Washington University in St. Louis

FOR IRB USE ONLY
IRB ID #: 202003072
APPROVAL DATE: 05/21/25
RELEASED DATE: 05/22/25
EXPIRATION DATE: 05/20/26

INFORMED CONSENT DOCUMENT

Project Title: A Pilot Study to Assess the Safety, Feasibility, and Immunogenicity of a Neoantigen-based Personalized DNA Vaccine Combined with Immune Checkpoint Blockade Therapy in Patients with Newly Diagnosed, Unmethylated Glioblastoma

Principal Investigator: Tanner Johanns, M.D., Ph.D.

Research Team Contact: Tanner Johanns, M.D., Ph.D. – (314) 273-2723

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.

If you are the legally authorized representative providing consent the word "you" in this document refers to the person you represent.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you have been diagnosed with a type of brain cancer called glioblastoma and will be treated with radiation therapy on its own.

The purpose of this research study is to learn more about the safety and feasibility of treating glioblastoma with a personalized DNA vaccine to work with the immune system to fight cancer. DNA is material that contains the information needed to produce many substances in the body. The personalized DNA vaccine (GNOS-PV01) is designed to target mutations (changes in the DNA) 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 glioblastoma 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. The DNA vaccine will be given with another substance called INO-9012 (which is intended to improve the activity of the vaccine by boosting the immune response your body has to the vaccine). The DNA vaccine + INO-9012 will be given using an electroporation device, which administers the vaccine through an injection into your muscle, followed by a short electrical signal to your muscle at the spot of the injection. The device is called the CELLECTRA®2000 electroporation device.

In this protocol, you will not be receiving temozolomide, which is a standard of care chemotherapy for patients with glioblastoma. Typically, people with glioblastoma will receive radiation therapy and temozolomide together, followed by temozolomide by itself for several cycles. Studies have shown that patients whose MGMT genes are unmethylated have a significantly lower response to temozolomide than patients with MGMT methylation. Because temozolomide can also decrease the counts of your white blood cells, if you choose to participate in this study you will not receive temozolomide so it does not interfere with your immunotherapy. You can also choose not to participate in this study and may receive radiation therapy and temozolomide as your standard care.

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

WHAT WILL HAPPEN DURING THIS STUDY?

All procedures will be given in the outpatient 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. Visits to the site will range from 6-8 hours in length. 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 can 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 done to see if you are eligible to continue to participate in the study. You will have the following tests and procedures:

- Physical exam, including review of your medical history, height, weight, and performance status (which is an assessment of your day-to-day functioning)
- Blood draw to check your counts and organ function (approximately 2 teaspoons of blood will be drawn)
- A pregnancy test (if you are a woman of childbearing potential) (approximately ½ teaspoon of blood will be drawn)
- 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 or for research purposes. DNA refers to 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.
- Review of your standard of care post-op brain imaging to check the status of your disease

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 radiation therapy. This vaccine development 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. The above tests will be repeated shortly before you are scheduled to begin treatment with the personalized vaccine to confirm that you are still able to continue in the study.

Please know that if your disease progresses 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 the Personalized DNA Vaccine:
You will receive the DNA vaccine + INO-9012 at different time points during each cycle of treatment. A cycle is 9 weeks (63 days). During the first cycle of treatment, you will receive the DNA vaccine + INO-9012 on Days 1, 22 and 43. After that, you will receive it on Day 1 of each subsequent cycle beginning with Cycle 2. You will continue to receive study vaccine until either progression, intolerance, end of supply, or if your doctor decides it is not within your best interest to continue. For each vaccination, you will receive 1 injection at each time point in the muscle of your left or right shoulder, although it may be necessary for you to have the injections in one of your thighs instead. The location of your injections may be rotated.

To administer the injection, a member of the study staff will press the CELLECTRA®2000 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 five 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 be offered a cream called EMLA (Lidocaine 2.5% and prilocaine 2.5%) before receiving the DNA vaccine + INO-9012. It may be applied to your skin to numb the area of the injection. You may also be offered a pain reliever (such as acetaminophen) 30 minutes before the injection or you may be offered an analgesic (such as ibuprofen or ketorolac) afterwards. You may be offered a sedative (such as lorazepam) for anxiety related to the injection. Your doctor will help you decide which medicines you may need.

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:
During your participation in the study, you will have the following tests and procedures:

- Physical exam, review of medications, and evaluation of any side effects you may be experiencing on Day 1 of each cycle
- Check of vital signs on each vaccine injection day
- Blood draw to check your blood counts and organ function on each vaccine injection day (approximately 2 teaspoons of blood will be drawn at each time point)

- Pregnancy test (if you are a woman of childbearing potential) (approximately ½ teaspoon of blood will be drawn at each time point)
- Brain MRI to check the status of your disease every 9 weeks; you may have a CT scan of your head if you are unable to undergo an MRI for any reason (for example, if you have a pacemaker that is not compatible with an MRI scanner)
- We will track steroid or other immunosuppressive agents and anti-seizure medications to make sure that these concomitant medications do not impair or increase the adverse effects associated with the study medications.

You will also have blood taken for research purposes at the following time points:

- At the time when you enroll into the study and prior to radiation therapy (about ¼ cup of blood from a vein)
- Any time between when you consent, after the completion of radiation therapy and 7 days after the first vaccine dose (2 teaspoons of blood from a vein plus either leukapheresis (see description below) or another ¼ cup of blood from a vein)
- Day 1 of each Cycle from Cycle 2 through Cycle 8 (about ¼ cup of blood from a vein)
- At Cycle 2 Day 8 blood from vein plus leukapheresis will be drawn (2 teaspoons of blood from a vein plus either leukapheresis or another ¼ cup of blood from a vein)
- At time of progression or leaving the study, a final blood collection will be obtained (2 teaspoons of blood from a vein plus either leukapheresis or another ¼ cup of blood from a vein)

The amount of blood being drawn at each time point depends on whether you are able to undergo a leukapheresis or not. Leukapheresis is very similar to donating blood, but instead this procedure separates white blood cells from a sample of blood. A needle attached to sterile tubing will be inserted into a vein in your arm or chest. One tube removes blood and passes it into a machine that removes white blood cells. The rest of your blood cells and blood fluid (plasma) go back into your body through a second tube. If you are able to undergo leukapheresis without the placement of a special catheter, it is required that you undergo this procedure, but if your veins are such that a special catheter would be required, you can elect to either undergo leukapheresis or you can have an additional ¼ cup of blood drawn instead.

There may be optional blood draws at other time points of interest throughout the study that may be done if it is determined to be needed.

You will continue to receive treatment on this study until your disease progresses, you experience intolerable side effects, or you or your study doctor decide you should come off study. After your last day of study treatment, you will have an end of treatment visit during which the following tests and procedures will take place:

- Physical exam and evaluation of any side effects
- Blood for research purposes as described above

Follow-Up:
You will be followed as per your routine care. Members of the study team from this study may review your medical records to collect information on your health and wellbeing.

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

These studies may include genetic research. Genetic research can look at DNA to look for mutations (changes) that may increase the risk of disease or affect the way a person responds to treatment.

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

If you change your mind and do not want us to store and use your 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 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**

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**

- Identifiers may be removed from your private information including blood, tissue, 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 12 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 as long as you continue to benefit from treatment. You will be followed 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 Personalized DNA Vaccine

Although the DNA vaccine used in this study (GNOS-PV01) has not been tested in humans before, below is a list of possible side effects of GNOS-PV01 + INO-9012, based on experience with similar investigational products delivered using the CELLECTRA® device.

Very common

- Injection site pain or tenderness
- Injection site redness
- Injection site swelling or hardening

Common

- Injection site itching
- Injection site bruising

Uncommon or rare

- Administration site lesions or bleeding
- Severe administration site pain or tenderness

Potential and theoretical risks

(These risk have not happened but could be possible)

- Severe localized injection site reaction (for example, sterile abscess or secondary bacterial infection)
- Electrical injury
- Disruption of function of implanted electronic medical device(s)
- Abnormal heart rhythm
- Worsening of unstable cardiac disease
- Effects on fetus and/or pregnancy
- Allergic reaction (for example, hives or anaphylaxis)
- Chills or flu-like illness
- Autoimmune disease

- Muscle damage or renal insufficiency
- Increased brain inflammation and swelling

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 Leukapheresis

It is possible (but not likely) that the medicine used to prevent blood from clotting in the machine can cause tingling or numbness around your mouth, feet, or hands that lasts for only a short time, and rarely bleeding. You will be monitored closely during leukapheresis. There is a rare risk of high or low blood pressure, muscle cramping, chills and fever, loss of red blood cells leading to anemia, and loss of platelets which may lead to easy bruising and bleeding.

Risks of Brain MRI

Common

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

Rare

- a loud hammering noise which has caused hearing loss in a small number of patients.
    - To minimize this risk, you will be given earplugs.
- temporary sensation of flashing lights while in the MRI scanner
- burns that could be serious
    - To minimize this risk, we will have you change out of your clothing and into clothing that we provide.

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

Devices

If you have a device such as a pacemaker, bone hardware, or device placed in your uterus there may be additional risks. We will review what device you have and inform you of these risks. In general, these risks could be:

- heating or movement of the device
- device malfunction
- damage to the tissue that surrounds the device

Contrast agent

A contrast agent, such as gadolinium, may be used during the MRI scan to make the pictures clearer. Recent information shows that when you receive gadolinium repeatedly it may collect in the brain. This

would apply whether you receive the gadolinium as part of a research study or as part of your healthcare. The importance of this information and how it impacts your health are not known.

Gadolinium given during pregnancy could cause a stillbirth or the baby could have skin diseases later in their childhood. If you are a woman of childbearing age, you must have a negative urine pregnancy test within 24 hours prior to getting the gadolinium.

Risks of CT Scans (if applicable)
Rare

- Malfunction of worn or implanted electronic medical devices

If you have electronic medical devices implanted such as a pacemaker or a drug pump, please make sure you tell your study doctors and research staff. The CT scan may cause a malfunction of electronic medical devices.

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 and for at least 5 months after your last day of study treatment. 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 and for at least 7 months after your last day of study treatment. 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.

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).

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.

Re-Identification from Genetic Sample

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.

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 the immune system to treat glioblastoma.

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; this could include treatment with radiation therapy and temozolomide together, followed by temozolomide alone (which is the standard treatment for glioblastoma)
- take part in another research study
- get no treatment
- get palliative care, also called comfort care

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.

Geneos Therapeutics is providing the other study products at no cost to you. These are the personalized DNA vaccine (GNOS-PV01), INO-9012 (IL-12), and the CELLECTRA®2000 delivery device.

WILL I BE PAID FOR PARTICIPATING?

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

WHO IS FUNDING THIS STUDY?

Geneos Therapeutics and the Foundation for Barnes-Jewish Hospital (BJHF) are funding this research study. This means that Washington University is receiving payments from Geneos Therapeutics and BJHF 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 Geneos Therapeutics or BJHF for conducting this study.

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

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at (314) 362-3570 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University and Geneos Therapeutics. 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
- Inovio/Geneos Therapeutics, manufacturer of GNOS-PV01 and CELLECTRA®2000
- The Foundation for Barnes-Jewish Hospital
- 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 Quality Assurance and Safety Monitoring Committee at the Siteman Cancer Center for auditing purposes
- The Siteman Cancer Center Clinical Trials Office

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

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. 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. Sharing this information will allow 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.

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.

Are there additional protections for my health information?

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

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

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

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

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

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

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

If you sign this form:

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

    - **If you revoke your authorization:**
        - The research team may only use and share information already collected for the study.

- Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
- You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

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

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

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

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

Will I receive new information about the study while participating?

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

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because staying in the study would be harmful, you need treatment that is not allowed while on the study, you fail to follow instructions, you become pregnant, or the study is canceled.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact Dr. Tanner Johanns at (314) 273-2723. If you experience a research-related injury, please contact Dr. Johanns 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, 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: 05/20/26.

_____ _____

(Signature of Participant) (Date)

_____

(Participant's name – printed)

Legally Authorized Representative's Name and Relationship to Participant:

Do not sign this form if today's date is after EXPIRATION DATE: 05/20/26.

_____
(Participant's name – printed)

_____ _____
(Signature of Legally Authorized Representative) (Date)

_____ _____
(Name of Legally Authorized Representative - printed) (Relationship to Participant – printed)

Who should sign as the Legally Authorized Representative (LAR)?
If the participant has a legal guardian or attorney-in-fact this individual must sign as the LAR.

If there is no legal guardian or attorney-in-fact the individuals listed below may sign in order of priority.

(1) Spouse unless the participant has no spouse, or is separated, or the spouse is physically or mentally incapable of giving consent, or the spouse's whereabouts is unknown or the spouse is overseas;
(2) Adult child;
(3) Parent;
(4) Brother or sister;
(5) Relative by blood or marriage.

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)