Washington University in St. Louis

INFORMED CONSENT DOCUMENT – EXPANSION PHASE

Project Title: A Single-Arm, Open-Label, Pilot Study and Expansion Study of JAK Inhibitor Itacitinib for the Prophylaxis of Graft-Versus-Host Disease and Cytokine Release Syndrome after T-cell Replete Haploidentical Peripheral Blood Hematopoietic Cell Transplantation

Principal Investigator: Ramzi Abboud, M.D.

Research Team Contact: Ramzi Abboud, M.D. – (314) 454-8304

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.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

KEY INFORMATION

The first section of this document contains some key points that the research team thought you would find important. The research study is described in more detail after this section.

This is a research study conducted by Dr. Ramzi Abboud having to do with receiving a stem cell transplant from a haploidentical donor. A stem cell is a type of cell found in the blood or bone marrow which helps form more blood cells. The purpose of a stem cell transplant is to use the stem cells from a healthy donor to replace the diseased bone marrow in the recipient. You are invited to be in this study because you have been diagnosed with a hematologic (bone marrow and blood cells) malignancy and are planning to receive a stem cell transplant from a haploidentical donor. You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. It is your choice whether to participate or not. Before you decide whether to be in this study, you may wish to consider other options that are available to you. Instead of being in this study, you could get treatment or care for your cancer without being in a study, take part in another research study, or get no treatment.

If you agree and sign this consent, you will be volunteering to participate in the research study. The research team must give you a copy of this signed consent document.

1. **What is the research study about?**
   The purpose of this research study is to look at the effects (good and/or bad) of giving a drug called itacitinib when you receive your transplant in an effort to prevent or lessen the effect of GVHD and CRS while still effectively treating your disease.

2. **Why should I consider participating?**
   To prevent or lessen the effect of GVHD and CRS while still effectively treating your disease.

3. **What will I be asked to do?**
   If you are eligible to participate and agree to continue in the study, you will begin taking itacitinib on Day -3, which is 3 days before your scheduled day of transplant (Day 0). Itacitinib is an oral medication that you will need to take approximately the same time every day, with or without food. You will be asked to complete a medication diary which you will need to bring with you to each of your clinic visits. You will continue to take itacitinib through Day 180, followed by a 30 to 60 day taper period where you will take a lower dose of itacitinib. This study includes some procedures you might have for your care if you weren't in this study, which is described in further detail later in the consent document. Follow up will take place until one year following transplant. You will have monthly visits from Day 241 until you reach that one year post-transplant time point.

   If you agree to take part in this study, your involvement will last for approximately one year (180-240 days of treatment with itacitinib plus follow-up to one year post-transplant).

   You may choose to stop participating and withdraw from the study at any time. If you withdraw from the study, the research team may continue to use the information already collected about you.

4. **What are the risks?**
   There are some risks to you if you agree to volunteer for this study. The most serious/most common risks are anemia (low red blood cells), pyrexia (fever), headache, platelet count decreased, and neutropenia. The risks to you are described in more detail later in this consent document.

5. **What are the benefits to me? To others?**
   There may be no direct benefit to you. However, we hope that, in the future, other people might benefit from this study because it will help researchers learn more about how to prevent GVHD.

6. **Is there any financial cost to me?**
   As part of this study you will receive tests and procedures that are similar to what you would receive during routine clinical care of your condition. Your health plan/insurance company will be billed for some or all of these costs, and you will be responsible for any co-pays and deductibles that are normally required by your health plan/insurance. Incyte is providing the itacitinib at no cost to you.

7. **Will my information be confidential?**
   Yes, your identity will be kept confidential. Your information will be available only to those who are working on this study.

8. **Who is the sponsor?**
   The study is sponsored by Incyte, The American Society of Hematology, and the National Institutes of Health.

The rest of this document provides more details about the study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you have been diagnosed with a hematologic (bone marrow and blood cells) malignancy and are planning to receive a stem cell transplant from a haploidentical donor. A stem cell is a type of cell found in the blood or bone marrow which helps form more blood cells. The purpose of a stem cell transplant is to use the stem cells from a healthy donor to replace the diseased bone marrow in the recipient. One of the side effects of a stem cell transplant is the development of graft versus host disease (GVHD). GVHD occurs when some of the cells from the donor attack the recipient's tissues, resulting in mild, moderate, or even life-threatening side effects to the recipient's skin, stomach, intestine, and liver. Another side effect is cytokine release syndrome (CRS), which can cause fever, nausea, headache, rash, rapid heartbeat, low blood pressure, and trouble breathing.

A haploidentical stem cell transplant is a type of transplant that occurs when a person who needs a transplant can't find a donor who exactly matches their tissue type (either among family members or through a matched unrelated donor). When no matched donor is available, half-matched related (haploidentical) donors may be used. A haploidentical donor is a first degree relative such as a sibling, child, or parent.

Itacitinib 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?

All procedures will be given in the inpatient or outpatient setting at Siteman Cancer Center unless you have made other arrangements with the study team. We feel it is important to remind you that any procedures regardless of whether they are tests you would have if you did not take part in the research or are research-related will require you to remain at the Siteman Cancer Center up to several hours to complete the necessary testing. There may also be a wide variability in the length of clinic visits due to the unique characteristics of your medical history and health condition as well as due to clinic factors such as physician availability, staffing shortages, and weather delays. This will also vary depending upon your needs at the visit as determined by your physician. It is important that you are able to be available to complete the procedures at each visit to ensure that your safety and treatment needs are met.

Pre-Study Evaluations:

Prior to treatment, an overall assessment of your health will need to be taken to see if you are eligible to continue to participate in the study. You will have the tests and procedures listed below.

- Physical examination, including review of your medical history, height, weight, and performance status
- Routine blood draw to check your blood counts and organ function (about 2 teaspoons of blood will be drawn from a vein in your arm)
- Pregnancy test (if you are a woman of childbearing potential)
- Echocardiogram or MUGA (multiple gated acquisition) scan to check how your heart is functioning
- Blood draw to check your blood type and human leukocyte antigen (HLA) typing (a protein found on most cells in your body) (about 1 teaspoon of blood will be drawn)

- Blood draw for a virology screening to make sure you don't test positive for hepatitis and HIV (about 1 tablespoon of blood will be drawn)
- Blood draw for chimerism testing, which allows researchers to compare your blood cells before you receive the transplant to your blood cells after the transplant (about 2 teaspoons of blood will be drawn)
- Bone marrow aspirate and biopsy to check the status of your disease; this is a procedure during which a few teaspoons of your bone marrow and a little of the tissue will be removed using a hollow needle
- Two questionnaires to assess your quality of life (which will take approximately 15 minutes to complete)

It is possible that after your medical history, tests, and procedures are reviewed, you will not be able to continue in this study. If this occurs, your study doctor will go over the reasons with you.

Procedures throughout the study:
If you are eligible to participate and agree to continue in the study, you will begin taking itacitinib on Day -3, which is 3 days before your scheduled day of transplant (Day 0). If you are unable to receive your transplant for any reason, you will stop taking itacitinib and will come off study. Itacitinib is an oral medication. You will need to take it at approximately the same time every day, with or without food. You will be asked to complete a medication diary which you will need to bring with you to each of your clinic visits. You will continue to take itacitinib through Day 180, followed by a 30- to 60-day taper period where you will take a lower dose of itacitinib.
If you are one of the first 3 patients enrolled in this study, the person who is donating cells for your transplant will also need to consent to this study. We will be asking them if we can collect another batch of cells from them in case the itacitinib prevents the transplant from working properly. If that happens, you will stop taking itacitinib and will come off study.

While you are taking itacitinib, you will have the following tests and procedures:

- Physical exam, review of medications, and evaluation of any side effects you may be experiencing at the following time points:
  - daily from Day -3 through Day 14
  - weekly from Day 21 through Day 42
  - Day 60
  - Day 74
  - every 4 weeks from Day 100 until Day 365
- Evaluation to see whether you are experiencing CRS at the following time points:
  - Day -3
  - Daily from Day 0 through Day 14
  - Day 21
  - Day 28
- GVHD assessment beginning on Day 14 and then at all of the same time points as the physical exam
- Routine blood draw to check your blood counts and organ function at the following time points:
  - daily from Day -3 through Day 14
  - weekly from Day 21 through Day 42

  - Day 60
  - Day 74
  - Every 4 weeks from day 100 through Day 180
  - during the taper period as needed
- Monthly follow up visits till day 365. Blood draw for chimerism testing at the following time points:
  - Day 28
  - Day 35 if your transplant hasn't been successful
  - Day 60
  - Day 100
  - Day 180
  - Day 365
- Questionnaires to assess your quality of life at the following time points:
  - Day 14
  - Day 28
  - Day 42
  - Day 60
  - Day 74
  - Day 100
  - Every 4 weeks from Day 128 to 180
  - monthly from Day 181 to 365

- Bone marrow biopsy at the following time points:
  - Day 28
  - Day 35 if your transplant hasn't been successful
  - Day 100
  - Day 180
- Research blood tests on the following days:
  - Before the start of conditioning treatment for your transplant (approximately 7 tablespoons)
  - Day 3 (approximately 7 tablespoons)
  - Day 7 (approximately 2 tablespoons)
  - Day 14 (approximately 2 tablespoons)
  - Day 28 (approximately 6 tablespoons)
  - Day 60 (approximately 6 tablespoons)
  - Day 100 (approximately 4 tablespoons)
  - Day 180 (approximately 6 tablespoons)
  - Taper Period Days 180-240 (approximately 6 tablespoons)
  - Post Treatment (Between 14 and 35 days after the last dose of study drug) (approximately 6 tablespoons)
  - If you are diagnosed with acute GVHD (approximately 2 tablespoons)

These research tests will include genetic research, including whole exome sequencing (which determines the order of DNA building blocks in your individual genetic code).

Follow-Up:

Follow-up will take place until one year following transplant. You will have monthly visits from Day 241 until you reach that one year post-transplant time point. Each month, the following tests and procedures will take place:

- Physical exam, review of medications, and evaluation of any side effects you may be experiencing
- GVHD assessment
- Questionnaires to assess your quality of life
- Blood draw for chimerism (last follow-up visit only)

Will you save my samples or research data to use in future research studies?

As part of this study, we are obtaining bone marrow, blood, and data from you. We would like to use this bone marrow, blood, and data for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding blood cancers, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your bone marrow, blood, and data you give up any property rights you may have in the bone marrow, blood, and data.

We might remove identifiers from your private information and your bone marrow, blood, and data and then use the information and your bone marrow, blood, and data for future research studies or share them with other researchers for their future research. If this occurs we will not ask you for additional consent for these uses of your information or bone marrow, blood, and data.

These studies may include genetic research. Genetic research can look at DNA to look for mutation (changes) that may increase the risk of disease or affect the way a person responds to treatment. This could include the database of Genotypes and Phenotypes (dbGaP), which is a repository that shares genomic data. The data within dbGaP remains anonymous, but de-identification of data cannot eliminate a risk of disclosure, which could affect you and even your family members.

We will share your bone marrow, blood, and data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your bone marrow, blood, and data for future research you should contact the research team member identified at the top of this document. The bone marrow, blood, and data will no longer be used for research purposes. However, if some research with your bone marrow, blood, and data has already been completed, the information from that research may still be used. Also, if the bone marrow, blood, and data has been shared with other researchers it might not be possible to withdraw the bone marrow, blood, and data to the extent it has been shared.

Please place your initials in the blank next to Yes or No for each of the questions below:

My bone marrow, blood, and data may be stored and used for future research as described above.

_____ Yes **_____ No**
Initials **Initials**

My bone marrow, blood, and data may be shared with other researchers and used by these researchers for the future research as described above.

_____ Yes **_____ No**
Initials **Initials**

Unless you agree to future use as described above, your private information your bone marrow, blood, and data collected as part of this study will not be used or distributed for future research studies, even if identifiers are removed.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 40 people will take part in this study conducted by investigators at Washington University.

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 of Itacitinib

Very Common (greater than or equal to 20%)

- Anemia (low red blood cells) which could make you feel tired or dizzy
- Pyrexia (fever)
- Headache
- Platelet count decreased
- Neutropenia a condition in which you have a low number of white blood cells called neutrophils in your blood. This causes your immune system to be weakened, making it harder for your body to fight infection.

Common (greater than or equal to 10%)

- Hypophosphatemia (low phosphate)
- Decreased appetite
- Hypokalemia (low potassium)
- Fatigue
- Nausea
- Pneumonia
- Pneumonia pseudomonal

- Sepsis

Rare, and severe

- Graft failure can occur after haploidentical transplant (low blood counts after transplant requiring transfusions, antibiotics and other support). It is unknown if itacitinib will increase this incidence. Graft failure can result in death.

Risks of Stem Cell Transplant

The side effects of stem cell transplant may include GVHD, as well as the development of low blood counts. If you develop GVHD, you will be treated with steroids and other standard of care treatments for GVHD if necessary. If you develop low blood counts, you will be supported with blood transfusions, antibiotics, and G-CSF (a growth factor for white blood cells) as necessary.

Specific effects of GVHD:

- Bone marrow---low white blood cell, red blood cells and/or platelets---this may lead to requirements for transfusions or antibiotics
- Gastrointestinal toxicity---can result in inflammation of intestines causing malabsorption or diarrhea
- Liver toxicity---can lead to liver dysfunction or failure—can result in fluid accumulation or jaundice, which can lead to yellow skin and itching
- Skin toxicity—can cause rash, thickened skin with decreased mobility, or skin sloughing

Altered immune function is common after stem cell transplantation. You therefore have a significant risk of getting a variety of infections, including bacterial or fungal infections. Antibiotic or antifungal therapy will be given as medically indicated.

Another side effect is cytokine release syndrome (CRS), which can cause fever, nausea, headache, rash, rapid heartbeat, low blood pressure, and trouble breathing.

Rarely (5-10%) the stem cells transplanted fail to fully engraft the recipient. Patients who are not complete or are mixed chimeras (not all blood and bone marrow cells are replaced with donor cells) are at risk of bone marrow failure (the bone marrow is unable to produce enough blood cells) after the infusion of stem cells. The bone marrow failure may be lethal if the bone marrow does not recover afterwards. If you develop bone marrow failure, you will be supported with blood transfusions, antibiotics and growth factors until additional stem cells can be infused from the original donor.

Risks of Blood Draw

The blood draw may cause bleeding, bruising, or pain. Some people become dizzy or feel faint. There is also a rare risk of infection.

Testing for Reportable Diseases

If you decide to participate in this study, we will test you for HIV and hepatitis B and C. The results of these tests could indicate that you have one of these conditions. If that happens, we will refer you to a doctor who specializes in treating your condition. We will make every effort to keep your personal information confidential. However, we are required by law to report certain positive tests to the state of Missouri and/or local agencies. The test results could also be reported to the Centers for Disease

Control. You may be contacted by these agencies for more information. Becoming aware of a new diagnosis could have serious health, personal and/or social consequences. For more information about the risks of this testing, please talk to your study doctor.

Risks of Bone Marrow Aspiration and Biopsy

It is likely that you will experience discomfort or pain, redness, swelling, and bruising at the site of the needle insertion. It is less likely that you will experience bleeding from the site of the needle insertion. There is a rare chance (approximately less than 1/100) of developing a significant infection or bleeding from this procedure. An allergic reaction to the anesthetic may occur. A scar may form at the site of needle entry.

Risks of Echocardiogram

An echocardiogram is a test that uses sound waves to create a moving picture of the heart. An instrument that transmits high-frequency sound waves called a transducer is placed on your ribs near the breast bone and directed toward the heart. You should feel no pain with this test. You may experience discomfort from lying quietly for a long period of time.

Risks of MUGA Scan

The MUGA (Multiple Gated Acquisition) scan is used to assess the function of the heart. The MUGA scan produces a moving image of the beating heart, and from this image several important features can be learned about the health of your heart. A small amount of low-level radioactive substance (tracer) is injected into your vein and temporarily "labels" your red blood cells. Then the heart is scanned by a camera which can "see" the marked blood and produce the moving image. The final product is a movie of the heart beating. Allergic reactions to the tracer are rare. Most of the tracer will be eliminated from your body within a day. You may have some pain or swelling where the tracer is injected into your vein.

Risks of Questionnaires

Some of the questions may make you feel uncomfortable. You have the right to refuse to answer any question for any reason.

Risks for Women Capable of Becoming Pregnant

If you are a woman capable of becoming pregnant, we will ask you to have a pregnancy test before beginning this study. You must use effective birth control methods and try not to become pregnant while participating in this study. If you become pregnant, there may be unknown risks to your unborn child, or risks to your unborn child that we did not anticipate. There may be long-term effects of the treatment being studied that could increase the risk of harm to an unborn child. You must tell the doctor if your birth control method fails while you are on the study. If you believe or know you have become pregnant while participating in this research study, please contact the research team member identified at the top of this document as soon as possible. Please discuss with the research team how long you need to wait before becoming pregnant after completing the treatment or procedures on this study.

Risks for Sexually Active Males

If you are a sexually active male it is important that your partner not become pregnant during your participation in this study. There may be unknown risks to the unborn child or risks we did not anticipate. You and your partner must agree to use birth control if you want to take part in this study. If you believe or know that your partner has become pregnant during your participation in this study,

please contact the research team member identified at the top of this document as soon as possible

Risks of 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.

Risk of 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.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could:

- get treatment or care for your cancer without being in a study
- take part in another research study
- get no treatment

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

As part of this study you will receive tests and procedures that are similar to what you would receive during routine clinical care of your condition. Your health plan/insurance company will be billed for some or all of these costs, and you will be responsible for any co-pays and deductibles that are normally required by your health plan/insurance. Not all insurance plans cover the costs associated with being in a study. Even if they do, you may be responsible for more out-of-pocket expenses, such as co-pays and deductibles, when there are more tests and procedures or more expensive tests and procedures involved in the study than if you were to receive routine clinical care outside the study.

If you wish to know whether there are more tests and procedures or more expensive tests and procedures in the study, you should ask your study doctor.
If you wish to know whether your insurance will pay, you should contact them directly, or speak with the study team about obtaining a financial pre-certification prior to enrolling in the study.

Incyte is providing the itacitinib at no cost to you.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

Incyte, the American Society of Hematology, and the National Institutes of Health (NIH) are funding this research study. This means that Washington University is receiving payments from Incyte, the American Society of Hematology, and 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 Incyte, the American Society of Hematology, or 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) 454-8304 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 and Incyte. 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. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- Incyte, manufacturer of itacitinib
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Public health agencies to complete public health reporting requirements
- 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.
- Other researchers in other laboratories, to conduct research on cancer or other projects; these may be individual researchers at other institutions, or they may be other researchers as part of a cooperative group.
- The Quality Assurance and Safety Monitoring Committee at the Siteman Cancer Center for auditing purposes
- The Siteman Cancer Center Clinical Trials Office
- 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.
- NIH (National Institutes of Health)

To help protect your confidentiality, we will make sure that your study information is kept secure. We will keep study information in a secure database that requires a username and password. To help protect

your confidentiality, no identifying information such as your name, birth date, or social security number will be made available to researchers who receive your health information. Furthermore, the study team will keep the master code list that links your unique study number with your name and other identifying information in locked storage in a locked office (for paper copies) or on a secured network on a password-protected computer (for electronic copies). Access to either paper or electronic copies will be limited to the Principal Investigator and members of the study team.

The research team will send study results to Incyte. Information sent to Incyte will be de-identified and may be used to analyze the safety and effectiveness of the study medication. In the future, Incyte may continue to use your health information that is collected as part of this study. For example, Incyte may combine information from this study with the results of other studies to re-analyze the safety and effectiveness of the study medication, to evaluate other products or therapies, to develop a better understanding of a disease, or to improve the design of future research studies. Incyte may also share information from the study with regulatory agencies in foreign countries.

If you receive Medicare benefits, are injured as part of your participation in this research study and medical treatment relating to this injury is paid by anyone other than you or your insurance company, that payer will need to collect personal information about you. This information includes your name, date of birth, gender, social security number, Medicare identification number and information related to this research study. The payer will report this information to the Centers for Medicare & Medicaid Services (CMS), the federal agency that oversees the Medicare program, during your participation in the study and for as long as the payer is required by CMS to report this information. If you do not want to release your personal or treatment related information you have the right to refuse reimbursement by the payer for any research injury. The payer will not use this information for any other purpose.

The Siteman Cancer Center at Washington University School of Medicine and Barnes-Jewish Hospital is supported by funding from the National Cancer Institute (NCI). To meet NCI requirements, your protected health information relating to your participation in this study (including your social security number) will be stored in a secure database at the Siteman Cancer Center. This database and also your health care records may be reviewed by Siteman Cancer Center personnel. All information will be securely and confidentially maintained.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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.

If you decide to leave the study early, we will ask you to tell the study doctor if you are thinking about stopping so any risks can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

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 staying in the study would be harmful, you need treatment that is not allowed while on the study, you fail to follow instructions, you become pregnant, or the study is canceled.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact Dr. Ramzi Abboud at (314) 454-8304. If you experience a research-related injury, please contact Dr. Ramzi Abboud as well; if this is after hours, you will be directed to the exchange number, which will be covered by a resident or fellow on call. Please tell this person that you are a research participant.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 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: 08/12/25.

_____ _____
(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)