one is available, receiving no treatment, or receiving comfort care, also called palliative care.

## J. DATA SHARING

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

## K. DISCLOSURE OF RESULTS

We do not plan to share the results of the blood tests with you as the tests are done for research only.

## L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

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

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

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

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

- The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

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

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

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

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

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

## M. 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.

## N. SPONSOR COMMITMENT

In the event you require medical treatment for a physical illness or injury, Rain Therapeutics shall pay MUSC or other emergency care provider for the reasonable and necessary costs associated with the immediate treatment of your physical illness or injury sustained as a direct result of taking the study drug or undergoing a procedure required by the Protocol, provided that those costs are not covered by your insurance, excluding government entitlement programs such as Medicare or Medicaid. For government entitlement programs, such as Medicare or Medicaid, the Rain Therapeutics will pay for all costs related to the covered illness or injury.

## O. COLLECTION OF SPECIMENS

Blood samples for research will be collected on the first day of the first two cycles of study treatment and when you complete study treatments. About 10 teaspoons of blood will be collected when you have routine labs drawn at these visits.

## P. STUDY TREATMENT BEYOND RADIOLOGIC DISEASE PROGRESSION_(IF APPLICABLE)

If your radiographic scans show that your disease has gotten worse, you may still be able to continue receiving study treatment if your study doctor believes you are otherwise receiving benefit clinically and do not have any other symptoms of disease that have also gotten worse. Your study doctor will explain the possible benefits of continuing study treatment, discuss with you any other available treatment options, including any FDA-approved therapies you may not yet have received, and other clinical trials. You will be asked read and sign a new informed consent document if you agree to continue receiving study treatment.

_____
*Name of Participant

_____
Signature of Participant Date

## Q. FUTURE CONTACT

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

____Yes, I agree to be contacted

____No, I do not agree to be contacted

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

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

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

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

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. Mariam Alexander at 843-792-4271. I may contact the Medical University of SC Subject 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

_____

_____ _____

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.