Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: A Phase II Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate Uproleselan (GMI-1271) for GI Toxicity Prophylaxis During Melphalan-Conditioned Autologous Hematopoietic Cell Transplantation (auto-HCT) for Multiple Myeloma (MM)

Principal Investigator: Keith Stockerl-Goldstein, M.D.

Research Team Contact: Keith Stockerl-Goldstein, M.D. – (314) 454-8304

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

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

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you have been diagnosed with multiple myeloma and will be receiving a drug called melphalan as part of the autologous hematopoietic cell transplant you will be having. The melphalan and the transplant are part of your standard care.

Some of the most common side effects of melphalan include diarrhea, sores in the mouth and digestive tract and inflammation of the digestive tract. There are a number of treatments that are routinely given to help people who experience these side effects. The purpose of this research study is to look at how a drug called uproleselan performs in preventing these side effects from occurring in the first place or in decreasing their severity. In this study, participants will be randomly assigned (like the flip of a coin) to receive either uproleselan or placebo (something that looks like the study drug being used but does not contain any active medication) so that doctors can study the effects of uproleselan. Everyone will receive the other medications that are given routinely as standard of care to treat these side effects.

Uproleselan is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration.

WHAT WILL HAPPEN DURING THIS STUDY?

All treatment will be given in the inpatient setting at Siteman Cancer Center, and follow-up procedures may happen in the inpatient or outpatient setting. 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 tests to check how your blood is clotting (approximately ½ teaspoon of blood will be drawn from a vein in your arm)
- Blood tests to check for hepatitis or HIV (approximately 1 teaspoon of blood will be drawn from a vein in your arm)
- Blood will be drawn for a pregnancy test if you are a woman of childbearing potential (about ½ teaspoon of blood will be drawn from a vein in your arm)
- Bone marrow aspiration for research purposes (approximately ½ teaspoon of aspirate will be collected)

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 continue in the study, you will be randomly assigned, like the flip of a coin, to receive infusions of either uproleselan or placebo. Neither you nor your care team will know whether you are receiving uproleselan or placebo. This is called being "blinded."

You will be admitted to the hospital 3 days before your transplant day. You will receive infusions of uproleselan (or placebo) in the evening of the first day you're admitted (Day -3), then in the morning and evening on Days -2 and -1, and finally one last dose in the morning on Day 0, your transplant day. You will also receive the pre-transplant infusion of melphalan on Day -2 sometime after your third dose of uproleselan (or placebo). The infusion of melphalan and the transplant are not occurring because you are participating in this study; you would have these treatments anyway. The infusions of uproleselan (or placebo) are being given only because you are participating in this study.

In addition to those treatments, you will have the following tests or procedures while you are admitted to the hospital:

- Blood tests to check your blood counts and organ function (as per routine care, typically daily)
- Blood draw for research purposes on Days -3 and 0 (½ teaspoon of blood will be drawn from a vein in your arm)
- Some stool will be collected for research purposes on Days -3, 0, 8, and 14 (or the day you're

discharged, whichever comes first)
- Questionnaire to assess your quality of life on Days -3, 8, and 14 (or the day you're discharged, whichever comes first). You are free to skip any questions you prefer not to answer.

Follow-up procedures:
After you are discharged, you will return for follow-up visits on Day 30, Day 100, Month 6, and Month 12. After that, you will be contacted by phone or your medical record will be reviewed for another year to collect information on your health and wellbeing.

At your follow-up visits, you will undergo a physical exam, have approximately 2 teaspoons of blood drawn to check your counts and organ function, will be assessed for side effects, and will have a bone marrow aspiration as standard of care (on Day 100 only).

Will you save my research information and biospecimens to use in future research studies?
We would like to use the blood, bone marrow aspirate, stool, 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 multiple myeloma, 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, bone marrow aspirate, stool, and data you give up any property rights you may have in the blood, bone marrow aspirate, stool, 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, bone marrow aspirate, stool, 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, bone marrow aspirate, stool, and data for future research you should contact the research team member identified at the top of this document. The blood, bone marrow aspirate, stool, and data will no longer be used for research purposes. However, if some research with your blood, bone marrow aspirate, stool, and data has already been completed, the information from that research may still be used. Also, if the blood, bone marrow aspirate, stool, and data has been shared with other researchers it might not be possible to withdraw the blood, bone marrow aspirate, stool, 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, bone marrow aspirate, stool, 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, bone marrow aspirate, stool, 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 50 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 up to 2 years. There will be 3 days of treatment, an additional 2 weeks of active monitoring and specimen collection during the autologous hematopoietic cell transplant, and the remaining time will be passive follow-up.

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 Uproleselan

Uproleselan is an investigational medication; how it may affect humans is being studied. It is not known if you will have side effects from this medication and if uproleselan will cause additional side effects from ones caused by medications you are taking. As with any investigational medication, there is the possibility of side effects that are unknown or unforeseen at this time. There is always a chance that you can have an unexpected side effect, and possibly a severe side effect, including death, if you take part in this study. This can happen to people who take this or any other medication.

There is a chance that any other medications you may be taking could have a negative interaction with uproleselan. In a clinical research study like this one, not every risk or side effect can be known. Each person's reaction to a study medication may be different.

To date, a total of 189 study participants (86 healthy volunteers and 103 participants) have received uproleselan alone or with different chemotherapy medicines.

The following side effects considered by Study Doctors to be possibly caused by uproleselan treatment are shown below.

Very common (greater than10% of participants).

- nausea
- diarrhea

Common (5-9% of participants)

- headache
- back pain
- febrile neutropenia (fever when white blood cell count is low)
- fatigue (tiredness)
- decreased appetite
- thrombocytopenia (low number of platelets in the blood)

Less common (2-4% of participants)

- stomach pain or upper stomach pain
- chills
- vomiting
- constipation
- colitis (inflammation of the digestive tract)
- stomatitis (inflammation of the mouth and lips)
- infusion site pain
- pyrexia (fever)
- dysgeusia (distorted sense of taste)
- anemia (low numbers of red blood cells) or neutropenia (low levels of neutrophils, a type of white blood cell)
- platelet count decreased
- increased liver enzyme (aspartate aminotransferase)
- electrolyte imbalance (low potassium levels in the blood)
- dizziness
- arthralgia (pain in a joint)
- pneumonia (an infection in the lungs)
- pruritus (itchy skin) or rash

Rare (1% of participants)

- asthenia (physical weakness or lack of energy) or somnolence (sleepiness or drowsiness)
- electrolyte imbalances (including low calcium, magnesium or phosphate levels in the blood)
- musculoskeletal pain or neck pain or pain in extremity
- myalgia (muscle pain) or muscle spasms or muscular weakness
- increased liver enzyme (alanine aminotransferase)
- white blood cell or neutrophil count decreased
- sepsis (a severe type of infection)
- bradycardia (slow heart rate)

- dyspepsia (indigestion)
- chest discomfort
- edema peripheral (accumulation of fluid causing swelling; usually lower limbs)
- tumor lysis syndrome (when large amount of tumor cells is killed by treatment and contents enter the blood stream)
- alkaline phosphatase or ALP increase (elevated levels of ALP in the blood are most commonly caused by liver disease, bile duct obstruction, gallbladder disease, or bone disorders)
- increased bilirubin (yellowish substance in your blood)
- dry skin or generalized pruritus (itchy skin) or rash maculopapular (a specific type of rash)
- cough or dyspnea (difficult/labored breathing)
- hypoxia (low level of oxygen in the blood)
- stomach discomfort or swelling/stretching
- pulmonary edema (excess fluid in the lungs)
- sinus tachycardia (fast heart rate)
- restlessness
- hypertension/hypotension (high/low blood pressure)

Very rare (less than 1% of participants)

- enteritis or enterocolitis (inflammation of the digestive tract)
- stomach tenderness or symptoms
- ascites (the accumulation of fluid, causing abdominal swelling)
- digestive tract swelling or thickening or hemorrhage (bleeding)
- dry mouth or gum pain or blisters in the mouth or blisters on the tongue or oral candidiasis (yeast/fungal infection in the mouth)
- retching (to make the sounds and movement of vomiting without actually vomiting)
- tachycardia (fast heart rate)
- proctalgia (pain due to a spasm of the pelvic floor muscles, the muscles of the anal sphincter, or the muscles of the rectum)
- infusion site reactions such as redness or swelling or extravasation (leakage of intravenously infused into the tissue around the site of infusion)
- feeling hot or a burning sensation
- lack of energy
- eosinophilia (high levels of eosinophils; Eosinophils are a type of disease-fighting white blood cell)
- lymphadenopathy (disease of the lymph nodes, in which they are abnormal in size or consistency)
- dehydration
- hypoalbuminemia (level of albumin in the blood is low) or hyponatremia (level in sodium in the blood is low)
- international normalized ratio (INR) decrease (INR is a lab test to check how your blood clots)
- liver function test increases
- musculoskeletal stiffness
- weight changes (increase or decrease)
- electrocardiogram changes

- cellulitis (painful bacterial skin infection. It may first appear as a red, swollen area that feels hot and tender to the touch)
- clostridium difficile colitis (a bacteria that causes diarrhea and colitis (inflammation of the colon))
- enterococcal bacteremia or streptococcal bacteremia (types of bacteria that can cause a variety of infections)
- otitis media (inflammatory disease of the middle ear)
- upper or lower respiratory infections
- alopecia (hair loss)
- erythema multiforme (hypersensitivity reaction usually triggered by infections)
- palmar erythema (rare skin condition where the palms of both hands become reddish)
- palmar-plantar erythrodysesthesia (hand-foot syndrome causes redness, swelling, and pain on the palms of the hands and/or the soles of the feet. Sometimes blisters appear)
- purpura (purple-colored spots that are mostly seen on the skin)
- erythemeous or macular rash (specific types of rash)
- skin exfoliation (peeling skin)
- acute respiratory distress syndrome (lung injury that allows fluid to leak into the lungs)
- breathing becomes difficult and oxygen cannot get into the body or tachypnea (faster than normal breathing)
- nasal congestion or discomfort or nosebleed
- throat pain or swelling
- dry eye or pink eye or eye swelling or blurred vision or retinal hemorrhage (disorder of the eye in which bleeding occurs in the retina)
- anxiety or confused state
- painful urination or kidney injury or urinary tract infections
- transfusion reaction

Risks of Placebo

You may receive a placebo (an inactive substance) during this study. This means that you would receive no active study treatment while participating but will receive all standard of care treatments and supportive care for the gastrointestinal side effects you experience as a result of treatment with melphalan.

Risks of Randomization

Because chance decides whether you will receive uproleselan or placebo, your treatment may not be what your own doctor would choose for you if both options were presented to him/her to choose from.

Risks of Blood Draw

Possible side effects from a blood draw include fainting, feeling dizzy, 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 Bone Marrow Aspiration

It is likely that you will experience discomfort or pain, redness, swelling, and bruising at the site of the needle insertion. It is less likely that you will experience bleeding from the site of the needle insertion.

There is a rare chance (approximately less than 1/100) of developing a significant infection or bleeding from this procedure. An allergic reaction to the anesthetic may occur. A scar may form at the site of needle entry.

Risks of Testing for Reportable Diseases

If you decide to participate in this study, we will test you for hepatitis and HIV. The results of these tests could indicate that you have one of these conditions. If that happens, we will refer you to a doctor who specializes in treating your condition. We will make every effort to keep your personal information confidential. However, we are required by law to report certain positive tests to the state of Missouri and/or local agencies. The test results could also be reported to the Centers for Disease Control. You may be contacted by these agencies for more information. Becoming aware of a new diagnosis could have serious health, personal and/or social consequences. For more information about the risks of this testing, please talk to your study doctor.

Risks of Questionnaires

There is a risk that some of the questions may make you feel uncomfortable. You don't have to answer any questions you'd prefer not to answer.

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 for 12 weeks after you discontinue 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. 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 and for 12 weeks after you discontinue treatment. 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 ways to prevent or reduce melphalan-related gastrointestinal side effects.

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:

- receive standard of care treatments for melphalan-related gastrointestinal side effects
- take part in another research study

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.

GlycoMimetics, Inc., the manufacturer of uproleselan, is providing it 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 Barnes-Jewish Hospital Foundation is funding this research study. This means that Washington University is receiving payments from the BJH Foundation 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 BJH Foundation 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) 454-8304 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in

research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- GlycoMimetics, Inc., manufacturer of uproleselan
- 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 Siteman Cancer Center Clinical Trials Office
- The independent data and safety monitoring board (DSMB)
- 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 research team will send study results to GlycoMimetics, Inc. Information sent to GlycoMimetics will be deidentified and may be used to analyze the safety and effectiveness of the study medication. In the future, GlycoMimetics may continue to use your health information that is collected as part of this

study. For example, GlycoMimetics may combine information from this study with the results of other studies to re-analyze the safety and effectiveness of the study medication, to evaluate other products or therapies, to develop a better understanding of a disease, or to improve the design of future research studies. GlycoMimetics 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.

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 and/or text?

We would like to contact you by email and/or text for the purposes listed below. Some of these messages may contain health information that identifies you.

- Appointment reminders and scheduling
- Education
- Check-ins

Only the research team will have access to your email and/or text communications. We will only communicate in this method to send you the information listed above. If you have any questions, wish us to stop sending these messages 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 and/or text.

- Text messaging is not a secure communication method.
- There is always a risk that the message could be intercepted or sent to the wrong email address and/or phone number. To avoid this, we will send a test message to ensure we have the correct email address and/or telephone number.
- 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 or cell phone 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 messages sent or received on any electronic devices used for work or through a work server.
- If you lose your phone, others may be able to access the messages that we send.

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

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

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

_____ 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. Keith Stockerl-Goldstein at (314) 454-8304. If you experience a research-related injury, please contact Dr. Stockerl-Goldstein 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: 03/01/23.

_____ _____

(Signature of Participant) (Date)

_____

(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)