Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: Neoantigen Vaccines in Pancreatic Cancer in the Window Prior to Surgery

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.

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. Will Gillanders having to do with using an individualized vaccine to treat pancreas cancer. You are invited to be in this study because you have recently been diagnosed with pancreatic cancer and will be starting standard chemotherapy soon, after which you will have surgery.

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 this study about?**
   This study is looking at the safety and effects on the immune system of using an individualized peptide vaccine to treat people with pancreas cancer.

2. **Why should I consider participating?**
   The purpose of this study is to learn more about the safety and feasibility of treating pancreas cancer with an individualized peptide vaccine. The peptide vaccine is given by injection at several time points over the course of approximately 12 weeks. By participating in this study, you will contribute to knowledge about how to harness the immune system to treat pancreatic cancer.

3. **What will I be asked to do?**
   If you decide to take part in this study, you will have to a have a research biopsy (where a small piece of tumor tissue is taken from your cancer using a long hollow needle). That tumor tissue will be analyzed to make the peptide vaccine. While the peptide vaccine is being made, you will have treatment with standard chemotherapy. When you enroll in the study, you will be randomly assigned a start time for the vaccine. People who are assigned to Arm 1 will receive the peptide vaccine approximately 1 month after standard surgery. People who are assigned to Arm 2 will

receive the peptide vaccine approximately 1 week after the end of standard chemotherapy but before standard surgery. The individualized peptide vaccine is given at 7 time points over the course of approximately 12 weeks. After you finish your treatment, your doctor and study team will watch you for side effects for one year.

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 having a study injection). The active part of the study will last for 6 months, with required follow-up for another year, and continued long-term yearly follow-up thereafter.

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.

If you choose not to participate 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

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 vaccine site reaction (including fever and/or pain), soreness, and flu-like symptoms. 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. It is not possible to know if the study drugs will extend your life compared to the usual approach. This study will help the study doctors learn things that will help people in the future.

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.

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 the National Cancer Institute (NCI), the Foundation for Banres-Jewish Hospital, and UNICO Foundation, Inc.

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

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research study is to learn more about the safety and feasibility of injecting an individualized peptide vaccine into people with pancreatic cancer. Individualized vaccines include up to 20 peptides as well as a dose of a drug called Hiltonol, which is a medication that improves the activity of the vaccine. A peptide is a naturally occurring biological molecule made up of amino acids. The individualized vaccine is designed to target mutations specific to each person's tumor that are discovered during genetic testing of the tumor. Injection of this vaccine may be a way to generate an immune response to pancreatic cancer 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 individualized vaccine, this study is also looking at the immune response that your body has after each injection.

The peptide vaccine injections are considered investigational, which means that they have not been approved by the U.S. Food and Drug Administration (FDA). Furthermore, the development of the 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.

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) (this may be a urine or blood test; if it is a blood test, about 1 teaspoon of blood will be drawn from a vein in your arm)
- Research blood tests to check your immune function and to help with the development of the personalized vaccine (approximately 5 tablespoons of blood will be drawn from a vein in your arm)
- A research biopsy will be performed to collect tumor tissue for genome sequencing (a process that determines the complete DNA sequence of an organism). Genes are a unique combination of molecules (called DNA) that we inherit from our parents. There are millions of tiny differences in our genes. These differences may make us more or less likely to develop certain diseases or

conditions or to have certain characteristics. Genetic research involves studying the differences in genes and DNA between individuals. This type of testing creates information that is as unique to you as your fingerprint. 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 you will be randomized to either Arm 1 or Arm 2, which dictates when you receive the personalized vaccine. Randomization means to be assigned by chance, like the flip of a coin. You have a 50/50 chance of being assigned to either Arm 1 or Arm 2 of this study. At this time, the process for developing the vaccine will begin while you receive your standard pre-operative chemotherapy. This process involves sequencing 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.

Standard pre-operative chemotherapy takes about 4 months to complete. At Washington University, the standard pre-operative chemotherapy is a combination of drugs called mFOLFIRINOX. If your disease progresses while you are receiving mFOLFIRINOX or if you experience bad side effects, you can switch to another combination of drugs called GemAbrax. This treatment is being done as part of your routine care and would occur even if you were not participating in the study.

While the personalized vaccine is being prepared and you are receiving your 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. Please know that if your disease progresses during the time it takes the scientists to prepare the vaccine (after sequencing your tumor), or if any of the repeated test results show that you are no longer eligible, you may no longer be able to participate in the remainder of the trial. However, it is possible that even if you are no longer eligible to participate, your treating physician may determine that it is still safe for you to receive the vaccine that has been prepared for you. If that is the case, you will be treated as described below. However, you would need to sign a separate consent form for this treatment.

Administration of Peptide Vaccine:
You will receive the peptide vaccine at seven time points during the course of your participation in this study – Days 1, 4, 8, 15, 22, 50, and 78.

People who are assigned to Arm 1 will have their first injections after standard surgery. Day 1 of the vaccine will occur approximately one month after surgery, although it may be delayed to up to 3 months after surgery, depending on how long it takes to recover from surgery.

People who are assigned to Arm 2 will have their first injections after finishing standard chemotherapy. Day 1 of the vaccine will occur approximately one week after the end of chemotherapy, although it may be delayed to up to 3 weeks after the end of chemotherapy. Days 50 and 78 will occur after standard surgery. If there is a significant delay in the preparation of the personalized vaccine, people assigned to Arm 2 may receive their vaccines on the same schedule as Arm 1 (with all injections after surgery).

Everyone will receive up to 4 intramuscular injections at each time point, one in each of your limbs. If you are unable to receive a dose in one of your limbs, your left or right midriff may be substituted. The number of injections you receive will depend on the number of peptides you will be receiving.

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).

Study Evaluations:

- Physical exam, review of medications, and evaluation of any side effects you may be experiencing on each injection day and at your end of treatment visit
- Routine blood tests to check your blood counts and organ function on injection Days 1 and 22 (approximately 2 teaspoons of blood will be drawn)
- Pregnancy test on Days 1, 22, 50, and 78 (this may be a urine test or a blood test; if it is a blood test, approximately 1 teaspoon of blood will be drawn)
- Research blood tests to check your immune function on Days 1, 15, 22, 50, and 78, and on the day of surgery (approximately 5 tablespoons of blood will be drawn)
- Routine imaging to check the status of your disease (as per standard care)

You will also have blood collected for research purposes at the time of your surgery, as well as a piece of the removed tumor tissue collected for research purposes.

Follow-Up:
You will have follow-up visits 4 weeks after your last vaccine injection and 1 and 2 years after your last vaccine injection. At each follow-up visit you will have a physical exam and blood drawn for research purposes (mandatory at the 4-week visit, optional depending on your availability at the 1- and 2-year visits). We may follow up with you after that by phone or in person (or by review of your medical records) to check on your health status and the status of your disease.

Will you save my research information and/or biospecimens to use in future research studies?
As part of this study, we are obtaining data and samples (blood and tissue) from you. We would like to use these data and samples for studies going on right now as well as studies that may be conducted in the future. Your data and samples may also be used for broad sharing throughout the research community. This means your data and samples 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 for use of your data and samples. By allowing us to use your data and samples you give up any property rights you may have in the data and samples.

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 has 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 the question below:

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

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

Unless you agree to future use as described above, your private information (including blood, tissue, 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 36 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for several years. The period of active participation will last for approximately 6 months. There is required follow-up for another two years.

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 Peptide Vaccine

The experimental 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 experimental 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 breast, 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
- Injection site infection
- Nerve damage at the site of the injection

Theoretical risks

Long-term effects of synthetic long peptide 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 synthetic long peptide vaccines.

Risks of Hiltonol

Occasional, some may be serious

- Anemia which may require blood transfusion
- Diarrhea, nausea, vomiting
- Chills, tiredness, fever
- Flu-like symptoms including body aches, muscle pain
- Swelling and redness at the site of the medication injection
- Bruising, bleeding
- Infection, especially when white blood cell count is low
- Loss of appetite

Theoretical risks

Some instances of transient fever, malaise, or flu-like symptoms have been associated with a more serious condition called cytokine release syndrome, or CRS. CRS may include symptoms like fevers, chills, shortness or breath, rapid heartbeat, changes in blood pressure, low oxygen levels, headache, and muscle aches. At this time, no instances of CRS have been attributed to poly-ICLC, but since the association has been seen, we wanted to make you aware and let you know we are monitoring this.

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 Tumor Biopsy

Your doctor will inform you in detail about the risks associated with biopsy. The level of risk will depend on where the tumor is located and the specific procedure by which the tumor is accessed. If a biopsy cannot be obtained with an endoscope, it may be necessary to biopsy through the skin (this is rare). In general, having a biopsy can cause pain, swelling, bleeding, and/or infection at the site where the biopsy penetrates through the skin. There is also the possibility that having this procedure may shift some cells from the tumor into the surrounding tissues that come in contact with the biopsy needle. This means that the tumor may spread to that particular area. Depending on the area of the biopsy, a local anesthetic (to numb the area) may be injected into the skin, or a sedative medication may be given orally or intravenously. The risks of this anesthetic are minimal and include bleeding, bruising, infection, and allergic reaction. The risks associated with use of a sedative are similar, but also include drowsiness, slurred speech, staggering gait, poor judgment, inflammation of the vein where medication is injected, low blood pressure, decreased breathing, and slowed reflexes. More serious complications to the endoscopic biopsy can include perforation (a whole in the intestine), and pancreatitis.

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 you not impregnate anyone or donate sperm during your participation in this study. There may be unknown risks to the unborn child or risks we did not anticipate. If pregnancy is a possibility, you must agree to use birth control if you want to take part in this study. If you believe or know that you have impregnated anyone, donated sperm or otherwise fathered a child during your participation in this study, please contact the research team member identified at the top of the document as soon as possible.

Risks of Genetic Research

There may be information obtained from the genetic testing that indicates that you, or potentially a family member (since we inherit genes from our parents, and pass genes on to our children) are at risk for a particular disease or condition. For example, genetic sequencing may indicate that an individual is more prone to develop certain types of cancer or other types of diseases, (e.g. Alzheimer's or other inherited diseases).

While the data developed for this study is being stored without traditional identifiers (stored only with coded ID numbers, no names), there may be ways of linking the genetic materials back to you. Because your DNA is unique to you, it is possible that someone could look at the information in the DNA database and compare it to information in another database, and use that to identify you. This is difficult to do and is very unlikely to happen.

If made available to persons or agencies outside of our research group, information about genetic test results could affect your employment or insurance. For instance, employers, insurers, or others may use this information when making decisions about you or your family members regarding employment, insurance, or other benefits.

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.

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.

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 listed 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 Cancer Institute, which is the funding source for this study
- Oncovir, manufacturer of Hiltonol
- UNICO Foundation, Inc.
- The Foundation for Barnes Jewish Hospital
- 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 Quality Assurance and Safety Monitoring Committee at the Siteman Cancer Center, to monitor the conduct of this study
- Siteman Cancer Center
- 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. 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.

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.

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.

This Certificate may not be effective for information held in foreign countries.

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?

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. 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.

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: 11/03/26.

_____ _____

(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)