Interleukin-1 Blockade for Treatment of Cardiac Sarcoidosis

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VCU IRB PROTOCOL NUMBER: HM20015843

NCT04017936

Version 3-10-22, Approved 4/1/2022

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: **Interleukin-1 Blockade for Treatment of Cardiac Sarcoidosis**

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[redacted]

SPONSOR: **Virginia Commonwealth University**

FUNDING: **American Heart Association**
Virginia Commonwealth University
National Center for the Advancing Translational Sciences

ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the study doctor or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

Why is this study being done?

The purpose of this research study is to test the safety, tolerability, and effectiveness of the medication Anakinra (Kineret®) when used to treat Cardiac Sarcoidosis. You are being asked to participate in this study because you have been diagnosed with Cardiac Sarcoidosis, and may meet the study entry requirements.

Anakinra (Kineret®) is a naturally occurring protein that blocks inflammatory signaling in the body. The Food and Drug Administration (FDA) has approved Anakinra for the treatment of rheumatoid arthritis, but Anakinra is not currently approved for the treatment of cardiac sarcoidosis.

What will happen if I participate?

If you participate in this study, you will be randomly assigned (like the flip of a coin) to receive Anakinra (Kineret®) on top of standard of care or standard of care only. Anakinra (Kineret®) is administered as an injection under the skin, given once a day for 28 days in a row. You will be instructed how to give yourself the injections at home. If you are assigned to the standard of care only, you will not receive any additional treatment.

In this study, you will be asked to do the following things:

1. Visit Dr. Kron's Clinic up to 4 times for study visits: a Screening visit (to make sure you meet the study entry requirements), a Randomization visit (where you will be randomly assigned to receive Anakinra on top of standard of care or standard of care only), at 28-days (after you've completed the study injections), and at 60 days for a blood draw.
2. If you are assigned to the Anakinra (Kineret®) arm, administer the study drug injections once a day for 28 days in a row. Anakinra (Kineret®) syringes will need to be stored in your refrigerator at home.
3. Have your blood drawn up to 3 times (Screening, 28-day, and 60-day study visits). You may have up to 3 tablespoons of blood drawn at each visit, which amounts to about 9 tablespoons of blood that we may draw over the entire course of the study.
4. If you are a woman of child-bearing potential, a urine pregnancy test will be done at the Screening visit. Pregnant women and nursing mothers may not be in this study.
5. Have a Cardiac FDG-PET scan done 2 times (between the Screening and Randomization visits if you have not had one as part of your routine care within 2 months of enrollment and after the after 28-days of study injections or standard of care).
6. Have a Cardiac MRI scan done 2 times (between the Screening and Randomization visits and after 28 days of study injections or standard of care). You may need an additional X-ray of your chest or other part of your body to exclude loose fragments of metal before an MRI is performed.
7. Wear a 24-hour Holter monitor 2 times (between the Screening and Randomization visits and after 28 days of study injections or standard of care)
8. Complete a quality of life questionnaire about Cardiac Sarcoidosis 2 times (at the Randomization and the 28-day visits)
9. Give permission for the study staff to contact you at around 6 months after you enroll to ask how you are doing.
10. Give permission for the researchers to collect information from your medical records about your medical history, medications, and any side effects or hospital visits for up to 6 months after you start the study.

Your participation in this study will last up to 6 months.

This is a multi-center study. This study will enroll 28 participants. Approximately 14 people will participate in this study at VCU.

This study will not use your samples to sequence all or part of your DNA.

What alternative treatments or procedures are available?

If you decide not to participate in this study, you can still receive the usual treatments for cardiac sarcoidosis.

What are the risks and benefits of participating?

There are both risks and benefits of participating in research studies. We want you to know about a few key risks right now. We will give you more information in the "WHAT RISKS AND DISCOMFORTS CAN I EXPECT FROM BEING IN THE STUDY?" section.

Risks and Discomforts	Benefits to You and Others
1. There is a risk that adding Anakinra (Kineret®) may not be as good as the usual approach for cardiac sarcoidosis. Your condition may not get better (or could become worse) while you are in this study. 2. There is a risk that you could have side effects from taking study drug. Anakinra is generally well-tolerated but some side effects are possible, including: • Injection site reaction (> 10%) such as pain, redness or irritation at the site of the injections • Serious infection (< 5%) • Headache (1 – 10%) • Nausea (1 – 10%) • Diarrhea (1 – 10%) • Low white blood cell count (< 1%, but not associated with increased risk of infection) 3. There may be some risks that the study doctors do not know about yet, so we will let you know of any new findings. 4. Other risks to participation in this study include: • Blood draws may cause pain, bleeding, and/or bruising. You may faint and could develop an infection at the site where blood is drawn.	There is no guarantee that you will receive any medical benefits from being in this study. The information from this research study may lead to a better treatment in the future for people with cardiac sarcoidosis.

• For the FDG-PET scan, an IV will be inserted. This scan uses a small amount of radioactive tracer given through the IV. The amount of radiation you are exposed to is low and short-lived. There is a rare risk of allergic reaction to the tracer agent. There may be discomfort associated with being positioned in the scanner with your arms above your head. • For the Cardiac MRI, an IV will be inserted. The contrast agent given through the IV contains a metal called gadolinium. Gadolinium based contrast agents may stay in the body, including the brain for months to years after receiving these drugs. Gadolinium retention has not been directly linked to adverse health effects in patients with normal kidney function. There is a small risk of allergic reaction to the contrast agent. Some people may feel anxious while they are in the scanner. If you have an implanted defibrillator, coming in contact with the strong magnetic field of the MRI scanner might damage the beeper function on the defibrillator, or may cause other device malfunctions. • Select cases may require an X-ray before the MRI, which will expose you to a very small amount of radiation. This small amount will pose very little risk to you. • The study questionnaires ask questions about your health and symptoms and daily activities. Some people may feel uncomfortable answering some of the questions. 5. Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you. **Please see the "WHAT RISKS AND DISCOMFORTS CAN I EXPECT FROM BEING IN THE STUDY?" section for more information.**	

Now that you have a general overview of the study, we want to provide the details about what your participation involves. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the study staff.

WHY IS THIS STUDY BEING DONE?

Sarcoidosis is an inflammatory disease that most commonly involves the lungs. Sarcoidosis can involve nearly any organ system, including the skin, liver, and eyes. Cardiac sarcoidosis occurs when sarcoidosis causes inflammation in the heart. Cardiac sarcoidosis is an uncommon disease that can lead to sudden cardiac death and/or heart failure.

Anakinra (Kineret®) is a naturally occurring protein that blocks inflammatory signaling in the body. The Food and Drug Administration (FDA) has approved Anakinra for the treatment of rheumatoid arthritis, but Anakinra is not currently approved for the treatment of cardiac sarcoidosis. Anakinra is generally well-tolerated, but can cause pain or redness at the injection site and may affect your risk of infections. The study team will work with you to help you avoid (or manage) any side effects throughout the study.

The purpose of this research study is to test the safety, tolerability, and effectiveness of Anakinra in patients with cardiac sarcoidosis.

WHAT WILL HAPPEN IF I PARTICIPATE IN THE STUDY?

You will have your usual clinic visits with your doctor and some routine diagnostic tests for care related to your cardiac sarcoidosis. Some of the information for this study will be collected from your medical records and from your routine care (such as vital signs, lab work, ECGs , and other diagnostic tests), and some tests and assessments will be done specifically for the study.

If you decide to participate in this study, after you provide your consent, you will have a **Screening visit** at Dr. Kron's Clinic located at the Stony Point campus, or at the downtown hospital campus. This visit will take approximately 30-60 minutes, and you will:

- Be seen by the study doctor/study staff.
- Have a blood sample (up to 3 tablespoons) taken. The blood will be used for chemistry and hematology tests and cardiac specific biomarkers.
- Complete the Cardiac Sarcoidosis Quality of Life Questionnaire: You will be asked to complete the Sarcoidosis Assessment Tool (SAT) which asks you questions related to your sarcoidosis. The questionnaire will take about 10-15 minutes to complete.
- If you are a woman of childbearing potential (meaning if you are not post-menopausal and/or have not had a hysterectomy) you will have a urine pregnancy test.
- Schedule several baseline diagnostic tests. These tests include:
    - Cardiac F-18 Fluorodeoxyglucose Positron Emission Tomography (FDG-PET) scan with Myocardial Perfusion Imaging (MPI): If you haven't had one in the 2 months prior to enrolling in the study, a FDG-PET scan with MPI will be done. PET scans use a small amount of radioactive tracer to show the difference between healthy and unhealthy

tissue. F-18 Fluorodeoxyglucose is the name of the tracer used in this type of PET scan. Myocardial Perfusion Imaging (MPI) shows how well blood flows through heart muscle and is done prior to the FDG-PET scan. These tests are done at the downtown location of VCU hospital and will take 1½ - 3 hours.

Testing Procedure: You will come in a day or two before your FDG-PET scan to have the MPI scan done. This will take 1½ to 2 hours.

The evening before the FDG-PET scan, you will eat a high-fat/high-protein, low-carbohydrate diet, and you will be given an instruction sheet about this. After the high-fat/high-protein, low-carb meal, you will need to fast (nothing to eat or drink except water) for 12 hours before the scan. You are allowed to take your usual pills with a sip of water. On the day of the scan, you will come in at 7:30 AM. An intravenous (IV) line will be started and your blood sugar will be checked. Before the scan is done, you will be given a dose of heparin (a blood thinner) and the tracer agent (F-18 Fluorodeoxyglucose). When it is time to do the scan, you will be positioned in the scanner with your arms above your head. This allows for better images of your heart to be obtained. The prep time before the scan is about 45-60 minutes, and the scan itself will take about another 45-60 minutes. The total time on the day of the FDG-PET scan is about 3 hours.

- Cardiac Magnetic Resonance Imaging (Cardiac MRI) scan: This scan uses magnetic fields, radio waves and a computer to produce detailed images of heart structures. This test will be done at the downtown campus of VCU hospital, and will take approximately 1½ - 2 hours from the time you arrive to the time you leave. The scan itself takes about 30-45 minutes; however, some cases may require an X-ray before the MRI can be conducted.
  Testing Procedure: You will have an IV started before the test which will be used to give the contrast agent (gadolinium) during the scan to make better images. You will need to lie very still while the scan is being done to minimize any distortion on the images. There may be some discomfort or anxiety associated with being in the scanner, especially for people who fear being in enclosed spaces (claustrophobia). The scanner produces some loud knocking noises, and earplugs can be provided to minimize the noise.
- 24-hour Holter Monitor: This test will be done at the downtown location of VCU hospital. It will take 15-30 minutes each on 2 consecutive days.
  Testing Procedure: You will come in to have the monitor applied. This involves applying electrode patches to your chest which are attached to a small monitor box with wires, and takes about 15-30 minutes. You will come back 24 hours later to have the monitor and electrode patches removed, which takes about 15 minutes.

After these tests are completed, you will come to Dr. Kron's Clinic at the downtown campus for the **Randomization Visit** which will take about 30-60 minutes. At this visit you will:

- Be seen by the study doctor/study staff.
- Be randomized (like a flip of a coin) to receive either Anakinra on top of standard of care or standard of care only.
- Be scheduled to return to the Cardiac Sarcoidosis Clinic in 28 days.
- Patients randomized to Anakinra will also be instructed on how to give yourself the daily study injections and will receive 28 Anakinra (Kineret®) syringes.

On a case by case basis, the Screening and Randomization Visits may be combined in one visit.

At the **28-day Visit** (which will take about 30-60 minutes at the downtown hospital campus) you will:

- Be seen by the study doctor/study staff. Have a blood sample (up to 3 tablespoons) will be taken. The blood will be used for chemistry and hematology tests and cardiac specific biomarkers.
- Complete the Cardiac Sarcoidosis Quality of Life Questionnaire.

Within 2 weeks of the 28-day visit you will have the following tests:

- FGD-PET scan with MPI
- Cardiac MRI (and potential X-ray)
- 24-hour Holter Monitor

At the **60-day Visit** (which will take about 30-60 minutes at the either the Stony Point campus or the downtown hospital campus) you will:

- Be seen by the study doctor/study staff.
- Have a blood sample (up to 3 tablespoons) taken. The blood will be used for chemistry and hematology tests.

Around 6 months after you enroll in the study, you will be seen in person at a regular office visit (if you have one scheduled) or you will be contacted by telephone by the study staff to check on how you are doing. Additionally, the study staff will review your medical records for medical history, medications, and any side effects or hospital visits for up to 6 months after you enrolled in the study.

You will not be able to participate if you have been recently affected by COVID-19 in the prior 60 days or you have been in close contact with a person affected by COVID-19 in the prior 21 days. At each visit, you may be asked to undergo screening questions and tests for COVID-19 as

per standard protocol at VCU Health, which may include answering questions about your health and/or measuring your temperature.

WHAT ALTERNATIVE TREATMENTS OR PROCEDURES ARE AVAILABLE?

If you decide not to participate in this study, you can still receive the usual treatments for cardiac sarcoidosis.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

There is no guarantee that you will receive any medical benefits from being in this study. The information from this research study may lead to a better treatment in the future for people with cardiac sarcoidosis.

WHAT RISKS AND DISCOMFORTS COULD I EXPERIENCE FROM BEING IN THE STUDY?

Possible Risks Associated with Anakinra

Anakinra is generally well-tolerated, but some side effects are possible.

- Injection site reaction (>10%) such as pain, redness, or irritation at the site of injection.
- Serious infection (<5%)
- Headache (1 –10%)
- Nausea (1 – 10%)
- Diarrhea (1 – 10%)
- Low white blood cell count (rare, but not associated with increased risk of infection)

Anakinra may block your body's ability to have a fever. This means that you may not have a fever if you become sick or ill. If you are feeling sick during the study, please contact your study doctor immediately. Allergic reaction to Anakinra is possible. Severe allergic reactions can be life threatening. Please contact your study doctor or seek immediate medical attention if you experience skin rash, swelling, or difficulty breathing as these may be signs of allergic reaction.

Only the study participant can take the study drug. It must be kept out of the reach of children and persons who may not be able to read or understand the label.

Possible Risks Associated with Study Tests:

- Blood collection: Pain or bruising may occur. In rare cases, blood draws may result in skin/tissue infection. Blood draws will be completed by trained personnel.
- IV insertion (for FDG-PET scan and Cardiac MRI scan): Pain/soreness, bruising, light-headedness, fainting, bleeding, or infection may occur. Multiple needle-sticks may be necessary. The IV will be inserted by trained personnel.

FDG-PET scan: As a participant in this study, you will receive extra radiation exposure from one (1) PET scan that is for research purposes only (not for your direct clinical benefit). The radiation dose from this procedure is approximately 21% of the annual permissible occupational exposure level for radiation workers. The National Council on Radiation Protection and Measurements has set permissible occupational radiation exposure limits for many radiologists, technologists, and scientists who work with radiation and are exposed nearly every day. These limits are defined as the dose of radiation that, in light of present knowledge, is not expected to cause appreciable bodily injury to a person at any time during his/her lifetime. The risk of this amount of occupational exposure to radiation is, thus, considered to be very small and less than that associated with normal everyday activities. The radiation dose mentioned is what you will receive from the research component of this study only and does not include any exposure you may have received or will receive in the future from other tests.

- There is a rare risk of allergic reaction to the tracer agent. You will also be given a dose of heparin (a blood thinner) for this test. There is a small risk of allergic reaction to the heparin. If you have a known allergy to heparin, you will still have the FDG-PET scan done, but no heparin will be given to you. There may be discomfort associated with being positioned in the scanner with your arms above your head. There will be a technician with you during the scan to assist with any discomfort you may have.
- Cardiac MRI scan: The contrast dye used for MRI contains a metal called gadolinium. This is not the same type of dye that is sometimes used for CT scans. There is a small risk of allergic reaction to the gadolinium contrast dye used for the cardiac MRI, and the contrast could cause side effects of headache, nausea, dizziness, rash, itching, tingling feeling in the lips, arms, hands or feet. The majority of the gadolinium contrast dye is removed from the body through the urine within 24 hours, however gadolinium-based contrast agents may stay in the body, including the brain for months to years after receiving these drugs. Gadolinium retention has not been directly linked to adverse health effects in patients with normal kidney function. There may be some discomfort or anxiety associated with being in the scanner, especially for people who fear being in enclosed spaces (claustrophobia). The scanner produces some loud noises, and earplugs can be provided to minimize the noise. There will be a technician with you during the scan to assist you with any discomfort you may have. If you were to experience anxiety about the procedure or anxiety of being in small places (claustrophobia) you may be evaluated by a licensed clinician and you may be offered medication to help alleviate the anxiety. These medications are called benzodiazepines and are used to relieve anxiety. The licensed clinician will explain to you that the use of benzodiazepines can cause sleepiness (sedation) and difficulty breathing and, in rare cases this can even cause respiratory arrest. You will be assessed and monitored by the clinician before, during and after the procedure until you recover. You will not be required to take this medication if you wish not to and decide to undergo the procedure

without the medication or to cancel. If you cannot participate in the MRI due to anxiety, you can continue to participate in the other portions of the study.

- If you have an implanted defibrillator, it must be FDA approved to undergo the MRI scan and it will be turned to MRI mode during the scan. After the scan your device will be checked, MRI mode will be turned off and it will be returned to its original settings. For some devices, coming into contact with the strong magnetic field of the MRI scanner could likely damage the beeper function on the defibrillator such that it may no longer be heard (> 50% chance that this will happen). This means that the device will no longer beep when the battery is low or for certain patient conditions or device malfunction. However, your heart doctor will be able to check the device with a programmer at every clinic visit to make sure the battery is replaced before it runs out or identify and address any patient conditions or device malfunctions. Other risks associated with defibrillator devices and MRI are rare (< 1 % chance of happening) and include discomfort due to slight movement or heating of the device, mechanical damage to the device or leads, and improper function/malfunction of the defibrillator. To minimize the risks of defibrillator malfunction during the MRI, the standard clinical protocols for MRI-conditional defibrillator devices will be followed, the device will be checked before and after the MRI, will be set to MRI mode during the scan, and returned to its original settings after the scan.
- X-ray: X-rays produce small amounts of radiation. You are exposed to safe levels of radiation on a daily basis; the amount of radiation you will be exposed to should you require an X-ray prior to the MRI is the equivalent of a couple of days of normal radiation exposure. To minimize the risks associated with an X-ray, only a professionally trained technician will conduct it.
- 24-hour Holter Monitor: There may be some minor skin irritation from the electrode patches that are applied to the skin for 24 hours, or discomfort when the patches are removed.

Non-Physical Risks

Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you. The questions in the Cardiac Sarcoidosis Quality of Life questionnaire may be upsetting to some patients.

Unknown or Unforeseeable Risks

During the course of the research, we will inform you of any significant new findings that may affect your willingness to continue participation.

Reproductive Risks

As the study procedures might injure an unborn child, pregnant women may not participate. Women who might become pregnant should use a medically accepted form of birth control such as total abstinence, birth control pills, an IUD, diaphragm, progesterone injections or implants, or condoms plus a spermicide. Methods of birth control other than total abstinence are not 100% effective, and should a woman become pregnant there is a risk of injury to an unborn child. For similar reasons, women who are nursing an infant may not participate in this study.

For men, the study procedures might increase the risks for birth defects of any child conceived during treatment and several months after treatment is stopped. Men in this study who have the potential of fathering children should be aware of this possibility and consider using a medically accepted form of birth control. For men this would include total abstinence and condoms plus a spermicide, or for the female partner, birth control pills, an IUD, diaphragm, progesterone injections or implants. Methods of birth control other than total abstinence are not 100% effective, and should a woman become pregnant there is a risk of injury to an unborn child.

WHAT ARE THE COSTS?

Anakinra (Kineret®) will be provided at no cost to you. You and your insurance plan will need to pay for the costs of medical care you get as part of the usual care for your condition, even if this information is collected for the study. This includes the Screening clinic visit, bloodwork, and FDG-PET scan (if done within 2 months of enrollment) which will be billed to you and/or your insurance provider as part of your routine care. If you have not had a FDG-PET scan done within 2 months of study enrollment as part of your routine care, the baseline FDG-PET scan will be done for the study and will not be billed to you/your insurance provider.

You and your insurance plan will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. This includes:

- Screening, Randomization, 28-day, and 60-day clinic visits.
- Study bloodwork done at Randomization and 28-day visits.
- FDG-PET scan and Cardiac MRI scan done between the Screening and Randomization visit and at the 28-day visit.
- 24-hour Holter Monitor done between the Screening and Randomization visit and at the 28-day visit.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You will receive $100 compensation (in the form of a gift card or check) at 3 of the study visits: the randomization visit, and the 28-day visit, and the 60-day visit. You will not receive compensation for the visits required to complete the study tests. The total compensation for completing the 3 study visits would be $300. Transportation costs may also be reimbursed up to $100 per visit if the cost of transportation for your study visits is a financial barrier to your participation.

Total payments within one calendar year that exceed $600 will require the University to report these payments annually to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

Please be aware that the investigative team and the University may receive money for the conduct of this study.

WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THE STUDY?

If you are injured by, or become ill, from participating in this study, please contact your study doctor immediately. Medical treatment is available at the Virginia Commonwealth University Health System (VCU Health System). Your study doctor will arrange for short-term emergency care at the VCU Health System or for a referral if it is needed.

Fees for such treatment may be billed to you or to appropriate third-party insurance. Your health insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study. To help avoid research-related injury or illness, it is very important to follow all study directions.

CAN I STOP BEING IN THE STUDY?

You can stop being in this research study at any time. Leaving the study will not affect your medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent. The reasons might include:

- the study doctor thinks it necessary for your health or safety;
- you have not followed study instructions;
- the sponsor has stopped the study; or
- administrative reasons require your withdrawal.

HOW WILL INFORMATION ABOUT ME BE PROTECTED?

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- The study Sponsor, representatives of the sponsor and other collaborating organizations
- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services or the Federal Food and Drug Administration

It will be noted in your protected electronic health record at VCU Health that you are in this study. Information about the study including any medications you may receive, will be included in the record. This information is protected just as any of your other health records are protected.

In general, we will not give you any individual results from the study. If we find something of medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

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.

There are no plans to share any money or profits with you if the use of your sample(s) results in inventions or discoveries that have commercial value.

In the future, identifiers might be removed from the information and samples you provide in this study, and after that removal, the information/samples could be used for other research studies by this study team or another researcher without asking you for additional consent.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality helps the researchers keep your information private. For example, researchers can refuse to give out your information in a court case. Researchers may have to give your information if the study is audited, or if the information is required by the Food and Drug Administration (FDA).

The researchers cannot prevent you or others, for example a member of your family, from sharing information about you or your involvement in this research. If you give an insurer, employer, or other person permission to receive research information, then the researchers may not use the Certificate to withhold that information.

HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your healthcare records. New health information may also be created from study-related tests, procedures, visits, and/or questionnaires. This type of information is considered "Protected Health Information" that is protected by federal law.

What type of health information will be used or shared with others during this research?

The following types of information may be used for the conduct of this research:

☒ Complete health record	☐ Diagnosis & treatment codes	☐ Discharge summary
☒ History and physical exam	☐ Consultation reports	☐ Progress notes
☒ Laboratory test results	☒ X-ray reports	☒ X-ray films / images
☐ Photographs, videotapes	☐ Complete billing record	☐ Itemized bill
☐ Information about drug or alcohol abuse		☐ Information about Hepatitis B or C tests
☐ Information about mental health		☐ Information about sexually transmitted diseases

Who will use or share protected health information about me?

VCU and the VCU Health System are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Health Care Providers at VCU Health
- Institutional Review Boards
- Study Sponsor
- Data Coordinators
- Research Collaborators

- Government/Health Agencies
- Others as Required by Law
- Data Safety Monitoring Boards

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?
This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Statement of Privacy Rights
You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator at:

Dr. Jordana Kron
[redacted]
Virginia Commonwealth University Medical Center
[redacted]

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?
The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

Principal Investigator/Study Doctor:

Dr. Jordana Kron
[redacted]

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research (804) 827-2157
800 East Leigh Street, Suite 3000
Box 980568
Richmond, VA 23298
https://research.vcu.edu/human_research/volunteers.htm

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form, I have not waived any of the legal rights or benefits to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form for my records.

Adult Participant Name (Printed)	
Adult Participant's Signature	Date
Name of Person Conducting Consent Discussion (Printed)	
Signature of Person Conducting Consent Discussion	Date
Principal Investigator Signature (if different from above)	Date