Washington University in St. Louis

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INFORMED CONSENT DOCUMENT – EXPANSION COHORT B

Project Title: Phase I Dose Escalation and Dose Expansion Study of Duvelisib Following Chimeric Antigen Receptor T-Cell Therapy

Principal Investigator: Armin Ghobadi, M.D.

Research Team Contact: Armin Ghobadi, M.D. – (314) 453-8304

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.

KEY INFORMATION

This is a research study conducted by Dr. Ghobadi having to look at the effects, good and/or bad, of treating people who are receiving CAR T therapy with duvelisib. 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. Before you decide whether to be in this study, you may wish to consider other options that are available to you. Instead of being in this study, you could receive CAR T therapy without taking duvelisib or participate in another study.

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, good and/or bad, of treating people who are receiving CAR T therapy with duvelisib.
- You were selected because you are eligible to receive a type of treatment for your cancer called chimeric antigen receptor T-cell therapy (CAR T therapy) as part of your regular cancer care.
- You will be in this study for approximately 7 months (6 months of treatment and 1 month of follow-up). The study team will continue to follow your health status for up to 5 years from your CAR T therapy.
    - Before you begin study treatment
        - Physical exam
        - Blood tests
        - Pregnancy test (if you are of childbearing potential)
        - PET/CT scan to check the status of your disease (unless you had a usable scan within that past 60 days)
    - During study treatment
        - Physical exams on Days 0, 3, 5, 7, 14, 21, 28, 42, 56, 70, 90, 120, 150, and 180
        - Blood tests on Days 0, 3, 5, 7, 14, 21, 28, 42, 56, 70, 90, 120, 150, and 180
        - PET/CT scan to check the status of your disease; this will occur on Days 28, 90, and 180

  - One month after you discontinue duvelisib, you will have a follow-up visit where a physical exam will be performed and you have blood drawn (approximately 2 teaspoons) to check your counts and organ function.
  - The study team will continue to follow your health status for up to 5 years after CAR T infusion by chart check or phone call.
- You will need to come to Siteman Cancer Center
- The main risks to you are
  - Common, some may be serious
    - Anemia, which may require blood transfusion
    - Pain
    - Diarrhea, nausea
    - Tiredness, fever
    - Infection, especially when white blood cell count is low
    - Cough
    - Rash
  - More detail about risks is provided below.
- 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 we hope it will help researchers learn more about ways to improve the outcomes of people receiving CAR T therapy.
- 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. 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 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 are eligible to receive a type of treatment for your cancer called chimeric antigen receptor T-cell therapy (CAR T therapy) as part of your regular cancer care.

One of the common side effects of CAR T therapy is called cytokine release syndrome, which is caused by a large, rapid release of cytokines into the blood from immune cells affected by the treatment. Cytokines are immune substances that have many different actions in the body. Signs and symptoms of cytokine release syndrome include fever, nausea, headache, rash, rapid heartbeat, low blood pressure, and trouble breathing. Most patients who experience cytokine release syndrome have a mild reaction, but sometimes, the reaction may be severe or life-threatening.

The purpose of this research study is look at the effects, good and/or bad, of treating people who are receiving CAR T therapy with duvelisib. Based on other studies, we believe duvelisib is a kind of drug

that might help prevent cytokine release syndrome and improve the effectiveness of CAR T therapy. However, the combination of treatment with these drugs has not been studied in depth, and the risks are unknown.

Duvelisib is approved by the U.S. Food and Drug Administration to treat relapsed or refractory chronic lymphocytic leukemia, small lymphocytic leukemia, or follicular lymphoma after at least 2 other treatments. However, the use of duvelisib is considered investigational in this study.

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 to complete the necessary testing. There may also be a wide variability in the length of clinic visits due to the unique characteristics of your medical history and health condition as well as due to clinic factors such as physician availability, staffing shortages, and weather delays. This will also vary depending upon your needs at the visit as determined by your physician. It is important that you are able to be available to complete the procedures at each visit to ensure that your safety and treatment needs are met.

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 counts and organ function (approximately 2 teaspoons of blood will be drawn) and for research (approximately 2 additional teaspoons of blood will be drawn)
- Pregnancy test (if you are of childbearing potential) (approximately 1 teaspoon of blood will be drawn)
- PET/CT scan to check the status of your disease; the PET (positron emission tomography) part of the scanner uses a radioactive tracer injected into a vein in your arm to make 3D images of structures in your body, while the CT (computed tomography) part of the scanner uses X-rays to create a picture of the bones and soft tissues in your body. 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 for 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 images will be clear. The table will then slide into a large tunnel-shaped machine. It is possible that if you have already had a scan within the past 60 days it can be used for the study and an additional scan will not be needed.

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

During study treatment:
If you are able to continue and you agree to take part in this study, you may begin the standard lymphodepleting regimen that takes place prior to the administration of the CAR T therapy. These treatments are being given as part of your regular care and are not study treatments.

Beginning on Day -2 (two days before the CAR T cell infusion), you will begin taking duvelisib by mouth twice a day. The dose of duvelisib you take will depend on how the people enrolled to this study before you have done. You should take duvelisib at the approximately the same times each day, with or without food. If you miss a dose by fewer than 6 hours, you should make your dose up – but if you miss a dose by more than 6 hours, or if you vomit a dose that you take, you should just wait and continue taking duvelisib with your next scheduled dose. You will be given a medication diary for recording each dose that you take, and you should bring that with you to each clinic visit.

You will take duvelisib from Day -2 through Day 180. You will receive continuous treatment with duvelisib from Day -2 to Day 28. You will then take 14 days off of therapy. You will restart duvelisib around Day 42 and continue until you have received five additional cycles of duvelisib. Each cycle is 28 days long and you will take duvelisib only on Days 1-14 of each cycle.

While you are taking duvelisib, you will have the following tests and procedures:

- 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, including assessing you for cytokine release syndrome. This will occur on Days 0, 3, 5, 7, 14, 21, 28, 42, 56, 70, 90, 120, 150, and 180.
- Blood tests will be drawn for the following purposes. Up to 12 total teaspoons will be drawn at each of these time points:
  - To check your counts and organ function on Days 0, 3, 5, 7, 14, 21, 28, 42, 56, 70, 90, 120, 150, and 180
  - To check for infection and to look at certain immune cells in your blood, which can tell your doctor how well your immune system is functioning, on Days 0, 3, 5, 7, 14, 28, 42, 56, 70, 90, 120, 150, 180, and at 1 year after CAR T infusion
  - You will also have blood drawn for research purposes on Days 0, 3, 5, 7, 14, 28, 42, 56, 70, 90, 120, 150, and 180.
- PET/CT scan to check the status of your disease; this will occur on Days 28, 90, and 180.

One month after you discontinue duvelisib, you will have a follow-up visit where a physical exam will be performed and you will have blood drawn (approximately 2 teaspoons) to check your counts and organ function.

The study team will continue to follow your health status for up to 5 years after you receive the CAR T therapy by chart checks or phone calls.

<u>Will you save my research information and/or biospecimens to use in future research studies?</u>
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, including possible genetic research. These studies may provide additional information that will be helpful in understanding cytokine release syndrome, 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.

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 the question below:

My blood 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 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 43 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 approximately 7 months (6 months of treatment and 1 month of follow-up). The study team will continue to follow your health status for up

to 5 years after the CAR T infusion by chart checks or phone calls.

WHAT ARE THE RISKS OF THIS STUDY?

The risks of combining duvelisib with CAR T therapy are not known. You may experience one or more of the risks indicated below from being in this study, and some risks may be severe or life-threatening. 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 Duvelisib

Common, some may be serious

- Anemia, which may require blood transfusion
- Pain
- Diarrhea, nausea
- Tiredness, fever
- Infection, especially when white blood cell count is low
- Cough
- Rash

Occasional, some may be serious

- Sores in the bowels
- Swelling of the body
- Severe blood infection
- Cold symptoms such as stuffy nose, sneezing, sore throat
- Bruising, bleeding
- Loss of appetite, weight loss
- Headache
- Kidney damage which may require dialysis
- Shortness of breath
- Damage to the lungs which may cause shortness of breath
- Dry skin

Rare and serious

- Skin rash developing 1-8 weeks after a drug is given which may be accompanied by fever, lymph node swelling and organ failure
- Severe skin rash with blisters and peeling which can involve the mouth and other parts of the body

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 PET/CT Scan

CT scans involve exposure to radiation. Although the amount of radiation exposure is higher than a typical X-ray, the risk of harmful effects from a single exam is very small. 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 medical devices. If you wear or have electronic medical devices such as a pacemaker or a drug pump, please make sure you tell your study doctors and research staff.

A PET scan uses a radioactive tracer to make 3D images of structures in your body. It is likely that you will experience discomfort from lying still on the enclosed scanning table. You may also experience claustrophobia. There is a slight risk of a possible allergic reaction to the injection of the radioactive tracer, which could include symptoms such as itching, a rash or hives, or difficulty breathing.

Risks of Radiation Exposure

This study will expose you to radiation from PET/CT scans, which are necessary to monitor your response to study treatment. You will receive up to 3 PET/CT scans during your participation in this study. You would receive these scans at approximately the same intervals if you were receiving any other treatment for your disease that was not part of a research project. Because only the frequency of the scans is dictated by this research study and the exact scanning parameters are not dictated, we cannot give you an exact amount of radiation exposure you will receive. Please be assured that modern scanners are designed and operated to keep your radiation exposure as low as possible. While it is true that you will be exposed to more radiation than a person in the general population, these scans are necessary because of your disease. If you want to know more about radiation exposure, please see the "Radiation Fact sheet" at http://hrpo.wustl.edu or ask the study staff for a copy.

Because certain research studies are subject to specific radiation exposure limits, it is important that you inform us if you have been in any other research studies in the last 12 months that involved exposure to radiation for research purposes (from X-rays, CT scans, PET scans or other nuclear medicine procedures). It is also important that you tell future investigators about your participation in this research study if you are asked to participate in another research study.

Risks to Women Capable of Becoming Pregnant

If you are a woman capable of becoming pregnant, we will ask you to have a pregnancy test before beginning this study. You must use effective birth control methods and try not to become pregnant while participating in this study. If you become pregnant, there may be unknown risks to your unborn child, or risks to your unborn child that we did not anticipate. There may be long-term effects of the treatment being studied that could increase the risk of harm to an unborn child. You must tell the doctor if your birth control method fails while you are on the study. If you believe or know you have become pregnant while participating in this research study, please contact the research team member identified at the top of this document as soon as possible. Please discuss with the research team how long you need to wait before becoming pregnant after completing the treatment or procedures on this study.

Risks of 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 to 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 we hope it will help researchers learn more about ways to improve the outcomes of people receiving CAR T therapy.

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 CAR T therapy without taking duvelisib or participate in another 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.

Secura Bio is providing the duvelisib 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?
Secura Bio, The Foundation for Barnes-Jewish Hospital, and the National Institutes of Health (NIH) are funding this research study. This means that Washington University is receiving payments from Secura Bio, The Foundation for Barnes-Jewish Hospital, and 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 Secura Bio, The Foundation for Barnes-Jewish Hospital, or 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) 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 and Secura Bio. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

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

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- Secura Bio, manufacturer of duvelisib
- The Foundation for Barnes-Jewish Hospital
- National Institutes of Health (NIH)
- 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.
- Siteman Cancer Center
- The Siteman Cancer Center Clinical Trials Office

- The Quality Assurance and Safety Monitoring Committee for monitoring 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.

The funding source for this research may require that we share the data from this study with others to make sure the results are correct and to use for future research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will ensure that all information about patients identified and recruited for this study is stored securely at Washington University. Any information that is collected about you for the purposes of this study will be stored either on paper in a locked cabinet in a locked office or in an electronic database, which requires a password in order to gain access. Your samples will be labeled with a study code. The research team will maintain a list that links you to that code in a separate location.

The research team will send study results to Secura Bio. Information sent to Secura Bio will be de-identified. Secura Bio may use this information and combine it with other research information to learn more about duvelisib as a preventive treatment for cytokine release syndrome. In the future, Secura Bio may continue to use your health information that is collected as part of this study. For example, Secura Bio 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. Secura Bio 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.

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.

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.

- Patient education, appointment scheduling

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 talk to the study doctor so any risks can be evaluated and so that follow-up care and testing can be arranged.

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 develop a major side effect, 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. Armin Ghobadi at (314) 454-8304. If you experience a research-related injury, please contact Dr. Ghobadi 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: 06/10/26.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

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

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)