CONSENT DOCUMENT

Protocol Title: CCR2 Targeted Molecular Imaging and Treatment of Abdominal Aortic Aneurysms (NIH CCR2 AAA study)

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INFORMED CONSENT DOCUMENT

Project Title: CCR2 Targeted Molecular Imaging and Treatment of Abdominal Aortic Aneurysms (NIH CCR2 AAA study)

Principal Investigator: **Mohamed Zayed, M.D.**

Research Team Contact: **Laura McDonald, RN, BSN** **(314) 747-7828**
Ashley Cosentino, RN, BSN **(314) 362-6257**

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

KEY INFORMATION

This is a research study conducted by Dr. Mohamed Zayed. The goal of this research study is to evaluate the imaging performance of an imaging agent in healthy human volunteers, as well as individuals with aortic aneurysms or aortas with atherosclerosis. You should carefully consider the information in this consent document and discuss it with the research team. Be sure you understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. All of the information below will be explained and is listed in more detail in the consent document below. The research team must give you a copy of this signed consent document.

How will this study affect me?

- The purpose of this study is to look at a radiotracer, ^{64}Cu-DOTA-ECL1i (an imaging agent), to see if it will assist us during the PET/CT/MRI scanning to possibly help identify individuals who may have an increased risk of aortic aneurysm progression or rupture.
- As a volunteer participant, you will be asked to spend approximately 6 hours at the imaging facility. It will take approximately 60 minutes for the first PET/CT imaging session, then you will come out of the scanner and wait from 1-4 hours. After that time, you will be placed back into the scanner for another 20-minute PET/CT followed by a Computed Tomography Angiography (CTA). You will also be asked to undergo an optional PET/MRI scan of the abdominal aorta.
- You were selected because you are a healthy volunteer, or because you have an aortic aneurysm, or aortic atherosclerosis. The study aims to enroll 20 patients without aortic pathology, and 50 patients with aortic pathology (aneurysm or atherosclerosis).

- You will need to come to the 10th Floor of Barnes-Jewish Hospital in the Center for Clinical Imaging Research (CCIR) at Washington University for the research imaging (PET/CT scan and optional PET/MRI scan).
- The main risks to you are pain from the placement of one or two IVs and a blood draw. You may also experience some stiffness from lying still for the PET/CT/MRI imaging. More detail about risks is provided below.
- You will not benefit directly from this study; however, we hope that, in the future, other people may benefit from the study findings and from what we learn.
- You will be paid $250.00, receive meal vouchers, and a parking pass for completing the imaging proposed in this study. For those who are chosen to complete repeat imaging at a later date, you will receive an additional $150.00, meal vouchers, and another parking pass. If you choose to complete the optional PET/MR(MRI), you will receive an additional $100.00. If you are traveling more than 80 miles, assistance with hotel lodging will be offered and provided to you. You will not have costs for participating in this study.
- If you withdraw from the study, the research team may continue to use information already collected about you in this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you may or may not have an aortic aneurysm or buildup of plaque in the aorta (atherosclerosis of the aorta). You may be scheduled for open or endovascular repair (surgery) for your condition, or you may be scheduled for medical management (without surgery) and follow-up with your doctor. The study aims to enroll seventy (70) patients within five (5) groups:

Two (2) main groups:
- 20 patients with aortic aneurysm undergoing planned open surgery
- 20 patients with aortic aneurysm being medically managed in follow-up

Three (3) control groups
- 10 patients with aortic aneurysm undergoing endovascular surgical repair
- 10 patients with atherosclerosis of the aorta undergoing aorto-femoral bypass repair
- 10 healthy patients without aortic pathology (aneurysm or atherosclerosis)

The purpose of this research study is to look at whether an investigational imaging agent, ^{64}Cu-DOTA-ECL1i, used during Positon Emission Tomography (PET)/Computerized Tomography (CT) and/or PET/MRI (magnetic resonance imaging) or MRI scanning can help to identify conditions that place patients with aortic aneurysm at an increased risk for rupture. The study is also looking more closely at cellular, molecular and inflammatory properties of the aortic wall. Having the ability to identify markers that predict aortic aneurysm progression/expansion and risk for rupture could allow the physician to manage patients in a more individualized, personal way.

The aorta is the main artery that supplies blood flow from the heart to the rest of the body. It is approximately the size of a garden hose. Due to the effects of hypertension (high blood pressure), atherosclerosis (hardening of the arteries), and tobacco use, the aorta may widen and enlarge to form an aneurysm. An aortic aneurysm is a dilation (enlargement or ballooning out) of a section of the aorta caused by disease or weakness in the aortic wall below the level of the kidney arteries.

Currently, surgical repair or placement of an endovascular stent is the only treatment for aortic aneurysm and there is no effective medication. Often patients remain without symptoms and are unaware that they have an aortic aneurysm until their aortic aneurysm ruptures, which carries a significant risk of death. For patients who are aware of their aortic aneurysm, ultrasound and computed tomography (CT) scans are used to measure the size of the aortic aneurysm in order to direct management strategies including the timing of repair.

If you have atherosclerotic disease (plaque buildup within the aorta), you may be having aorto-femoral bypass surgery that reroutes blood flow around a diseased artery to increase blood flow to your legs.

This study will not interfere with or change your planned treatment in any way.

The radiotracer being used in this study, ^{64}Cu-DOTA-ECL1i, is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration.

WHAT WILL HAPPEN DURING THIS STUDY?

There will be five (5) groups in this study.

For all participants, the study team will review your demographics, medical history, medications and laboratory results in order to determine your eligibility to continue to participate in the study. All participants will have laboratory testing to determine eligibility including chemistry, liver panel, complete blood count with differential (approximately 1.5- 2.0 tablespoons of blood) and a urinalysis. A urine pregnancy test will be performed if you are a female of reproductive capacity. You will also need to be able to tolerate lying on your back for 60 minutes for the PET/CT scan as all participants will have PET/CT images completed.

Aortic Aneurysm and Atherosclerotic Group scheduled for surgical repair:

Approximately 30 participants with aortic aneurysm and 10 participants with atherosclerotic aorta scheduled for surgical repair will undergo routine clinical evaluation of the aorta including ultrasound and CT and scheduling of open surgical repair as directed by their treating physician. The study doctor will record your age and tobacco use. If you have not had a renal function blood test performed within the last 1 week, we will draw approximately 2 teaspoons of blood for a glomerular filtration rate (GFR) test prior to the CTA with contrast. We will also ask for your permission to use a contrast dye for the CT portion of the PET-CT scan. The contrast agent helps us see the blood circulating (moving around) in your body and blood vessels. If you agree, we will ask you some additional questions to see if you are eligible to receive the contrast dye. On the day of your imaging, you will have an initial 60-minute PET/CT scan. After that time, you will be removed from the scanner and you will wait up to 4 hours. After the wait, you will go back into the scanner and have a 20-minute PET/CT scan followed by a CTA

with contrast. Aortic aneurysm and atherosclerotic aorta participants whose treatment plan includes open surgery will have their PET/CT imaging completed within 5-14 days of their scheduled surgery and if available, collection of discarded aortic tissue at the time of surgery. This discarded tissue will be kept as part of a Washington University vascular research repository. If you agree to this, there will be a separate consent form to sign allowing us to collect the leftover tissue along with some information about your medical history.

Aortic aneurysm participants whose treatment plan includes endovascular surgery will have their PET/CT imaging completed within at least 24 hours of their scheduled surgery.

Aortic Aneurysm Group not scheduled for surgery:
Additionally, approximately 20 aortic aneurysm participants who are not scheduled for surgery will be asked to have two PET/CT imaging studies, performed 10 days to 3 months apart in order to determine the ability to reproduce the uptake results of ^{64}Cu-DOTA-ECL1i. The study physician will tell you if you are a candidate for having a second PET/CT imaging study and will determine with you whether you are willing to complete the second study visit.

The first day of imaging, you will have an initial 60-minute PET/CT scan. After that time, you will be removed from the scanner and you will wait 1-4 hours. After the wait you will go back into the scanner and have a 20-minute PET/CT scan followed by a CTA with contrast.
You will be asked to come back to the imaging facility 10 days to 3 months later to repeat all imaging procedures listed above.

Non Aortic Aneurysm Group:
We will recruit 10 non-aortic aneurysm volunteers. Both men and women, age 30 and above, with or without active tobacco use will be considered for participation in our study.

If you are in this group, on the day of your imaging, you will have an initial 60-minute PET/CT scan. After that time, you will be removed from the scanner and you will wait from 1-4 hours. After the wait you will go back into the scanner and have a 20-minute PET/CT.

Procedures:
For participants in both groups, you will undergo simultaneous PET-CT scans of the aorta. Participants with aortic aneurysm and atherosclerotic aorta who are scheduled for open surgical repair will have their PET/CT within 5-14 days of their surgery. Participants with aortic aneurysm who are scheduled for endovascular surgical repair will have their PET/CT within at least 24 hours of their surgery. Prior to the scan, if you are a woman of childbearing age, we will perform a urine pregnancy test to rule out pregnancy. If you are pregnant or breastfeeding, please notify the study team because you cannot participate in this study.

You should arrive having fasted for a minimum of 4 hours. This means you will not eat solid food for this fasting period. You may drink only water and should drink at least two or three glasses of water during this time of fasting.

You may need to change into a hospital gown if you have anything on your body that contains metal,

such as jewelry, piercings, or zippers.

Imaging will be performed using a combined PET-CT (Positron Emission Tomography (PET) with Computed Tomography) scanner to take pictures of your body. The PET scan will allow us to image the function of different cells and organs in the body after you are injected with a radioactive tracer. The CT scan (computed tomography) is an x-ray scanner that images the anatomy (size or structure) of the body giving us detailed images such as pictures of the aorta, other blood vessels, and surrounding tissues. The PET-CT scanner is a large tube in the shape of a donut with a padded imaging table in the middle of the machine that records images of your body after the injection of the radioactive tracer. A radioactive tracer is often a naturally occurring substance that contains a small amount of radioactivity so pictures can be taken of your abdomen and pelvis.

PET scanning can make pictures of structures inside the body because the tracer "lights up" on the pictures. The radioactive material breaks down and leaves your body gradually through the urine. It takes about 1 day for the radioactive material to exit your body completely.
Since the effects of radiation can be cumulative, it is important to know about your past research related radiation exposure. If you have participated in other research studies in the past 12 months that have involved radiation exposure, please inform the investigators or study staff. If it is determined that your prior radiation exposure exceeds our current guidelines, it is possible that you will not be allowed to continue to participate in this study.

Please place your initials in the blank next to 'I have' or 'have not' for the question below:

I have _____have not _____participated in research studies involving radiation exposure within the last 12 months.

PET-CT Imaging:
An IV catheter is a thin, flexible tube that is placed in a vein with a needle. We will place one (or possibly two) IV's in your arm so that if necessary, we may obtain blood from an IV site separate from the site of the injection of the radiotracer. We will obtain approximately 2 teaspoons (10 mL) of blood for routine blood work such as chemistry, lipid profile, and complete blood count. An additional 1/2 teaspoon of blood will be drawn within the first 5 minutes and then another 1/2 teaspoon one hour after the radiotracer, ^{64}Cu-DOTA-ECL1i, is injected. Blood samples will be obtained at the end of each imaging session for blood metabolism measurements.

You will be positioned on the PET-CT imaging table lying flat with your arms resting above your head or across your chest out of the field of view. You will be made to feel as comfortable as possible. We will ask you to lie still during the imaging scan and the imaging table will slowly move you into the scanner. You will be injected with ^{64}Cu-DOTA-ECL1i through your IV and will be required to lie still for approximately 60 minutes of imaging. After the initial 60 minute imaging session, you will be asked to wait 1-4 hours. After the wait you will be put back into the scanner and have a PET/CT image

followed by a CTA with contrast. If you are in the non-aortic aneurysm group, you will not have a CTA with contrast. This imaging is only being done as part of this research study and not for your medical condition.

Contrast-Enhanced CT Angiography
At the end of both PET imaging sessions you will have a CT angiography with a contrast dye performed of your abdomen and pelvis. You will be instructed to hold a relaxed breathing position during the CT scan. You will hold your breath for 10-20 seconds at a time for the 20 minute scan. If you are in the non-aortic aneurysm group, you will not have a CTA with contrast. If you have not had a renal function blood test performed within the past 1 week, we will draw 2 teaspoons of blood for a glomerular filtration rate (GFR) test prior to the CTA with contrast.

After the scan is completed:
When you have completed the scans, we will remove the IV catheters and place bandages on your arms and take vital signs. You may feel tired after the imaging scans because you have been fasting for several hours. We will offer you a snack while you rest before leaving the imaging facility. You should drink plenty of water to help flush the radioactive material out of your body. This is a natural process for the body to rid itself of the radioactivity through your kidneys. A member of the study team will call you the day after you complete the imaging to see how you are feeling. There is no follow-up required.

Optional PET/MRI scan with ^{64}Cu-DOTA-ECL1i
Your imaging visit will consist of a PET/MR or MRI scan. This will be determined by the scanner's availability. You will be asked to lie flat while in the PET/MR or MRI scanner – a doughnut shaped machine similar to a CT machine with a padded imaging table in the middle. It will record images of your abdominal aorta. This scan can take up to 60 minutes. It will either be done between the first and second PET/CT scans or after all of the imaging has been completed.

An MRI scanner takes pictures of the inside of your body by sending out a magnetic field and radio waves. Because the MRI scanner contains a very strong magnet, you may not be able to have the MRI if you have certain kinds of metal in your body (for example, from medical devices or a metal plate). Someone will ask you questions about this before you have the MRI. To minimize damage to your hearing, we will give you ear protection to wear during the scan.

The MRI scanner is a large machine that contains a hollow tube. You will be asked to lie on your back on a special table that slides into the tube. The sides of the tube will be fairly close to your body and the scanner makes a loud hammering noise while you are inside.

During the procedure, you will be able to talk with the MRI staff through a speaker system. If you do not wish to continue, you can ask that the scan be stopped immediately.

Please place a mark next to your choice:

_____Yes, I agree to the optional MRI
Initials

_____ No, I do not agree to the optional MRI.
Initials

Will you save my research information and/or biospecimens to use in future research studies?

Identifying information may be removed from your data/tissue/blood, so that the data/tissue/blood cannot be connected it to you. If this occurs, we may share your data/tissue/blood with other researchers without asking you for additional consent.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Some risks described in this consent document, if severe, may cause death.

Risks associated with the blood draws, IV catheter insertion may include:
Likely: Mild
The insertion of a needle into a vein sometimes causes discomfort, bruising, or bleeding at the site of needle insertion.
Less Likely / Less Common: Mild
Occasionally some people experience dizziness or feel faint when a needle is placed in their arm.
Rare: Serious
There is also a rare risk of inflammation or infection.

Risks associated with PET/CT imaging:
Likely: Lying still in the scanner may produce some stiffness. Study staff will be nearby to stop the study in case you become too uncomfortable.
Less likely: You may experience aching in your joints and muscles from lying very still.
Rare: A small fraction of participants experience claustrophobia (anxiety due to being restrained or in a confined area) while some experience dizziness or feel faint. If you experience any of these symptoms and do not wish to continue for any reason, the study will be stopped immediately.

Medical Devices: There is a rare risk of malfunction of worn or implanted electronic medical devices with CT scanning. If you wear or have an electronic medical device implanted, such as an insulin pump, you will be asked to tell the study investigator and research staff.

Risks of Unexpected Findings:
We are doing the PET-CT scan in the study to answer research questions, not as part of your medical care. The information created by this study will not usually become part of your hospital record. This PET-CT scan is not the same as the one that your own doctor would order. It may or may not show problems that would be found on standard PET or CT scans.

The imaging performed for this study is for research purposes only. We will only evaluate the infrarenal (area below the kidneys) abdominal aorta. Other organs and anatomic structures in the field of view will be evaluated by a radiologist on the study team for incidental findings. You will be made aware of the results of any significant incidental findings of importance. The results of this study may be incorporated in the decision making regarding your aortic pathology; however, your ultimate management will be dictated by current standards of care.

Risks associated with Iopamidol (Isovue) Contrast Agent:
There are rare risks from the contrast agent, Iopamidol (Isovue) that include:

- Nausea (up to 2 in 100 of people);
- Hives (itchy red bumps on the skin, less than 1 in 100 people);
- Severe allergic reaction, which can be life threatening (very rarely happens, less than 1 in 100,000 people). If you have any signs of allergic reaction, we will treat you immediately.

Allergic reactions can be mild or serious, and can even result in death in some cases. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing. During the imaging visit, you are instructed to immediately notify a study team member/physician with any sign of having trouble breathing or any other symptoms of an allergic reaction. You are instructed to call 911 immediately and seek medical assistance if experiencing any swelling of the face and/or throat, and/or experiencing any trouble breathing after leaving the imaging center.

Risks associated with ^{64}Cu-DOTA-ECL1i:
^{64}Cu-DOTA-ECL1i is an investigational drug and is given in such small ("trace") amounts that they have no known harmful effect.

Less likely: Radioactive tracers used for PET imaging, such as ^{64}Cu-DOTA-ECL1i are not expected to produce any health risks other than those associated with radiation exposure.

Rare: There are no known risks or side effects from ^{64}Cu-DOTA-ECL1i at the low dose that you will receive. However, as with any drug, an allergic reaction can occur. Allergic reactions can be mild or serious, and can even result in death in some cases. Based on common responses to other tracers, we anticipate that some participants may experience dysgeusia (bad taste in mouth), flushing, headache, dizziness or lightheadedness, mild gastroenteritis, itching, skin rash or hives.

Severe allergic reaction: There is a rare possibility of such a reaction that could be serious and even

cause death. Symptoms include low blood pressure, difficulty breathing, swelling of your tongue, mouth and or throat, body itching or rashes. If you think you are having an allergic reaction, let us know right away.

Risks associated with Magnetic Resonance Imaging:
Common risks:

- discomfort inside the MRI scanner if you do not like to be in closed spaces (claustrophobia)
- muscle stiffness from lying still
- feeling warm
- feeling a twitching sensation briefly during the exam

Rare risks:

- temporary sensation of flashing lights while in the MRI scanner
- burns that could be serious
    - To minimize this risk we will have you change out of your clothing and into clothing that we provide.

Devices

- If you have shrapnel or a metal device such as a pacemaker, bone hardware, brain aneurysm clips, cardiac stent, or a device placed in your uterus, there may be additional risks. We will review what type of metal object or device may be inside your body, inform you of its risks during an MRI, and depending on the object or device, possibly exclude you from participating in the optional MRI. In general, these risks could be:
    - heating or movement of the device
    - device malfunction
    - damage to the tissue that surrounds the device.

Risks associated with Radiation Exposure:
Please note that this radiation exposure is not necessary for your medical care and is for research purposes only.

Likely: This study will expose you to radiation from the PET-CT imaging of your abdomen and pelvis with the radiotracer ^{64}Cu-DOTA-ECL1i, low-dose whole-body CT attenuation scans, and contrast enhanced CT angiogram (CTA) if performed.

Non-aortic aneurysm volunteers: You will be exposed to radiation from one complete PET-CT imaging, when averaged over the entire body, is about 15% of the amount that a person who works with radiation is allowed to have in one year.

Non-aortic aneurysm atherosclerotic aortic open repair: You will be exposed to radiation from one complete PET-CT imaging, when averaged over the entire body, is about 15% and if performed, additional exposure from the contrast enhanced CT angiogram (CTA) for a combined total of about 39% of the amount that a person who works with radiation is allowed to have in one year.

Aortic aneurysm Pre-operative patients scheduled for open or endovascular repair: You will be exposed to radiation from one complete PET-CT imaging, when averaged over the entire body, is about 15% and if performed, additional exposure from the contrast enhanced CT angiogram (CTA) for a combined total of about 39% of the amount that a person who works with radiation is allowed to have in one year.

Non-surgical aortic aneurysm patients: You will be exposed to radiation from two complete PET-CT imaging, when averaged over the entire body, is about 30% and if performed, additional exposure from the contrast enhanced CT angiogram (CTA) for a combined total of about 53% of the amount that a person who works with radiation is allowed to have in one year.

The risk from the radiation exposure, in this study is too small to be measured. It is not a big risk when compared with other risks you take every day. If you want to know more about radiation exposure, please see the "Radiation Fact sheet" at http://hrpo.wustl.edu or ask the study staff for a copy.

Radiation Exposure in Women Capable of Becoming Pregnant
You may not participate in this study if you are pregnant. If you are capable of becoming pregnant, we will perform a pregnancy test before exposing you to research-related radiation. You must tell us if you may have become pregnant within the previous 14 days because the pregnancy test is unreliable during that time.

Genetic Research
There is a federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans and employers with greater than 15 employees to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance or long term-care insurance.

Breach of Confidentiality
One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. It should take appropriately 2 – 4 weeks to receive payment for your participation in the study. If your social security number is obtained for payment purposes only, it will not be retained for research purposes. We will pay you $250.00 for your participation if you complete the study PET-CT scan. If you are unable to allow completion of the PET-CT scan, you will not receive the payment as mentioned above.

For the subset of patients who are being asked to complete a second imaging session you may receive an additional check for $150.00.

For the patients who complete the optional PET/MRI or MRI, you will be paid an additional $100.00.

If you are required to travel back to our site for the second imaging session and you live greater than 80 miles away, assistance with travel and lodging costs may be available.

We will provide parking validation if you drive to your study session and meal vouchers.

WHO IS FUNDING THIS STUDY?

The National Institute of Health (NIH) is funding this research study. This means that Washington University is receiving payments from the NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the NIH for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at (314) 362-5648 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- National Institutes of Health (NIH)
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The

Institutional Review Board has reviewed and approved this study.

- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, paper/hard copy records will be stored in a locked suite/locked office by the study team in the Vascular Surgery Office with access limited to only those on the study team. Electronic records for the study will be stored on a secure, password-protected, WU shared network drive with access limited to the study team. Urine pregnancy test (if required) will be performed by the study staff in the CCIR. The pregnancy samples will be drawn by the study team and then transported directly to a laboratory for analysis.

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.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not

discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.

    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
      - You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at

https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

Will I receive new information about the study while participating?
If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?
Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because in our judgment it would not be safe for you to continue, because you are or became pregnant, or because funding for the research study has ended.

WHAT IF I HAVE QUESTIONS?
We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Mohamed Zayed at (314) 362-5648. If you experience a research-related injury, please contact: Dr. Mohamed Zayed at (314) 362-5648.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 08/14/24.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)