Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: A Phase 1 Clinical Trial to Evaluate the Safety and Immunogenicity of a Neoantigen DNA Vaccine Strategy in Pancreatic Cancer Patients Following Surgical Resection and Adjuvant Chemotherapy

Principal Investigator: William Gillanders, M.D.

Research Team Contact: William Gillanders, M.D. – (314) 362-7201

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.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you have recently undergone surgery for pancreatic cancer and will be starting or have already started post-surgical treatment with chemotherapy.

The purpose of this research study is to learn more about the safety and feasibility of injecting a personalized DNA vaccine into people with pancreatic cancer. DNA is material that contains the information needed to produce many substances in the body. The personalized DNA vaccine is designed to target mutations specific to each person's tumor that are discovered during genetic testing of the tumor before study procedures start. Injection of this DNA vaccine may be a way to generate an immune response to tumor cells. An immune response is the way your body fights viruses and other infections. There is evidence that an immune response may be a way to fight cancer. In addition to evaluating the safety of the DNA injection, this study is also looking at the immune response that your body has after each injection.

The DNA injections are considered investigational, which means that they have not been approved by the U.S. Food and Drug Administration (FDA). In addition, the device used to give the injection, called an electroporation device, is considered investigational and is not approved by the FDA. Furthermore, the development of the personalized DNA vaccine uses genetic testing and a method for finding the best mutations, and these are both considered investigational and are not approved by the FDA.

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WHAT WILL HAPPEN DURING THIS STUDY?

All procedures will be given in the 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 medical history, height, weight, and performance status
- Routine blood tests to check your blood counts and organ function (about 2 teaspoons of blood will be drawn from a vein in your arm)
- Blood test to check how your blood is clotting (about 1 teaspoon will be drawn from a vein in your arm)
- Pregnancy test (if you are a woman of childbearing potential)
- Research blood tests to check your immune function (approximately 4 tablespoons of blood will be drawn from a vein in your arm)
- Electrocardiogram (EKG) to check how your heart is functioning
- Previously taken tumor tissue will be requested for genome sequencing (a process that determines the complete DNA sequence of an organism), if it hasn't already been done as part of your routine care. DNA is the molecules inside cells that carry genetic information and pass it from one generation to the next. We will also look at your RNA. RNA contains information that has been copied from DNA.

If these procedures show that you are eligible to continue participating in this study, and you choose to continue, then the process for developing the vaccine will begin while you receive your non-study post-operative chemotherapy. This process involves accessing the sequencing information from your tumor tissue, finding the most promising mutations to target with the vaccine, and then manufacturing that vaccine so that you can begin treatment with it.

While the personalized vaccine is being prepared and you are receiving your post-operative chemotherapy, you will have the above tests repeated to ensure that you are still eligible to participate, and we will access the routine imaging being done during treatment to check the status of your disease. We will also draw 4 tablespoons of blood for research purposes at two time points while you are receiving your post-operative chemotherapy. Please know that if your disease recurs during the time it takes the scientists to prepare the vaccine (after sequencing of your tumor), you may no longer be able to participate in the remainder of the trial.

Administration of DNA Vaccine:
You will receive the DNA vaccine at six time points during the course of your participation in this study – Week 1, Week 5, Week 9, Week 13, Week 17, and Week 21. You will receive 2 injections at each time point in the muscle of both your left and right shoulder, although it may be necessary for you to have the injections in each thigh instead. The location of your injections may be rotated.

To administer the injection, a member of the study staff will press the electroporation device against the skin of your upper arm (or thigh) and press a button. Although you will not be able to see them, the device will put an injection needle and four thin wires into your muscle. The DNA will be given through the injection needle into your muscle. After the injection, the device will give a very short electrical signal to your muscle at the spot of the injection. The electrical signal will last for about half a second. You will feel twitching in your muscle, which is often painful. Previous patients have described the feeling as a short "cramp" or "punch" in their muscle. Right after the electrical signals are finished, the device will be removed. You may have a little bleeding in your skin at the injection site, and your skin may also turn red or be a little irritated for a short time after the injection. Rarely, people have reported a mild tingling sensation immediately after injection in the limb which received the injection lasting for a few seconds up to several minutes after administration. Your muscle may also be sore to the touch for a short time.

You will be required to remain in the clinic for at least 30 minutes after each injection while a nurse or study coordinator monitors your vital signs (temperature, blood pressure, pulse, and respiratory rate). In addition, a nurse or study coordinator will call you a day or two after your injection to see if you are experiencing any side effects; if s/he thinks it's necessary, you may be asked to return the clinic to be seen by the doctor.

Study Evaluations:
- Physical exam, review of medications, and evaluation of any side effects you may be experiencing on each injection day
- Routine blood tests to check your blood counts and organ function on each injection day (approximately 2 teaspoons of blood will be drawn)
- Pregnancy test on each injection day
- Research blood tests to check your immune function on each injection day (approximately 4 tablespoons of blood will be drawn)
- Routine imaging to check the status of your disease (as per standard care)

Follow-Up:
You will have two follow-up visits after you finish treatment – one on Week 25 (4 weeks after your last injection) and one a year after that (Week 77). At each follow-up visit you will have a physical exam and approximately 4 tablespoons of blood will be drawn to check your immune function. At the Week 25 follow-up visit, you will also have blood drawn for routine tests to check your blood counts and organ function.

Will you save my samples or research data to use in future research studies?
As part of this study, we are obtaining blood, tissue, and data from you. We would like to use these blood, tissue, and data for studies going on right now as well as studies that may be conducted in the

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future. Your blood, tissue, and data may also be used for broad sharing throughout the research community. This means your blood, tissue, and data may be used for any sort of research and not just research related to your current condition. 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 for use of your blood, tissue, and data. By allowing us to use your data you give up any property rights you may have in the blood, tissue, and data. Your blood, tissue and data may be used to develop investigational test, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration.

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.

This future research may include genetic research. 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. The future genetic research may include looking at the difference in genes between different groups of people or it may include studying your entire DNA sequence. Studying your entire DNA sequence will provide a detailed description of your DNA and is sometimes called whole genome sequencing.

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

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

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

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

Autopsy Request

We are requesting permission from you to perform an autopsy at the time of your death. We do not expect that an autopsy will be necessary in all cases; we expect that it will be extremely rare for us to conduct an autopsy related to your involvement in this study. However, if you die while you are actively receiving the study vaccine or if you die unexpectedly while you are still enrolled in the study, we might consider an autopsy beneficial so that we can understand whether the cells in your body have been affected by the investigational DNA treatment. We might be able to obtain valuable scientific information.

You may wish to inform your family of your decision to have an autopsy performed and the reasons behind it. If any clinically relevant information is discovered from the autopsy that could affect your family members, we will inform them. You always have the right to change your mind regarding your decision to allow an autopsy to be performed. Agreeing to have an autopsy is not required for study participation.

Please ask the study doctor if you have any questions or concerns about this information. Note that this does not mean you are **required** to have an autopsy performed, and it would only be performed under rare circumstances.

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

Do you agree to allow for an autopsy at the time of your death as described above?

_____ **Yes, I agree to allow for an autopsy at the time of my death as described above.**

_____ **No, I do not agree to allow for an autopsy at the time of my death as described above.**

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 20 people will take part in this study conducted by investigators at Washington University and other institutions.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately a year and a half, although the period of active participation will last for approximately 6 months.

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.

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

Risks of DNA Vaccine

The investigational DNA vaccine may cause side effects that are mild and a minor inconvenience, or it could cause life-threatening reactions or death. You will be watched closely for side effects. Some of the suspected risks of the investigational DNA vaccine are listed below.

Likely

- Redness or swelling in the area where the injection was given lasting a few days at most
- Soreness at the site of the injection
- Mild flu-like symptoms such as fever, chills, rash, aches and pains, nausea, headache, dizziness, and fatigue

Less likely

- Immune reaction against normal tissues, meaning that your body may identify your normal tissue as foreign and start attacking it; this could cause pain or swelling in your abdomen, other organs, or redness, swelling, or blistering of the skin around the injection site
- Fever or low blood pressure from parts of the bacteria from which the vaccine is derived

Rare

- Allergic reaction, such as hives, difficulty breathing, wheezing, high fever, chills

Theoretical risks

- Other potential risks include insertion of the vaccine DNA into the body's DNA (leading to cancer) or into the DNA of a bacteria or virus in your body. None of these possible risks of DNA vaccines have been seen in laboratory tests or in animals or humans so far, but you need to be aware of these possible risks.
- People have also been tested after receiving similar DNA vaccines, including when administered using the investigational electroporation device (TDS-IM), to see if their bodies produced unwanted antibodies against human DNA. This has not happened in the past.
- Long-term effects of DNA vaccines have not been studied. Possible long-term effects include having a stronger local or systemic (of the whole body) reaction if you are exposed to a similar disease in the future, than a non-vaccinated person. These effects have been seen with other vaccines but not so far with DNA vaccines.

Risks of Electroporation Administration of the Vaccine

This device has been used to administer DNA vaccines or placebo to over 1000 people. Side effects observed in previous studies have included the following:

- Discomfort or pain at the time of electroporation application which feels like a "punch" or "cramp" in the muscle lasting for less than a second. Rarely, people have reported a mild tingling sensation immediately after injection in the limb which received the injection lasting for a few seconds up to several minutes after administration
- Bleeding at the sites of the 4 electrodes has been found to be similar to that of a normal (needle and syringe) injection and resolved quickly.. Localized itching and erythema (reddening of the

skin) at the injection site as well as mild to moderate bruising and/or the formation of small scabs is possible.

- Muscle soreness related to use of the device has been rated "mild" to "moderate" and may last for 24-72 hours, but has been observed for up to 5 days. This may be difficult to distinguish between that caused by the vaccine product or device use.
- On rare occasions, people have become dizzy or lightheaded after administration. This is called a vasovagal reaction. Vasovagal reactions can cause sudden, rapid drops in heart rate and blood pressure that can lead to fainting. In three cases to date, more severe vasovagal reactions have been observed. These reactions resulted in the participants becoming faint for approximately 30-60 seconds leading to loss of consciousness and muscle control in two of the three participants.
- If the injection depth for the device is set too deeply, it is possible that the needle or electrodes could contact your bone, which could result in pain at the injection site and/or deformation of the electrodes and/or injection needle with increased difficulty in device withdrawal.
- The device also carries a theoretical risk that excessive energy could be delivered to the local tissues, resulting in more pronounced local site reactions, that could be very painful, than have been observed to date. However, the device Pulse Stimulator incorporates multiple safety checks to prevent this hazard, including performance of a pre-pulse safety check and the use of multiple circuits that monitor total energy delivered and will which will terminate energy delivery. There have been no occurrences of excessive energy delivery in any of the nonclinical and clinical studies conducted with the pulse stimulator to date.

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.

Risks of EKG

An EKG is considered a non-invasive test. Skin irritation from the EKG electrodes or pain when removing the electrodes is a possible risk. Also, you may experience discomfort from lying quietly for a long time.

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,

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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 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 using personalized DNA vaccines in the treatment of pancreatic cancer.

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.

WILL I BE PAID FOR PARTICIPATING?

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

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WHO IS FUNDING THIS STUDY?

The National Institutes 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) 747-0072 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. 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
- The National Institutes of Health, which is the funding source for this study
- Ichor Medical Systems, manufacturer of the electroporation device
- 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

The Siteman Cancer Center at Washington University School of Medicine and Barnes-Jewish Hospital

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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.

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, members of the study team, and members of the Tissue Bank. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

Because of the innovative nature of this research, and because you will be among the first people receiving this vaccine, there may be interest from the news media and others about this study. Washington University, the investigators, and study staff will make every effort to protect your privacy if the news media becomes interested in this study. No one outside of the research team and government and university regulators will be provided information that could identify you.

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.

This consent form or similar documentation that you are participating in a research study will be included in your clinical medical record. Anyone with access to your medical record, including your health insurance company will be able to see that you are participating in a research study.

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.

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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 http://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

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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 http://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. William Gillanders (314) 747-0072. If you experience a research-related injury, please contact Dr. Gillanders 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.

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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: 04/26/23.

_____ _____
(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)