Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: An open label, multicenter, phase II trial testing single agent decitabine in TP53 mutated relapsed/refractory acute myeloid leukemia

Principal Investigator: John Welch, M.D., Ph.D.

Research Team Contact: John Welch, M.D., Ph.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

This is a research study conducted by Dr. John Welch having to do with using the drug decitabine to treat patients who have acute myeloid leukemia (AML) and a mutation in a gene called TP53. TP53 is a gene that, if mutated (changed), can fail to function normally in AML. It is a gene which helps to prevent cancer, and the current standard treatments for AML do not work well in leukemias that have TP53 mutation. You are invited to be in this study because you have AML with a mutation in your TP53 gene, and you have recurrent or resistant disease after receiving the standard treatment. 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.

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 determine if we can overcome TP53 malfunction with use of a drug called decitabine. Decitabine is approved by the U.S. Food and Drug Administration (FDA) for the treatment of myelodysplastic syndrome (another disease involving dysfunctional blood cells) and some forms of leukemia. We will perform detailed genetic testing to help us better understand how and why decitabine works when TP53 mutation is present.

2. **Why should I consider participating?**
   The current standard treatments for AML do not work well in leukemias that have TP53 mutation, and acute leukemias with mutations in this gene behave aggressively and tend to have a worse

outcome compared to leukemias that do not have this mutation. The purpose of this research study is to determine if we can overcome TP53 malfunction with use of a drug called decitabine.

3. What will I be asked to do?

You will receive treatment with decitabine as an IV infusion on a 28-day cycle. During Cycles 1 and 2, it will be given on Days 1 through 10 of each cycle. People who continue on to Cycle 3 will receive decitabine on Days 1 through 5 of that cycle and any subsequent cycles. The number of cycles of decitabine you receive will depend on your response to treatment, which is assessed by bone marrow aspirate and biopsy at the end of each cycle. We will collect additional bone marrow aspirate and blood for research purposes at each of these time points. A skin biopsy or buccal swab (a procedure during which you scrape the inside of your cheek with a small wooden stick) will be performed at the end of Cycle 2.

This study includes some procedures you might have for your care if you weren't in this study, such as regular physical exams, and blood draws to monitor your counts and organ function. When you come to the clinic for your study visits, you may be here for a short amount of time (less than an hour if you're just having blood drawn) or a longer amount of time (up to several hours if you're receiving decitabine or having a bone marrow aspiration). The length of your involvement in this study will depend on your response to decitabine treatment and whether you undergo a stem cell transplant. You will receive at least 2 months of treatment with decitabine and will have data collected on your health and disease status for 2 years after you come off treatment.

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 common risks are low white blood cells (which could increase your risk of infection), low platelets (which could increase your risk of bleeding), low red blood cells, fatigue, and pneumonia. 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 treat AML with TP53 mutation.

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 AML. 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.

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 Washington University School of Medicine. The National Institutes of Health (NIH) and Janssen Pharmaceuticals are funding this research 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 acute myeloid leukemia (AML) with a mutation in a gene called TP53 and have recurrent or resistant disease after receiving the standard treatment. AML is a type of cancer that makes your white blood cells grow fast and abnormally. Genes are a unique combination of molecules (called DNA) that we inherit from our parents. There are millions of tiny differences in our genes that determine things like our height or the color of our eyes. Some of these differences may make some people more or less likely to develop certain diseases or conditions or to have certain characteristics. TP53 is a gene that, if mutated (changed), can fail to function normally in AML. It is a gene which helps to prevent cancer, so it is not surprising that acute leukemias with mutations in this gene behave aggressively and tend to have a worse outcome compared to leukemias that do not have this mutation. The current standard treatments for AML do not work well in leukemias that have TP53 mutation.

The purpose of this research study is to determine if we can overcome TP53 malfunction with use of a drug called decitabine. We will perform detailed genetic testing to help us better understand how and why decitabine works when TP53 mutation is present.

Decitabine is approved by the U.S. Food and Drug Administration (FDA) for the treatment of myelodysplastic syndrome (another disease involving dysfunctional blood cells) and some forms of leukemia. Although the National Comprehensive Cancer Network (NCCN) recognizes decitabine as a standard treatment for patients over the age of 60 with AML, it is not approved by the FDA for the treatment of AML, so it is considered investigational as used in this study.

WHAT WILL HAPPEN DURING THIS STUDY?

All treatment will be given in either the outpatient or inpatient setting at Siteman Cancer Center. 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.

Before you begin study treatment:

You will need to have the following screening exams, tests, or procedures to find out if you can continue to be in the study. Most of these procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- Physical exam, including taking of vital signs, reviewing your medical history, and talking about any symptoms or health problems you're having

- Blood tests to check your blood counts and organ function (approximately 2 teaspoons of blood will be drawn)
- Blood tests to make sure you don't test positive for hepatitis or HIV
- Urine pregnancy test if you are a woman of childbearing potential
- Collection of blood for research purposes (approximately 2 teaspoons of blood will be drawn)

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 continue participating, you will begin receiving treatment with decitabine. Decitabine is given as an IV infusion on a 28-day cycle. During Cycles 1 and 2, it will be given on Days 1 through 10 of each cycle. People who continue on to Cycle 3 will receive decitabine on Days 1 through 5 of that cycle and any subsequent cycles. The number of cycles of decitabine you receive will depend on your response to treatment, which is assessed by bone marrow aspirate and biopsy at the end of each cycle.

- At the end of Cycle 2, people whose disease has progressed or relapsed will be removed from this study and will go on to receive another treatment.
- At the end of Cycle 3:
  - People who are eligible to have a stem cell transplant and whose disease has had a complete response to treatment will go on to conditioning and transplant.
  - People who are eligible to have a stem cell transplant but whose disease has not had a complete response to treatment will be removed from this study and will go on to receive another treatment.
  - People who are not eligible to have a stem cell transplant will continue to receive decitabine on a maintenance schedule.
- At the end of Cycle 4, people whose disease is stable may be removed from this study in order to receive another treatment or may stay on this study depending on their doctor's preference.

You will have the following tests and procedures during your participation in this study:

- Physical exam, including taking of vital signs, reviewing your medical history, and talking about any symptoms or health problems you're having (Day 1 of each cycle)
- Blood tests to check your blood counts (weekly and at the end of each cycle) (approximately 1 teaspoon of blood will be drawn)
- Blood tests to check your organ function (Day 1 of each cycle – more frequently if your doctor decides it's necessary) (approximately 1 teaspoon of blood will be drawn)
- Bone marrow aspirate and biopsy to check the status of your disease; at each time point, additional bone marrow will be taken for research purposes (including genetic research) (at the end of Cycles 1, 2, and 3, and if your disease progresses or relapses). If we are unable to obtain a sample from the bone marrow aspirate, two additional tubes of blood (10 mL each) will be collected.
- Patients at Washington University in St. Louis will undergo a bone marrow aspirate and biopsy on Day 10 of Cycle 1.
- Collection of blood for research purposes (at the same time as each bone marrow aspirate and

biopsy)
- Buccal swab for research purposes (Cycle 2 Day 28)

One goal of the present study is to identify/study genetic factors relating to how your disease responds to study treatment. We would like to study changes in your DNA to understand how decitabine turns on and off genes and how this impacts leukemia response to therapy. We will also compare the genetic material from your cancer tissue to the genetic material from your normal tissue (which we obtain from your skin biopsy or buccal swab) to find the differences that exist.

At the end of your participation, you will have the following tests and procedures:
- Physical exam, including taking of vital signs, reviewing your medical history, and talking about any symptoms or health problems you're having
- Blood tests to check your blood counts and organ function
- Bone marrow aspirate and biopsy to check the status of your disease

Follow-up procedures:
You will be followed for 30 days after the last dose of decitabine to check for side effects and response. After that, data will be collected from your medical record for up to 2 years after your last dose of decitabine on any additional treatments you receive, your response to treatment and the status of your disease, and your health status in general.

To help us better understand how and why decitabine works when TP53 mutation is present, we will perform whole genome sequencing on the research samples collected from you. No results from the research related genetic testing will be made available to you because the testing/sequencing is taking place in a research lab, not a clinical lab with rigorous certified procedures for verifying and reporting results. We would be unable to provide you with any certainty that the results were accurate. As it would not be recommended that you rely on the results to take any action with regards to your healthcare we will not be returning this information to you.

Will you save my samples or research data to use in future research studies?
As part of this study, we are obtaining blood, bone marrow, and data from you. We would like to use this blood, bone marrow, and data for studies going on right now as well as studies that are conducted in the future. Your blood, bone marrow, and data may also be used for broad sharing throughout the research community. This means your blood, bone marrow, and data may be used for any sort of research and not just research related to your current condition, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. These researchers may be at Washington University, at other research centers and institutions, or commercial sponsors of research. 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 blood, bone marrow, and data you give up any property rights you may have in the blood, bone marrow, and data.

One way in which we may share your data with others is by putting it into a large database of information, called a data repository. If your data is placed in one of these repositories it will be placed in the "controlled-access" portion of the repository. This means that only qualified researchers, who

have received permission from individuals that monitor the access to and use of the data, will be able to look at and use your information. Before we put it in this repository, we will remove any information, such as your name and birthdate, that might easily identify you. Even though these data will not have your name or other identifying information associated with it, it is still possible that someone may be able to trace these data back to you because genetic information is unique. Although your individual data will only be in the controlled access database certain summary information may be available to the general public.

Future research with your donated blood and bone marrow may include the study of genetic factors relating to AML. This future research may focus on one or more genes to study the differences in specific genes or small groups of genes in people who have AML when compared to people who do not have AML. Future research with your blood and bone marrow may also attempt to sequence large parts of your genome or even your entire genome. These types of sequencing provide detailed descriptions of your DNA and result in the creation of information that is as unique to you as your fingerprint.

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

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

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

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

- Identifiers may be removed from your private information, including blood, bone marrow, and data and used for future research or shared with others. If this occurs, we will not ask you for additional consent.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 30 people will take part in this study conducted by investigators at this site, and an additional 30 people will be enrolled at other institutions across the country for a total of approximately 60 people.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, the length of your involvement will depend on your response to decitabine treatment and whether you undergo a stem cell transplant. You will receive at least 2 months of treatment with decitabine and will have data collected on your health and disease status for 2 years after you come off treatment.

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 Decitabine

Likely

- neutropenia, or low white blood cells, which could increase your risk of infection
- thrombocytopenia, or low platelets, which could increase your risk of bleeding
- anemia, or low red blood cells, symptoms of which include fatigue
- bleeding under the skin which could result in red or purple spots known as petechiae or ecchymosis
- pneumonia
- fatigue (feeling tired)
- paleness
- fever
- rigors (chills and shivering)
- joint pain
- cough
- nausea/vomiting
- constipation
- diarrhea
- decreased appetite
- high blood sugar, symptoms of which include increased hunger, increased thirst, and increased urination
- low blood proteins, which may be indicative of liver problems
- low blood potassium, symptoms of which include increased blood pressure
- low blood salts, symptoms of which include nausea, vomiting, headache, and confusion
- abnormal heartbeat
- headache
- difficulty sleeping
- dizziness
- rash

Less likely

- increased number of platelets and hematoma (bruising)
- inflammation of tissue under the skin
- yeast infection
- urinary tract infection
- inflammation of the sinuses, symptoms of which include congestion
- abdominal pain
- increase in liver enzymes which could cause yellowing of the skin
- inflammation of the mucous membranes in the mouth and/or stomach
- heartburn
- fluid leaking in the abdomen, symptoms of which include distended belly and shortness of breath
- hemorrhoids
- mouth sores
- difficulty swallowing
- bloating
- painful or burning tongue
- high blood potassium, symptoms of which include weakness and heart palpitations
- dehydration
- difficult or painful urination
- increased urinary frequency
- itching
- hair loss
- hives
- swelling

Rare

- heart or lungs may stop
- rapid irregular heartbeat
- rapid heartbeat

Risks of Blood Draw

Possible side effects from a blood draw include fainting, dizziness, pain, swelling, bruising, or bleeding where the needle is inserted. There is also a slight possibility of infection where the needle is inserted.

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 this test could indicate that you have HIV or hepatitis B or C. If that happens, we will refer you to a doctor who specializes in treating HIV or hepatitis B or C. We will make every effort to keep your personal information confidential. However, we are required by law to report positive tests to the state of Missouri and/or local agencies. Becoming aware of a diagnosis of HIV or hepatitis B or C could have serious personal and/or social consequences, including difficult obtaining health insurance or employment. For more information about the risks of HIV and hepatitis B and C testing, please talk to your study doctor.

Risks of Bone Marrow Aspirate 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 Skin Biopsy
You will experience discomfort at the site of the biopsy. You may rarely experience bleeding and infection.

Risks of Local Anesthesia
You may likely experience pain at the injection site. There is a rare risk that you will experience nausea, rash, or inflammation at the injection site.

Risks of Buccal Swab
To obtain some normal cells, you may be asked to use a small stick to gently swab the inner surface of your cheek. You may feel some pressure as you swab your cheek, but it should not produce any other discomfort or side effects.

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.

No results from the research related genetic testing will be made available to you because the

testing/sequencing is taking place in a research lab, not a clinical lab with rigorous certified procedures for verifying and reporting results. We would be unable to provide you with any certainty that the results were accurate. As it would not be recommended that you rely on the results to take any action with regards to your healthcare we will not be returning this information to you.

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 ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because it will help researchers learn more about how to treat AML with TP53 mutation.

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;
- Get comfort care, also called palliative care, which helps reduce pain, tiredness, appetite problems, and other problems caused by the cancer without treating the cancer directly.

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.

WILL I BE PAID FOR PARTICIPATING?

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

WHO IS FUNDING THIS STUDY?

The National Institutes of Health (NIH) and Janssen Pharmaceuticals are funding this research study.

This means that Washington University is receiving payments from the NIH and Janssen Pharmaceuticals 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 and Janssen Pharmaceuticals 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. 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
- The National Institutes of Health (NIH)
- Janssen Pharmaceuticals
- Janssen Pharmaceuticals may also inspect any part of your medical record for the purposes of auditing the conduct of the study
- 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.
- The Siteman Cancer Center Clinical Trials Office
- The Quality Assurance and Safety Monitoring Committee to monitor the conduct of 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, we will make sure that your study information is kept secure. Medical records are considered confidential and records are kept in a secured area accessible to those involved in the conduct of the study. Information that is collected for the purpose of this study will be stored with your study number and initials on paper forms in locked cabinets and locked offices or in a password-protected database that only the study personnel will have access to which is also maintained in a locked office. A master list will be stored off-line (in a locked cabinet in a locked office) and will be available only to the Principal Investigator and his designee(s). Samples are stored in a locked freezer room only accessible by WU swipe card. Samples are stored with a linked code number as ID, and the study team for this specific study will be the only staff to have access to this information.

The research team will send study results to Janssen Pharmaceuticals. Information sent to Janssen Pharmaceuticals will be de-identified. Janssen Pharmaceuticals will use this information to study the safety and effectiveness of decitabine. In the future, Janssen Pharmaceuticals may continue to use your health information that is collected as part of this study. For example, Janssen Pharmaceuticals 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. Janssen Pharmaceuticals 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.

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.

If information about you or your involvement in this research is placed in your medical record the information may no longer be protected under the Certificate. However, information in your medical records is protected in other ways.

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 so they can evaluate any potential risks to you. 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, you develop a major side effect, 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. Welch at (314) 454-8304. If you experience a research-related injury, please contact Dr. Welch 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 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: 11/09/21.

_____ _____

(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)