INFORMED CONSENT DOCUMENT

TITLE: Early Phase I Evaluation of ^{64}Cu-LLP2A for Imaging Hematologic Malignancies Part B

PROTOCOL NO.: LLP2A-Part B
WCG IRB Protocol #20251948
202505198

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STUDY-RELATED PHONE NUMBER(S): 314-362-1242 (24 hours)

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

How long will I be in this research?
We expect that your taking part in this research will last up to 7 hours over 2 days for cohort 1B and up to 5 hours for cohort 2B.

Why is this research being done?
The purpose of this research is to evaluate an investigational imaging medication called ^{64}Cu-LLP2A in healthy volunteers and patients with multiple myeloma and lymphoma.

What happens to me if I agree to take part in this research?
If you decide to take part in this research study, the general procedures include:

- Cohort 1B (Healthy and Hematological disease volunteer): recording vital signs (blood pressure, heart rate, breathing rate and temperature) collecting and ECG (recording of the heart), placing an IV in vein of the arm, collecting laboratory samples and imaging at 2 time points on day 1 and returning the following day for follow up imaging.

- Cohort 2B (MM or low-grade lymphoma volunteers): recording vital signs (blood pressure, heart rate, breathing rate and temperature) collecting and ECG (recording of the heart), placing an IV in vein of the arm, collecting laboratory samples and imaging at 2 time points on day 1

Could being in this research hurt me?
The most important risks or discomforts that you may expect from taking part in this research include: discomfort from placing an IV and lying on the imaging table. Radiation exposure from the injection of the ^{64}Cu-LLP2A imaging medication and PET/CT scans. You might also be inconvenienced if there is a problem with the imaging medication or scanner and the scans cannot be completed as scheduled.

Will being in this research benefit me?
It is not expected that you will personally benefit from this research.

Possible benefits to others include developing a new imaging agent which might provide more information that helps to better plan treatments in the future.

What other choices do I have besides taking part in this research?
Instead of being in this research, your choices may include: receiving treatment as standard of care or as part of a treatment trial.

What else should I know about this research?
Other information that may be important for you to consider so you can decide whether to take part in this research is: For patients with multiple myeloma and lymphoma. This is an imaging only trial and does not provide any treatment. If you are a volunteer with cancer diagnosis, It is possible that participating in this trial could make you ineligible to participate in a different trial concurrently whose goal is to treat your disease.

There is a possibility that your deidentified information or biospecimens may be used or distributed for future research studies without your additional informed consent.

DETAILED RESEARCH INFORMATION

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 as a research participant.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are either a healthy volunteer or you have a diagnosis of multiple myeloma (MM) or lymphoma (referred to as disease or your disease).

The purpose of this study is to evaluate an imaging medication called ^{64}Cu-LLP2A. Currently, several different types of scans including CT, MRI and standard x-rays are used to provide doctors with a complete picture of the extent of disease. PET imaging with an imaging medication called FDG (a radioactive form of sugar) is often used in combination with a PET/CT scanner to get a picture of the metabolism or how active the multiple myeloma or lymphoma is in the body.

The goal of this study is to see if PET/CT scanning with ^{64}Cu-LLP2A can provide the same or more information about the status of your disease than has been obtained with the other scans that have already been obtained or will be obtained to assess the status of your disease.

The safety and tolerability of ^{64}Cu-LLP2Ais being studied. We will also look at the amount of ^{64}Cu-LLP2A that is found in cancerous and normal cells when it is injected into the blood stream and how the amount changes over time. ^{64}Cu-LLP2A is an investigational radioactive tracer that is not approved by the United Stated Food and Drug Administration.

WHAT WILL HAPPEN DURING THIS STUDY?

To participate in this study, you will be asked to read and sign this consent form before any study procedures are performed. The study team will determine if you are eligible to participate by reviewing your medical history, medical records, current medications and imaging scans. The study scans and scan results will be compared with testing that you have or will have done as your disease is staged and before you begin or change treatment.

All scanning will take place on a PET/CT scanner. The CT portion of the PET/CT scanner uses a low dose X-ray to take pictures of the inside of your body that can be combined with the PET scan. The PET/CT scanner looks similar to a standard CT scanner (tube with a table that moves through the tube while pictures are taken).

If you decide to participate you will undergo body ^{64}Cu-LLP2A-PET imaging at up to 3 different time points. On the day of the study, an intravenous (IV.) line will be inserted into a vein of your arm. The IV line will be used to draw blood samples for laboratory testing and to inject ^{64}Cu-LLP2A into your blood stream. In some patients, a second sample of blood will be drawn and used to be used to test the amount of study drug in the blood at different time points.

There are two cohorts or groups of people who will participate in this study: Which cohort you are assigned to will depend on when you enroll in the study and how many other people have been enrolled.

Cohort 1B: Will consist of up to 12 patients who will be imaged at 3 different time points. Cohort 1B will be made up of patients who are healthy volunteers or have disease. Healthy volunteers will have completed a telephone screening visit (approximately 15 minutes) prior to the imaging day that is used to confirm eligibility to participate.

Cohort 2B: Will consist of 30 patients with different types of disease (multiple myeloma and lymphoma)

Imaging Preparation All patients (approximately 30 minutes)

Prior to the start of imaging procedures, the following will occur:

- Review current medical history and medications
- Baseline assessment of how you are feeling before the start of any study procedures
- Vital Sign assessments: your current height and weight will be recorded along with your blood pressure, heart rate, breathing rate and temperature

- Electrocardiogram (ECG or EKG) this is a tracing to measure the electrical activity of your heart. Sticky electrode patches will be placed on your chest, arm and legs to measure the electrical impulses from your heart. The ECG machine does not emit electricity and there is no risk of shock.
- IV placement: An IV will be placed in a vein of your arm. The IV will be used to give you the injection of the study drug and to draw blood samples at different time points.
- Blood samples for baseline laboratory and metabolite assessments - approximately 3 teaspoons of blood will be drawn and sent to the lab to measure your blood count and organ function.
- If you are a female who is capable of being pregnant you will be asked to provide a urine sample for a pregnancy test

Blood for Metabolite Analysis (Some Patients) and Urine Collection (Cohort 1B)

- After the injection of ^{64}Cu-LLP2A occurs until you have completed all the imaging time points you will be asked to hydrate (orally or by IV) and to collect any urine that is voided
- Some participants will have blood drawn to test the amount of study medication in the blood stream or how the study medication moves through the blood stream. Samples may be drawn at baseline and / or approximately 60 minutes after study drug injection.

PET Imaging Cohort 1B (approximately 4-5 hours)

The PET imaging day for this cohort will consist of the following:

- 0-70 minutes: you will be asked to empty your bladder before being placed on the scanning table for injection of study drug and PET/CT imaging. While lying on your backside with your arms resting to your sides a series of scans from the top of your head to your upper thighs will be obtained after the study drug is given to you through your IV. A total of approximately 12 scans will be acquired over the first 60 minutes after you have received ^{64}Cu-LLP2A. The approximate time post injection for each scan will be as follows: 2, 4, 6, 8, 10, 15, 20, 25, 30, 40, 50 and 60 minutes. Each scan will take approximately 2 minutes to acquire. When a scan is not being performed you will be asked to rest quietly on the scanning table and remain as still as possible.
- Break – after the 60-minute scan you will be removed from the scanning table and allowed to take a break. During this time, you will be allowed to rest comfortably in a private room and your vital signs will be recorded. The amount of time you have for this break depends on the day of the week your scan is scheduled.
- Scan #2 – after emptying your bladder in the restroom you will be placed back on the scanning table. A scan from the top of your head to upper thighs will be acquired (approximately 20-30 minutes). Scan #2 will start either approximately 2 hours post study drug injection (for scanning on Tuesday or Thursday) or approximately 4 hours after study drug injection (for scanning on Wednesday or Friday).
- Scan #3 will occur the next day, approximately 15-28 hours after study drug injection. This will be done exactly the same way as scan #2 but will take longer to complete (approximately 45 minutes).

PET Imaging Cohort 2B (up to 4 hours)
The PET imaging day for patients with multiple myeloma or lymphoma will consist of the following:

- 0-70 minutes: you will be asked to empty your bladder before being placed on the scanning table for imaging. While lying on your backside with your arms resting to your sides you will be centered over a location that is known to have disease based on recent scans you have had. If you have not had any recent imaging the scan will be centered at your lower back/pelvis area. The scan will start with the injection of the study drug into your IV and continue for a total of 60 minutes.
- Break – following the first scanning session you will be removed from the scanning table and allowed to take a break. The amount of time you will be allowed to rest / relax will be based on the imaging results from the scans obtained in cohort 1B. Your break will be at least 30 minutes but may be as long as 4 hours or even until the next day. Your vital signs will also be recorded during this time
- Scan #2 – after emptying your bladder in the restroom you will be placed back on the scanning table. A scan from the top of your head to upper thighs will be acquired (approximately 20 -45 minutes)

All Subjects Imaging Day Discharge (approximately 30 minutes)
After imaging has been completed on scanning day #1 you will have the following tests / procedures before leaving the imaging center:

- Laboratory blood sampling: approximately 3 teaspoons of blood will be drawn from your IV and sent to the lab. The results will be compared to the samples that were collected at baseline and before study drug injection
- Vital Signs: your heart rate, breathing rate, pulse and temperature will be recorded
- ECG: another recording of your heart will be collected and compared to the baseline recording taken before study drug injection.

Follow up (approximately 15 minutes)
You will be asked how you have been feeling and whether or not you have experienced any problems since leaving the imaging center or after the biopsy procedure. (Alternatively, an in person visit if you are scheduled to be at the hospital for other reasons)

- Cohort 1B subjects will have a follow up assessment for adverse events on the day following study drug injection either before or after the scan on that day.
- Cohort 2B subjects will be contacted by telephone approximately 24 hours – 7 days following administration of study drug.

Blood and Tissue Testing
If you are a patient with multiple myeloma or lymphoma and you had a biopsy or testing performed as part of your diagnosis and there is left over tissue or blood that can be used for study testing and comparison to study scans we will request a small sample for testing as part of this project. You will not be asked to have a biopsy or tissue collected for any study specific testing.

Will you save my samples or research data to use in future research studies?
The blood, tissue and images we are obtaining in this study may be made available for studies going on right now as well as studies that are conducted in the future. These studies may be done by researchers at Washington University, other research centers and institutions, or private companies involved in research.

We may also share your research data with large data repositories (a repository is a database of information) for use by others, such as the research community, institutions, private companies and other researchers without additional consent from you. Therefore, you will not be informed of your individual results from future research projects.

If your individual research data is placed in one of these repositories, your name and other identifying information will be removed. All reasonable precautions will be taken to protect your privacy and confidentiality. Necessary approvals will be obtained to use the data. Certain summary information may be available to the general public.

These future studies may provide additional information that will be helpful in understanding multiple myeloma, lymphoma, or other diseases or conditions, including research to develop new commercial products such as diagnostic tests, treatments, drugs or devices . Should this occur, there are no plans to provide financial compensation to you. There are no plans to provide financial compensation to you should use of your blood, tissue or images occur. It is unlikely that what we learn from these studies will have a direct benefit to you. By allowing us to use your blood, tissue, and images, you give up any property rights you may have in the blood, tissue, and images. We will protect the confidentiality of your information to the extent possible.

Your scan data, blood and tissue (if applicable) will be stored without your name or any other kind of link that would enable us to identify which sample(s) or data are yours. Therefore, it will be available indefinitely for use in future research studies without your additional consent and cannot be removed.

HOW MANY PEOPLE WILL PARTICIPATE?
Up to approximately 42 people will take part in this study conducted by investigators at Washington University. Those who are unable or choose not to complete the study will be replaced.

HOW LONG WILL I BE IN THIS STUDY?
If you agree to take part in this study, your involvement will last for up to two days and you will be required to attend one or two study visits.

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.

IV Placement and Blood Drawing:

Mild / Likely: discomfort from placement of the IVs in your arm or hand or from the needle used to draw blood

Serious /Less Likely: There is a slight risk of bruising, some people feel dizzy or faint when an IV is placed or blood is drawn from them

Life Threatening / Rare: There is a rare risk of infection at the site of IV placement or blood drawing.

Vital Signs: You may feel discomfort from the squeezing of the blood pressure cuff around your arm.

ECG: You may feel discomfort from the placement and removal of the electrode patches from the skin. Remaining still while the ECG is taken (less than 1 minute) may cause anxiety.

Failed Tracer Production or Scanner Problems

There is a possibility that the ^{64}Cu-LLP2A study medication, which is made especially for you, will not be available on the planned day of scanning due to failed production, or that the scanner needed to perform your scan may not be working properly. These failures are possible and may not be known until you have arrived for your study procedure. This situation may be an inconvenience to you and a waste of your time. Depending on where you are with your treatment plan, another date for ^{64}Cu-LLP2A production and scan(s) may be scheduled if you are agreeable to returning on another day.

^{64}Cu-LLP2A Tracer Injection: ^{64}Cu-LLP2A is an investigational radioactive drug and is given in small ("trace") amounts. Based on the very low amount of the drug injected and the safety studies done in animals and humans to assess possible toxicity, no side effects are expected, however, you may notice the following at the time the study drug is given to you though your IV:

Likely / Common: pain or discomfort at the injection site this could include redness or bruising. Dysgeusia (distorted taste or a change in taste sensation – you may notice a metallic, or other unusual taste at the back of your throat following injection) this is common with many FDA approved radioactive drugs and the effect normally goes away within less than 1 minute.

Rare: There is a rare possibility of an allergic-type or other adverse reaction to radioactively labeled drugs. This could include symptoms such as difficulty breathing, unexplained rash, itching, hives, swelling, irregular heart beat and / or shortness of breath.

PET/CT Scan:

Mild / Likely: discomfort from lying on the imaging table including but not limited to backache, shoulder and arm discomfort and general feeling of stiffness following the scan.

Life Threatening / Rare: Malfunction of worn or implanted electronic medical devices from the CT scanner

Radiation Exposure: This study will expose you to radiation from the injection of an investigational radioactive drug, ^{64}Cu-LLP2A and CT scanning used as part of the PET/CT scan. The radiation exposure you will receive depends on which study group you are enrolled to:

- Cohort 1B: The radiation exposure you will receive is equal to approximately 42% of annual exposure for a radiation worker

- Cohort 2B: The radiation exposure you will receive is equal to approximately 32% of annual exposure for a radiation worker.

The risk from this level of radiation exposure is too small to be measured and is small when compared with other everyday risks. If you want to know more about radiation exposure, please see the "Radiation Fact sheet" on the Guidelines page of the Human Research Protection Office website, at http://hrpo.wustl.edu or ask the study staff for a copy.

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.

Sexually Active Male
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.

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, and we think the risk of accidental disclosure is very small. Please see the section in this consent form titled "How will you keep my information confidential?" for more information

Participation in future research studies: There is a risk that you would not be able to participate in other research or treatment protocols concurrently with this study and that you would need to complete a waiting period after this study before you would be allowed to participate in other research projects or studies.

WHAT ARE THE BENEFITS OF THIS STUDY?
You will not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because of the information learned from this study.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?
You will have costs for being in this research study. You will be asked to pay for:

- Cost to travel to the medical center up to two different times
- If applicable, cost associated with taking time off work to participate in the study

You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?
You will be paid for being in this research study. You will be asked to provide your social security number (SSN). You may also need to provide your address because payment will be made in the form of a check mailed to you. It can take up to 4-6 weeks for processing and delivery of the check to the address you provide.

We recognize and appreciate the time and effort to participate in a research study. The amount you will receive depends on which cohort of the study you are enrolled into and what procedures you undergo.

Subjects who participate will receive $100 for each imaging session completed, $50 for safety assessments and blood draws. Cohort 1B: $350 and Cohort 2B: $250

Overnight hotel stay(s) may be available if needed as well. If there is a problem with study drug production or the scanner and we are unable to start your study after you have arrived, you will be paid $25 for your time and trouble.

WHO IS FUNDING THIS STUDY?
The University and the research team are not receiving payment from other agencies, organizations, or companies to conduct this research 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 the telephone number listed on the first page of this form 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 listed below may become aware of your participation in this study and may inspect and copy records pertaining to this research, for example, past and present medical records, research records, and records about study visits and phone calls made as part of 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
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Hospital or Washington University representatives, to complete their 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.
- WCG IRB **(**An Institutional Review Board that has reviewed and approved this study).
- Siteman Cancer Center

Investigator Dr. Farrokh Dehdashti has received a Certificate of Confidentiality from the government which will help protect the privacy of research subjects. The certificate protects against the involuntary release of information about you collected during the course of this research. The researchers involved in this study cannot be forced to disclose any information collected in this study in any legal proceedings.

However, you may choose to voluntarily disclose the protected information and this certificate does not prohibit such voluntary disclosure. Furthermore, the parties listed in the Confidentiality / Authorization section of this consent form may review our records under limited circumstances and this certificate does not prohibit such disclosure.

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 above.

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA and may further be shared without your permission.

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 http://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 or text message?

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

- Appointment scheduling, confirmation of, or instructions related to parking, eating and drinking or other appointment related information and communication in case of problems with scanner and or imaging tracer.

Only the research team will have access to your email and 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 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 or phone number. To avoid this, we will send a test message to ensure we have the correct email address 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

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

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.

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 researchers might decide to end your participation in this research study earlier than planned. This might happen 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. Farrokh Dehdashti at 314-362-1474. If you experience a research-related injury, please contact: Dr. Dehdashti as well.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

OR

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445, or email hrpo@wusm.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.

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed consent document.

_____
Subject's Printed Name

_____ _____
Subject's Signature Date

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant . The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____
Signature of the Person Date
Conducting the Consent Discussion