Washington University in St. Louis

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INFORMED CONSENT DOCUMENT

Project Title: Testing the immunologic effects of CDX-301 and CDX-1140 in resectable pancreatic cancer patients

Principal Investigator: Roheena Panni, M.D.

Research Team Contact: Roheena Panni, M.D. – (314) 362-7046

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

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

KEY INFORMATION

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

This is a research study conducted by Dr. Roheena Panni having to do with the investigational treatment of pancreatic cancer. You should carefully consider the information in this consent document and discuss it with the research team. Be sure you understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. All of the information below will be explained and is listed in more detail in the consent document below. The research team must give you a copy of this signed consent document.

How will this study affect me?

- The purpose of this study is to look at the effects of treating pancreatic cancer with either a drug called CDX-1140 or with CDX-1140 in combination with CDX-301.
- As a voluntary participant, your treatment will last for 2 to 3 weeks and will also include 2 years of follow-up afterwards.
- You were selected because you have pancreatic cancer that can be surgically removed.
- You will be in this study for approximately 2 years and will have the following tests and procedures at various time points throughout the study:
  - Physical exam
  - Safety blood tests
  - Research blood tests

- You will need to come to the Siteman Cancer Center for your treatment.
- The main risks to you are muscle pain, joint pain, chills, nausea, fever, fatigue. More detail about risks is provided below.
- You will not be paid for participating 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.
- If you withdraw from the study, the research team may continue to use information already collected about you in this study.

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

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you have been diagnosed with pancreatic cancer that can be surgically removed.

The purpose of this research study is to look at the effects, good and bad, of treating pancreatic cancer with either a drug called CDX-1140 or with CDX-1140 in combination with CDX-301. People enrolling to this study will be randomly assigned (like the flip of a coin) to receive either a single dose of CDX-1140 before surgery to remove their cancer OR five doses of CDX-301 AND a single dose of CDX-1140 before surgery.

Both CDX-1140 and CDX-301 are considered investigational, which means that they have not been approved by the U.S. Food and Drug Administration.

WHAT WILL HAPPEN DURING THIS STUDY?

All treatment will be given in either the outpatient or inpatient setting at Siteman Cancer Center. We feel it is important to remind you that any procedures, regardless of whether they are tests you would have if you did not take part in the research or are research-related, will require you to remain at the Siteman Cancer Center up to several hours. There may also be a wide variability in the length of clinic visits. 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.

If you decide to join the study, you may experience side effects that could delay or prevent surgery.

Before you begin study treatment:

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

- Physical exam, including taking of vital signs, measuring your height and weight, reviewing your medical history, and talking about any symptoms or health problems you're having
- Blood tests to check your blood counts, organ function, and how your blood is clotting (approximately 1 tablespoon blood will be drawn from a vein in your arm)
- Pregnancy test if you are a person who can get pregnant (approximately ½ teaspoon blood will

be drawn from a vein in your arm)
- Blood draw for research purposes (approximately 2 tablespoons blood will be drawn from a vein in your arm)

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

Procedures throughout the study:
If you are able to continue in the study and you choose to do so, you will be randomly assigned (like the flip of a coin) to Arm 1 or Arm 2 of the study. People assigned to Arm 1 will receive a single dose of CDX-1140 as an IV infusion 7 to 12 days prior to standard surgery to remove the pancreas tumor. People assigned to Arm 2 will also receive a single dose of CDX-1140 as described above, but they will also receive 5 subcutaneous injections of CDX-301 3, 4, 5, 6, and 7 days before the CDX-1140 infusion.

Regardless of whether you are assigned to Arm 1 or Arm 2, you will have another 2 tablespoons of blood drawn for research purposes immediately before the infusion of CDX-1140, and again at the time of surgery. You will also have a piece of the tumor tissue that is removed from your pancreas collected for research purposes for this study.

Follow-up procedures:
After surgery, you will have routine follow-up with your doctor. For this study, we will continue to collect information about your health and wellbeing for up to 2 years after surgery. That could be done at the time of an in-person doctor's visit or by phone call from a nurse or research coordinator.

Will you save my research information and/or biospecimens to use in future research studies?
We would like to use the blood, tissue, and data we are obtaining in this study for studies going on right now as well as studies that are conducted in the future, including future genetic research. These studies may provide additional information that will be helpful in understanding pancreatic cancer, 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.

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. 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 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 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 24 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 2 to 3 weeks, with up to 2 years of follow-up afterwards.

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.

As of September 5, 2022, CDX-1140 has been administered to 129 patients in a Celldex sponsored study and the information below reflects data from that study. In the Celldex sponsored study, 58 patients received CDX-1140 as monotherapy, and 37 patients received CDX-1140 in combination with CDX-301. Side effects thought to be related to CDX-1140 monotherapy and in combination with CDX-301 are further detailed below.

Risks of CDX-1140 Monotherapy:
There have been 58 patients who have received CDX-1140 monotherapy in a Celldex sponsored study.

Side effects thought to be related to CDX-1140 monotherapy have included the following:

Very common
(Out of 100 people who receive CDX-1140, more than 20 people may have the following):

- Joint Pain
- Chills
- Nausea
- Fever
- Fatigue

Common
(Out of 100 people who receive CDX-1140, 11-20 people may have the following):

- Diarrhea
- Muscle pain
- Vomiting
- Digestive enzyme increase
- Liver enzyme increase

Less common
(Out of 100 people who receive CDX-1140, 6-10 people may have the following):

- Joint inflammation
- Swelling in arms and/or legs
- Anemia (low red blood cells)
- Influenza like illness
- Decreased appetite
- Pneumonitis (inflammation of the lungs)
- Rash

It is anticipated that most patients may experience at least some side effects. Most adverse events associated with CDX-1140 to date have started in the 24-48 hours following the CDX-1140 infusion, been mild to moderate, and have resolved with or without medications such as acetaminophen (Tylenol ®), anti-inflammatory medications such as naproxen sodium (Aleve ®), and/or anti-nausea medication such as ondansetron (Zofran ®). In a few cases, the side effects have been severe and have required hospitalization and treatment with corticosteroids or other immunosuppressive medications. You will be given medications to prevent or lessen the severity of side effects. You will take these medications prior to each CDX-1140 infusion and for at least 24-48 hours after each CDX-1140 infusion. It is important that you take the medications even if you do not have any symptoms.

It is expected that CDX-1140 will cause a decrease in certain white blood cells and platelets and an increase in liver enzymes (as noted above) as determined by blood tests in the first few days after the infusion. These effects have not generally been associated with any symptoms, have not required treatment, and the laboratory values usually resolved within approximately 1-2 weeks after the CDX-1140 infusion. The study requires that your doctor closely monitor these tests. If the effects of CDX-1140 on white blood cells and platelets are severe or prolonged, then you might be at increased risk of infection and bleeding and your doctor might need to treat you with other medications, for example,

with steroids. If your liver enzymes increase too much your doctor will follow you closely and will want to continue testing until the levels return to normal.

Significant and Common Side Effects Associated with CDX-1140 in a Celldex Sponsored Study

Cytokine Release Syndrome: Infrequently, patients who received CDX-1140 experienced more severe infusion reactions called cytokine release syndrome. Cytokine release syndrome has been reported in 12/129 (9%) patients in a Celldex sponsored study, with 3 occurring in patients who received CDX-1140 monotherapy, 5 occurring in patients receiving CDX-1140 in combination with CDX-301, and 4 occurring in patients receiving CDX-1140 in combination with another agent. Four patients discontinued study treatment due to cytokine release syndrome and no patients have died due to cytokine release syndrome. Symptoms included fever, weakness, low blood pressure, low blood oxygen, elevated liver enzymes, nausea, diarrhea, vomiting and poor functioning of the kidneys. Treatment for cytokine release syndrome may include strong medications like corticosteroids and other medications to reduce inflammation. These treatments can have serious side effects that can be outlined by your doctor.

Lung inflammation (pneumonitis): 7/129 (5%) patients who received CDX-1140 monotherapy experienced severe treatment related inflammation of the lungs called pneumonitis, 4 occurring in patients who received CDX-1140 monotherapy, 2 occurring in patients who received CDX-1140 in combination with CDX-301, and 1 occurring in patients who received CDX-1140 in combination with other agents. Patients developed shortness of breath and imaging of the lungs demonstrated new inflammatory changes. These patients required hospitalization and treatment with stronger medications, such as corticosteroids and other medications to reduce inflammation. Pneumonitis can be life-threatening, and one patient died in the CDX1140-01 study where the cause of death was partially attributed to pneumonitis. Please immediately inform your physician and study team if you develop any new or worsening shortness of breath, pain or discomfort while breathing, cough, chest pain or other respiratory symptoms.

Fever: Fever is common following the CDX-1140 infusion, occurring in approximately 41% of patients. Onset is typically within 48 hours of the CDX-1140 infusion. Some patients may have accompanying dehydration along with the fever. Therefore, if you do develop a fever, you should try to stay well hydrated as instructed by your doctor. Pre- and post-infusion acetaminophen and a non-steroidal anti-inflammatory drug (NSAID) should be taken as described above.

Joint pain and muscle pain: Joint pain and muscle pain are common treatment side effects following CDX-1140 administration, occurring in 53% and 24% of patients, respectively. Please inform your physician and study team if you are having joint pain and/or muscle pain and you may be told to take acetaminophen or NSAID medications or prescribed a short course of corticosteroids if the symptoms are not relieved with over-the-counter medicine.

Immune-related inflammatory reactions: Drugs that increase anticancer immune responses can sometimes cause swelling (or inflammation) in normal (non-diseased) organs. These reactions may cause a range of symptoms and involve any organ. Side effects that have been reported with other types of immune activating agents include:

- Ocular: Eye inflammation

- Digestive: Inflammation of the gut lining that could be associated with diarrhea, constipation, bleeding, abdominal pain; inflammation of the pancreas (pancreatitis)
- Skin: Rash, itching, loss of skin pigmentation (color)
- Liver: Inflammation in the liver (hepatitis)
- Endocrine: Overactive or underactive glands that produce hormones. These hormones regulate a number of body processes; Diabetes (increase in blood glucose levels)
  Other: weakness, numbness, and pain usually in hand or feet, disorder in which your body's immune system attacks your nerves (Guillain-Barre syndrome)

These kinds of side effects can occasionally be severe or even life-threatening. Sometimes, treatment with medications that suppress the immune system, such as corticosteroids, is required. These types of medications can also be associated with serious side effects, such as the development of infections. You should ask your doctor if you have questions about the side effects of any medications used to manage side effects of CDX-1140. Based on experience with other drugs that activate the immune system, it is expected that if events listed above were to occur, they would likely be quickly controlled with appropriate therapy. However, it is possible that side effects could potentially rapidly worsen and become life-threatening and even cause death. Any delay in treating these side effects may prolong their duration and make them more difficult to treat. **You should always immediately contact the study doctor if you develop any worrisome symptoms and report any new side effects during your regular study visit.**

Risks of CDX-301

Approximately 155 individuals (including 34 healthy volunteers or healthy stem cell donors) have been treated with CDX-301. Thirty-seven patients have been treated with the combination of CDX-1140 and CDX-301. There have been no side-effects that have reached the level of 6 or more people out of 100 people for the approximately 155 individuals who have received CDX-301.

Side effects thought to be related to CDX-301 have included the following:

CDX-301 is a fully human protein and it is unlikely, but possible, that it will induce an allergic reaction. No such reactions have been observed in the CDX-301 program. However, if such reactions were to be observed, possible symptoms could include fever, chills, rash, sudden feeling of cold with shivering accompanied by a rise in temperature (rigors), itching, or other symptoms. If not treated immediately, an allergic reaction could become life-threatening. If you think you might be having a reaction after being treated with CDX-301, or your symptoms are not going away, you must seek immediate medical attention.

In theory, CDX-301 could cause your body to have an immune response against the FLT3 your body normally makes. If that were to happen, you might be at increased risk for infections. Another theoretical risk of an anti-CDX-301 immune response is that your immune system might attack your body, resulting in a disease such as arthritis or kidney damage. However, none of these types of problems have been seen with CDX 301.

Certain blood cancers have a mutation in the receptor for FLT3L, called FLT3, and it is possible that CDX-301 could enhance the growth of such tumor cells. You should not receive CDX-301 if you have a history of chronic myeloid leukemia (CML) or have a known mutation in FLT3.

An increase in certain white blood cells may be observed on routine blood testing after treatment with CDX-301 and is expected to return to normal within 2-3 weeks after the last dose of CDX-301. You should tell your doctor if you are receiving any other drugs that can increase white blood cells, such as Neupogen (filgrastim) or Leukine (sargramostim), as the combination with CDX-301 could cause an unsafe increase in certain white blood cells.

CDX-1140 in Combination with CDX-301

There have been 37 patients who have received CDX-1140 in combination with CDX-301 (a growth factor for certain immune cells) in a Celldex sponsored study.

Side effects thought to be related to CDX-1140 in combination with CDX-301 have included the following:

Very common

(Out of 100 people who receive CDX-1140 and CDX-301, more than 20 people may have the following):

- Fatigue (tiredness)
- Fever
- Joint pain
- Muscle pain

Common

(Out of 100 people who receive CDX-1140 and CDX-301, 11-20 people may have the following):

- Chills
- Cytokine release syndrome, which may include symptoms such as fever, low blood pressure, and low blood oxygen levels
- Liver enzyme increase
- Hot flash
- Diarrhea
- Nausea
- Vomiting
- Headache
- Low blood pressure
- Decreased platelet count
- Low levels of salt in the blood

Less Common

(Out of 100 people who receive CDX-1140 and CDX-301, 6-10 people may have the following):

- Influenza like illness
- Dehydration (low fluids in body)
- Night sweats
- Increased blood creatinine
- Low levels of oxygen in the blood

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

Risks of Randomization
There is a risk that you may be assigned to a treatment group that is not the one your physician would choose for you.

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 or within 6 months after your last dose 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 you not impregnate anyone or donate sperm during your participation in this study or within 3 months after your last dose of study treatment. 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.

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 treatments for 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.

Celldex Therapeutics is providing the CDX-1140 and CDX-301 at no cost to you.

WILL I BE PAID FOR PARTICIPATING?

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

WHO IS FUNDING THIS STUDY?

The Foundation for Barnes-Jewish Hospital, the National Institutes of Health (NIH), and Swim Across America (through the Siteman Investment Program) as well as Celldex Therapeutics are funding this research study. This means that Washington University is receiving payments from the Siteman Investment Program and Celldex 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 Siteman Investment Program or Celldex 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) 362-7046 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 Celldex 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
- Celldex Therapeutics (manufacturer of CDX-301 and CDX-1140)

- Your primary care physician if a medical condition that needs urgent attention is discovered
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- The Siteman Cancer Center Clinical Trials Office
- The Quality Assurance and Safety Monitoring Committee (to monitor the conduct of this study)
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will make sure that your study information is kept secure. We will keep study information in a secure database that requires a username and password. You will have an opportunity to ask questions about this study privately. The research location will be in the clinic and treatment areas of the Center for Advanced Medicine where precautions are made to protect the privacy of all patients, not only research or non-research patients. We will store paper records (those containing identifiers and those that are de-identified) in a locked office in a locked suite and we will store electronic records (which will contain identifiers) in a password-protected database on a secure server. All biologic specimens will be stored in a coded fashion in a restricted-access lab.

The research team will send study results to Celldex Therapeutics. Information sent to Celldex will not be identifiable. Celldex will use this information to study the safety and effectiveness of the study drugs. In the future, Celldex may continue to use your health information that is collected as part of this study. For example, Celldex 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. Celldex may also share information from the study with regulatory agencies in foreign countries.

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

payer for any research injury. The payer will not use this information for any other purpose.

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

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

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

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.

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. Panni at (314) 362-7046. If you experience a research-related injury, please contact Dr. Panni 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: 10/08/24.

_____ _____
(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)