Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: Targeting pancreatic cancer with sodium glucose transporter 2 (SGLT2) inhibition

Principal Investigator: Kian-Huat Lim, M.D.

Research Team Contact: Kian-Huat Lim, M.D. – (314) 362-6157

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. Kian-Huat Lim having to do with the treatment of pancreatic cancer. Researchers are looking at adding a drug called dapagliflozin to regular chemotherapy given for pancreatic cancer. Dapagliflozin is commonly used to treat type 2 diabetes and heart failure, but researchers think that it can be used to help treat pancreatic cancer.

You are invited to be in this study because you have been diagnosed with pancreatic cancer and are planning to receive the standard chemotherapy drugs Gemzar and Abraxane. 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?**
   In this study, researchers will be looking at whether it's possible and safe for people with pancreatic cancer who are receiving standard chemotherapy to take dapagliflozin during their regular treatment. Dapagliflozin is approved by the U.S. Food and Drug Administration to reduce the risk of heart

failure and to improve glycemic control in patients with type 2 diabetes. However, the use of dapagliflozin is considered investigational in this study.

2. Why should I consider participating?

The purpose of this study is to test dapagliflozin alongside standard chemotherapy drugs to help treat pancreatic cancer. Researchers think that dapagliflozin can be used to help treat pancreatic cancer because it can change glucose metabolism in your body and decrease the availability of glucose to the tumor (which is something tumors need to grow).

3. What will I be asked to do?

This study includes some procedures you might have for your care if you weren't in this study as well as some procedures that are occurring for research only. We will ask you to take dapagliflozin once daily by mouth every day for up to 8 weeks. While you are taking dapagliflozin, you will have a physical exam every 2 weeks as well as weekly check-ins from the study coordinator, weekly weight checks, routine blood draws and urine monitoring, and blood draws for research purposes.

At home, you will also have daily ketone breath monitoring (where you breathe into a monitor to check for ketones, which will give researchers an idea of glucose metabolism) and weekly urine ketone monitoring.

You must stay hydrated (drink enough water), eat a "normal" amount of carbohydrates, and avoid drinking alcohol. An additional handout will be given to you that explains how you can do this.

You may choose to stop participating and withdraw from the study at any time. If you withdraw from the study, the research team may continue to use the information already collected about you.

4. What are the risks?

There are some risks to you if you agree to volunteer for this study. The most serious/most common risks are dehydration, yeast infection, and ketoacidosis. The risks to you are described in more detail later in this consent document.

5. What are the benefits to me? To others?

There may be no direct benefit to you. However, we hope that, in the future, other people might benefit from this study because it will help researchers learn more about new ways to treat pancreatic cancer.

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 Institutes of Health (NIH).

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 and are planning to receive, as part of your routine treatment, the standard chemotherapy drugs gemcitabine (Gemzar) and nab-paclitaxel (Abraxane).

The purpose of this research study is to look at whether it's possible and safe for people with pancreatic cancer who are receiving standard chemotherapy to take a drug called dapagliflozin during their regular treatment. Dapagliflozin is a drug that is commonly used to treat type 2 diabetes and heart failure, but researchers think that it can be used to help treat pancreatic cancer because it can change glucose metabolism in your body, and decrease the availability of glucose to the tumor (which is something tumors need to grow).

Dapagliflozin is approved by the U.S. Food and Drug Administration to reduce the risk of heart failure and to improve glycemic control in patients with type 2 diabetes. However, the use of dapagliflozin is considered investigational in this study.

The Biosense ketone breath monitoring device has 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.

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 and organ function (approximately 2 teaspoons of blood will be drawn from a vein in your arm)
- Blood test to check your hemoglobin A1c, which is a test that evaluates the average amount of glucose (sugar) in your blood over the last 2 to 3 months (approximately 1 teaspoon of blood will be drawn)
- Blood test to check your CA19-9, which is a protein in your blood; high levels of CA19-9 are

associated with pancreatic cancer (approximately 1 teaspoon of blood will be drawn)
- Pregnancy test if you are a person who can get pregnant (approximately ½ teaspoon blood will be drawn from a vein in your arm)
- CT scan (computerized tomography, which uses x-rays to create a picture of the bones and soft tissues in your body) or MRI scan (magnetic resonance imaging, which uses magnetic fields and radio waves to make detailed pictures of the inside of your body),to check the status of your disease. In some cases, a contrast medium will be used and you must not eat or drink anything for 4 hours before the test (the doctor will tell you if this is the case). A "contrast medium" is a liquid or solid that helps make a sharper image from the scan. Before the scan, you will need to remove all jewelry. During the scan, you will lie on your back on an X-ray table. A strap may be placed across your body to prevent movement so that the X-ray will be clear. The table will then slide into a large tunnel-shaped machine.

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 begin taking dapagliflozin at the time that you begin your standard chemotherapy (which you are receiving as part of your routine care and not as part of your participation in this study). Dapagliflozin is an oral drug which you will take once daily every day for up to 8 weeks, with or without food. Because it is an oral drug, you will be asked to complete a medication diary while you're taking it and to bring the medication diary with you to each study visit.

During the first 2 weeks, you will take 5 mg of dapagliflozin, and if you aren't having any unacceptable side effects, the dose of dapagliflozin you are taking will increase to 10 mg for the remaining 6 weeks. You will continue receiving chemotherapy after you discontinue the dapagliflozin provided your doctor finds that you are benefiting from that treatment.

While you are taking dapagliflozin, you will have the following tests or procedures:
- Physical exam, including talking about any symptoms or health problems you're having (Days 1 and 15 of each 28-day treatment cycle); you will also meet with an endocrinologist to review any side effects you might be experiencing
- Weekly phone call from the study research coordinator to check in
- Weekly weight check
- Blood and urine tests to check your blood counts and organ function (Days 1 and 15 of each 28-day cycle); you will be required to fast before these blood draws (no food after midnight and only sips of water)
- Blood tests for research purposes to look at how your body is metabolizing sugar (approximately 1 tablespoon of blood will be drawn on Cycle 1 Day 1 and Cycle 2 Day 15)
- Blood tests to check your CA19-9 levels (Cycle 1 Day 1 and Cycle 2 Day 1)
- At home daily BIOSENSE ketone breath monitoring (every day during study treatment; you will receive separate instructions describing how to accomplish this) and you may be asked to write down your daily results for the study team

- At home, urine tests to measure the levels of ketones in your urine (weekly during study treatment)
- Additionally, if you have diabetes, you may be asked to do a fingerstick to check your blood glucose levels during study treatment. The clinic team will guide you on the frequency and how to document, if necessary.

On Cycle 3 Day 1 of standard chemotherapy (the day after you complete study treatment with dapagliflozin), you will have the following tests and procedures:

- Physical exam, including talking about any symptoms or health problems you're having; you will also meet with an endocrinologist to review any side effects you might be experiencing
- Weight check
- Blood tests to check your blood counts and organ function; you will be required to fast before this blood draw
- Blood test to check your CA19-9 levels
- BIOSENSE ketone breath monitoring
- Urine tests to measure the levels of ketones in your urine
- Additionally, if you have diabetes, you will be required to do a fingerstick to check your blood glucose level
- CT or MRI scan, to check the status of your disease

Follow-up procedures:
After you finish study treatment, you may continue to receive standard chemotherapy provided your doctor feels you are benefiting. You will also have several follow-up assessments (in person, by phone, or by review of your medical record). Follow-up will be every 2 weeks for the first month after you complete study treatment and every 4 weeks for 3 months after that (for a total of 4 months of follow-up). During follow-up, we will collect information about your health status and wellbeing.

Will you save my research information and/or biospecimens to use in future research studies?

We would like to use the blood and data we are obtaining in this study 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 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 and data you give up any property rights you may have in the blood and data.

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

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

My blood 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 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 18 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 8 weeks of treatment and 4 months of follow-up. Each study visit may take as little as one hour or as long as an entire day depending on what procedures are occurring during that particular visit.

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 Dapagliflozin

Dapagliflozin can cause serious side effects, including:

- Dehydration, which may cause you to feel dizzy, faint, lightheaded, or weak, especially when you stand up; you may be at risk of dehydration if you:
  - Take medicines to lower your blood pressure, including water pills (diuretics)
  - Are 65 years of age or older
  - Are on a low salt diet
  - Have kidney problems
- Vaginal yeast infection, symptoms of which include vaginal odor, white or yellowish vaginal discharge (may be lumpy or look like cottage cheese), vaginal itching
- Yeast infection of the penis (balanitis), symptoms of which include redness, itching, or swelling of the penis, rash of the penis, foul smelling discharge from the penis, pain in the skin around the penis
- Ketoacidosis in people with diabetes (increased ketones in your blood or urine); stop taking dapagliflozin if you get any of the following symptoms:
  - Nausea
  - Vomiting
  - Abdominal pain
  - Tiredness
  - Trouble breathing
- Serious urinary tract infection that can lead to hospitalization, symptoms of which include a burning feeling when urinating, a need to urinate often, the need to urinate right away, pain in the lower part of your stomach, blood in the urine
- Low blood sugar (if you have diabetes), symptoms of which include headache, shaking or feeling jittery, irritability, fast heartbeat, weakness, drowsiness, sweating, confusion, dizziness, hunger
- A rare but serious bacterial infection that causes damage to the tissue under the skin in the area between and around the anus and genitals; seek medical attention immediately if you have fever or are feeling very weak, tired, or uncomfortable and you develop pain or tenderness, swelling, or redness in the area between and around the anus and genitals
- Stuffy or runny nose and sore throat
- Changes in urination, including urgent need to urinate more often, in larger amounts, or at night

Risks of Blood Draws

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 CT Scans

If you are scheduled for a CT with contrast, the dye that is injected into a vein for the scan is usually well tolerated. Some people feel dizzy, queasy, or get a headache when given the dye or notice a cold feeling near the injection site. There is a rare chance of having an allergic reaction to the dye that very rarely can be serious or life threatening. You must tell your doctor if you have had bad reactions to dyes before. There is also a rare chance that a CT scan may cause a 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.

Risks of MRI

Common risks:

- 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 risks:

- 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, cardiac stent, 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.

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 still birth or the baby could have skin diseases later in their childhood. If you are a woman of child-bearing age, you must have a negative urine pregnancy test within 24 hours prior to getting the gadolinium.

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.

Radiation Exposure in Women Capable of Becoming Pregnant
You may not participate in this study if you are pregnant. If you are capable of becoming pregnant, we will perform a pregnancy test before exposing you to research-related radiation. You must tell us if you may have become pregnant within the previous 14 days because the pregnancy test is unreliable during that time.

Risks of Radiation Exposure
This research involves exposure to radiation from 2 CT scans. Because of your condition, which may limit your life expectancy, there is little or no risk to you from the radiation exposure in this study. If you would like more information about radiation exposure, please see the "Radiation Fact Sheet" located at http://hrpo.wustl.edu/ or ask the study staff for a copy.

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.

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 new ways to treat 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, including receiving the same standard chemotherapy you'll be receiving when you're enrolled in this study
- 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.

WILL I BE PAID FOR PARTICIPATING?

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

WHO IS FUNDING THIS STUDY?

The National Institutes of Health (NIH) is funding this research study. This means that Washington University is receiving payments from the NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the NIH for conducting this study.

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

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at (314) 362-6157 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities

- The U.S. Food and Drug Administration
- The National Institutes of Health (NIH)
- 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. 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.

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

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

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

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or

others;
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

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

Are there additional protections for my health information?

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

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

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

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

If you decide not to sign this form, it will not affect
- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

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

If you sign this form:
- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at

https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.

- **If you revoke your authorization:**
  - The research team may only use and share information already collected for the study.
  - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
  - You will not be allowed to continue to participate in the study.

Can we contact you by email?
We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- Check in on any symptoms or side effects you may be experiencing
- Scheduling appointments

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your health information via email?

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

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. Lim at (314) 362-6157. If you experience a research-related injury, please contact Dr. Lim 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: 10/27/22.

_____ _____

(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)