Informed Consent/Authorization for Participation in Research

Title of Research Study:	^{177}Lu-PSMA-617 in Metastatic Castration Resistant Prostate Cancer (mCRPC) with Bone Marrow Involvement and Cytopenia
Study Number:	2024-1690
Principal Investigator:	Bagi RP Jana, MD
Sponsor:	MD Anderson Cancer Center
Drug Manufacturer:	Novartis Pharmaceuticals Corporation

_____ _____
Participant's Name Medical Record Number

Key Information

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are invited to take part in a research study because you have metastatic castration resistant prostate cancer (mCRPC) that has spread to the bone marrow, resulting in low blood cell counts.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The goal of this clinical research study is to learn if ^{177}Lu-PSMA-617 can help to control mCRPC that has spread to the bone marrow. The safety and effects of this treatment will also be studied.

This subset of mCRPC with bone marrow involvement has a poor prognosis and does not have an approved standard of care (SoC) nor clinical trials to study the efficacy and safety of agents that are currently approved for treatment of the mCRPC in patients with anemia and/or thrombocytopenia due to bone marrow infiltration of prostate cancer.

This is an investigational study. ^{177}Lu-PSMA-617 is FDA approved for the treatment of mCRPC in patients who have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy. It is investigational to give this treatment to patients with mCRPC that has spread to the bone marrow.

The study doctor can explain how the study treatment is designed to work.

How long will the research last and what will I need to do?

You are expected to be in this research study for about 6 months.

You will be asked to receive the study treatment and attend several study visits, at which various tests and procedures will be performed for routine and research purposes.

More detailed information about the study procedures can be found under ***"What happens if I agree to be in this research?"***

Is there any way being in this study could be bad for me?

Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. If you take part in this study, you may experience side effects. Lu-PSMA-617 may further worsen your anemia (low red blood cell count) and decrease platelet counts, so you may need a blood transfusion.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

It cannot be promised that there will be any benefits to you or others from your taking part in this research. Future patients may benefit from what is learned.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of your regular benefits.

Instead of being in this research study, you may choose to receive other investigational therapy, if available. Other investigational therapies have risks and benefits that may be the same or different than those in this research study. If other investigational therapies are available, the study doctor can discuss these, including their risks and benefits, with you.

You may choose not to have treatment for cancer at all. If you decide that you don't want any more active treatment, one of your options is called "comfort care." Comfort care includes pain medication and other support. It aims to maintain your comfort and dignity rather than cure disease. Usually, this care can be provided at home. If you think you might prefer comfort care, please discuss this with your family, friends, and your doctor.

In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

Who can I talk to if I have questions or concerns?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 713-563-0670.

This research has been reviewed and approved by the MD Anderson Institutional Review Board (IRB – an ethics committee that reviews research studies). You may talk to them at 713-792-6477 or IRB_Help@mdanderson.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be in this study?

It is expected about 40 people will be enrolled in this research study.

What happens if I agree to be in this research?

Screening Tests

Signing this consent form does not mean that you will be able to take part in this study. The following screening tests will help the doctor decide if you are eligible:

- You will have a physical exam.
- Blood (about 1-2 teaspoons) will be collected for routine tests, to check for viruses like hepatitis and HIV, and to check your testosterone and PSA levels.
    - Part of the blood sample will also be used for correlative testing. This testing is done for research purposes to better understand the profiles of patients who may or may not benefit from future treatments.
- You will have an EKG to check your heart function.
- You will have radiographic imaging scans (such as CT, MRI, PET-CT and/or bone scan) to check the status of the disease.
- You will have a bone marrow aspirate/biopsy to check the status of the disease. To collect a bone marrow aspirate/biopsy, an area of the hip or other site is numbed with anesthetic, and a small amount of bone marrow and bone is withdrawn through a large needle.
- You will have a PET/CT scan using the investigational contrast agent ^{68}Ga-PSMA-11 to see if the tumor cells have PSMA protein on their surface and to see where the cells are located in your body. This is required to ensure that the PSMA-

directed treatment acts on the tumor cells and that you are a candidate to receive such treatment. It gives off low-level radiation that does not kill cancer cells but identifies whether the tumor is likely to respond to PSMA-directed treatment such as ^{177}Lu-PSMA-617. This scan will be used to confirm that you are eligible to enroll on the study.
- If it is available, leftover tissue from an earlier procedure will be collected and used for correlative testing. If enough leftover tissue is not available for this research, you will have a tumor biopsy for this testing.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other treatment options will be discussed with you.

Study Drug Administration

If you are found to be eligible to take part in this study, you will receive ^{177}Lu-PSMA-617 by vein over 30 minutes 1 time every 6 weeks for up to a total of 4 cycles (1 cycle is 6 weeks). The status of the disease will be checked after the first 2 cycles. If you are responding to treatment and not experiencing any serious side effects, then you will receive 2 more cycles of treatment and then the status of the disease will be checked again.

Study Visits

On **Day 1 of each cycle**:
- You will have a physical exam.
- Blood (about 1-2 teaspoons) will be drawn for routine tests and to check your PSA levels. Some of these draws will also be used to check your testosterone levels.
- On Day 1 of Cycle 3, you will have an EKG.

Additionally, **every 2 weeks** during the treatment cycles, blood will be drawn for routine tests.

Between **Cycles 2 and 3 (Days 70-84):**
- You will have a PSMA PET scan and the other imaging scans you had at screening (CT, MRI, PET-CT and/or bone scan) to check the status of the disease.
- Blood (about 1-2 teaspoons) will be drawn for correlative testing.
- You will have a bone marrow aspirate/biopsy to check the status of the disease.

If the disease gets worse while you are on study, blood (about 1-2 teaspoons) will be drawn for correlative testing.

End-of-Treatment

About 42 days after your last dose:
- You will have a physical exam.
- Blood (about 1-2 teaspoons) will be drawn for routine tests and to check your PSA and testosterone levels.

- You will have an EKG.
- You will have the imaging scans you had at screening (CT, MRI, PET-CT and/or bone scan) to check the status of the disease.

Long Term Follow-Up

Every month after your last dose of study drug for 1 year or until the disease gets worse (if that happens), whichever occurs first:

- You will have a physical exam.
- Blood (about 1-2 teaspoons) will be drawn for routine tests, to check your PSA and testosterone levels, and for correlative tests.
- If the disease gets worse during the follow-up period, blood (about 1-2 teaspoons) will be drawn for correlative testing.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for the following:

- Tell the study team about any symptoms or side effects you have, follow study directions, and come to all study appointments (or contact the study team to reschedule).
- Tell the study doctor/study staff about all medications that you are taking or plan to take, including prescription and over-the-counter medications, supplements, vitamins, and herbal remedies.

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you. You may withdraw from participation in this study without any penalty or loss of benefits. If you withdraw from this study, you can still choose to be treated at MD Anderson.

If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor who can help you safely stop study treatment. The study doctor will also decide if you need to have any visits or tests to check on your health.

If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Is there any way being in this study could be bad for me? (Detailed Risks)

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after treatment is stopped, but in some cases side

effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Side effects will vary from person to person, and some may occur after you have stopped receiving treatment. Tell the study staff about any side effects you may have, even if you do not think they are related to the study drugs/procedures.

^{177}Lu-PSMA-617 Side Effects

Common (occurring in more than 20% of patients)

• abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure)	• low blood cell counts (red, white, platelets) • abnormal liver test (possible liver damage) • constipation • loss of appetite • nausea	• dry mouth • abnormal kidney test (possible kidney damage) • fatigue

^{177}Lu-PSMA-617 may commonly cause low blood cell counts (red, white, and/or platelet) in 10-30% of patients:

- A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood transfusion.
- A low platelet count increases your risk of bleeding (such as nosebleeds, bruising, stroke, and/or digestive system bleeding). You may need a platelet transfusion.
- A low white blood cell count increases your risk of infection (such as pneumonia and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

Occasional (occurring in 3-20% of patients)

• high blood pressure • dizziness • headache • dizziness • muscle and/or bone pain • weight loss • fever	• diarrhea • abdominal pain • vomiting • abnormal taste • blood in the urine • kidney injury • swelling (arm/leg)	• severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure) • dry eyes

Rarely (in fewer than 3% of patients), the study drug may cause a blockage in the lung (possible pain and/or shortness of breath).

As with any radioactive treatment, there is a risk for long-term side effects related to the amount of radioactivity after receiving the study drug compared to standard of care imaging radiation. The risk is mainly a possible long-term effect of damage to the kidneys and/or the development of another primary cancer. Both are rare occurrences with the standard regimen of 6 doses that was evaluated in the previous study with ^{177}Lu-PSMA-617.

A small number of study patients have had strokes and/or bleeding around the brain. It is not certain if this was related to study treatment. If you fall, hit your head, or develop unusual symptoms like drowsiness, confusion, or disturbances of speech, movement or sensation, you or your caregiver should contact your study doctor immediately. In addition, please notify the study doctor if you are currently taking or if you are prescribed a blood thinning medication during the course of the study.

In the days right after you receive ^{177}Lu-PSMA-617, you will need to take steps to prevent radiation exposure to the people around you. The radioactive medicine you received will gradually change to a non-radioactive form. This process releases radiation, which is similar to an X-ray. The amount of radiation released will decrease with time and will eventually go away.

You can reduce the radiation exposure to the others by keeping your distance, avoiding close contact, and decreasing time spent close to them. You should increase the amount of fluids you drink on each day you receive treatment and the day after that, in order to flush the drug through your system more quickly and minimize the risk of radiation side effects to your bladder.

You must avoid close contact with people who live with you by trying to stay at least 3 feet away from other people (including your spouse/family) for at least 3 days after you receive ^{177}Lu-PSMA-617 (and at least 7 days for children younger than 10 and pregnant women). You must also avoid all sexual activity for 7 days.

You will need to take other precautions with certain activities, such as using the bathroom, taking a shower, doing your laundry, and throwing out your trash. Your doctor will review these activities after you receive the study drugs and give you written instructions to follow after you leave the clinic. Make sure you keep these instructions with you at all times, especially when travelling.

Please review the discharge instructions provided after each dosing visit to receive more complete instructions about these precautions.

Gallium 68 Dotatate PET/CT Scan Side Effects

At this time, there are no side effects that are known to occur in more than 3% of patients.

Rare but serious (occurring in fewer than 3% of patients)

• low blood pressure (possible dizziness/fainting) • slow heartbeat • flushing	• headache • fever • dizziness • weakness • sweating	• nausea • low red blood cell counts • abnormal liver tests (possible liver damage) • joint pain

Gallium 68 dotatate PET/CT scans may cause low red blood cell counts.
A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood transfusion.

Other Risks

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

Having **bone marrow biopsies/aspirates** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsies. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy site.

EKGs may cause discomfort while lying on the exam table, and the tape on the EKG pads may cause skin irritation.

During the **MRI**, you may feel mild vibrations throughout your body. The machine will produce a loud knocking noise. This is normal. You will be given earplugs to protect your ears. Some people, especially those who tend to feel uncomfortable in small or closed spaces, may feel “closed in” and become anxious while in the scanner. The scanner has an intercom, which will allow you to speak to the staff during the procedure. If you feel ill or anxious during scanning, tell the MRI staff and the scanning will be stopped if you wish. The MRI will require a catheter to be inserted into one of your veins in order to inject the MRI contrast agent. This may cause skin irritation, bleeding, and/or infection. You may have an allergic reaction to the contrast agent.

The magnetic field used in MRI scanning may harm you if you have certain types of metal in your body (as might be found in pacemakers, neurostimulators, or certain clips). It may cause problems with devices, such as pacemakers. If you have metal in

your body or devices such as a pacemaker, you should discuss this with the study doctor.

CT scans send x-rays through the body at many different angles. You will be exposed to a small dose of radiation. All radiation adds up over a lifetime and may increase the risk of new cancer forming. Some people may feel “closed in” while lying in the scanner. However, the scanner is open at both ends, and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or radiology technicians will give comfort, or the scanning will be stopped. Solution may also be given by vein to make the x-ray pictures more accurate. This may cause an uncomfortable feeling of warmth, nausea, and/or severe allergic reactions. The solution injection may also cause pain, bleeding, bruising, hives, and/or itching.

A **PET scan** may cause you to feel “closed in” while lying in the scanner. However, the scanner is open at both ends and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or technicians will give comfort or the scanning will be stopped.

The PET scan exposes your body to radiation. The radioactive solution does not remain in your system for a long period of time. However, you should wait 2 hours before holding an infant or getting close to a pregnant woman to avoid exposing them to radiation. You should drink fluids after the scan to help remove the solution from your system.

A standard **bone scan** exposes you only to the radiation that comes from injecting the standard radioactive imaging solution for bone imaging.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

You will be told about any new information that may affect your health, welfare, or choice to stay in the research.

Pregnancy Related Risks

Taking part in this study can result in risks to an unborn baby, so you should not father a child or donate sperm while on this study and for at least 6 months following your last dose of ^{177}Lu-PSMA-617. You must use birth control during the study and for at least 6 months following your last dose of ^{177}Lu-PSMA-617if you are sexually active. Tell the doctor right away if your partner becomes pregnant or suspects pregnancy. Talk to the study doctor about the birth control method(s) you and/or your partner should use.

Will it cost anything to be in this study? Will I be paid to be in this study?

^{177}Lu-PSMA-617 and ^{68}Ga-PSMA11 for PET PSMA will be provided at no cost to you on this study.

You and/or your insurance provider will not have to pay for certain research exams and procedures done that are covered by the study. These include archival tissue sample testing, bone marrow biopsy/aspirate, single 12-lead electrocardiograms, research imaging scans (SPEC/CT scans), and the GA-PSMA-11 PET/CT CABI scans.

You and/or your insurance provider will be responsible for the costs of routine clinical services (such as diagnostic/therapeutic procedures, drugs, devices, laboratory assays, and other services that would ordinarily be ordered for medical care, regardless of whether or not you are participating in a study). These include the optional Ga-PSMA-11 PET/CT scan, the PSMA PET scan, and routine imaging scans to check the status of the disease. There may be extra costs that are not covered by your medical plan that you will have to pay yourself.

Taking part in this study may result in added costs to you (such as transportation, parking, meals, or unpaid leave from work). You may have to pay for medication prescribed to treat or prevent side effects, and you may have to visit the clinic/hospital more often than if you were not participating in this study.

If you have insurance, talk to your insurance provider and make sure that you understand what your insurance pays for and what it does not pay for if you take part in this study. Also, find out if you need approval from your plan before you can take part in the study.

You may ask that a financial counselor be made available to you to talk about the costs of this study.

You will not receive any compensation for taking part in this study.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who need to review this information. Complete secrecy cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Any personal information that could identify you will be removed or changed before data are shared with other researchers or results are made public.

The sponsor, monitors, auditors, the IRB, and the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. The results of this research may be published. However, your name and other identifying information will be kept confidential.

Federal law provides additional protections of your medical records and related health information. These are described below.

Will my data or samples be used for future research?

Your personal information and/or samples are being collected as part of this study. These data and/or samples may be used by researchers at MD Anderson and Novartis or shared with other researchers and/or institutions for use in future research.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the MD Anderson IRB before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

Some of your specimens and genetic and/or health information might also be placed into one or more external publicly-accessible scientific databases. Your name and other information that could directly identify you (such as your address or social security number) will never be placed into these external databases. A researcher who wants to study information from these databases must have an approved study and work with the group overseeing the database to obtain the information.

Can I be removed from the research study without my permission?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include:

- It is in your best interest.
- You have a side effect that requires stopping the research.
- The research is stopped by the FDA or the sponsor.
- You are unable to keep your scheduled appointments or follow the study directions.

What happens if I get hurt from being in this study?

If you become injured or ill and it is related to your participation in this study, you will be given care at MD Anderson (if you are at the clinic). If you become injured or ill and you are not at the clinic (for example, you are at home or at another doctor's office):

- call your personal doctor right away (or in an emergency, call 911)
- tell your personal doctor or ER staff that you are in this study (try to give them a copy of this consent form)
- call the study doctor (Dr. Jana, at 713-563-0670) or 713-792-2121 (24 hours)

A research-related injury is an illness directly caused by your participation in the study. A research-related injury does not include:

- injuries directly caused by the natural worsening (progression) of an underlying disease or medical condition, or
- injuries caused by you not following the instructions in this consent form.

You will not be reimbursed for expenses or receive any money from MD Anderson or Novartis, the Drug Manufacturer, for this injury. Costs of treatment received because you become injured or ill will be billed to you or your insurance company. No other form of payment is available.

You may also contact the MD Anderson IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

What else do I need to know?

This research is being funded by Novartis Pharmaceuticals Corporation, who is the manufacturer of the study drug.

MD Anderson may benefit from your participation and/or what is learned in this study.

Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will not contact you to let you know what they have found.

This research study involves genetic testing. The Genetic Information Nondiscrimination Act (GINA) prohibits health insurers or health plan administrators from requesting or requiring genetic information of you or your family members, or using such information

for decisions regarding your eligibility for insurance or your premiums. However, this law does not provide the same protection for disability, life insurance, or long-term care insurance. GINA also prohibits most employers (with 15 employees or more) from using genetic information when making decisions on your employment, including decisions related to hiring, firing, promotion, pay, and job assignments. Please contact the study doctor if you would like more information about GINA and how it protects you from genetic discrimination.

This research study involves genetic testing, which will include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you.

Optional Procedures for the Study

You do not have to agree to the optional procedure(s) in order to take part in this study. There are no benefits to you for taking part in the optional procedures. Future patients may benefit from what is learned. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedures.

Optional Procedure #1: If you agree, you will have an additional PSMA PET scan at the End-of-Treatment visit.

Optional Procedure Risks: The risks of PET scans are listed in the “Other Risks” section.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES
Circle your choice of “yes” or “no” for each of the following optional procedures:

Optional Procedure #1: Do you agree to have an additional PSMA PET scan at the End-of-Treatment visit?

YES NO

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:

- Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP) and governmental agencies in other countries where the study drug may be considered for approval
- The IRB and officials of MD Anderson
- Novartis, the Drug Manufacturer, and its authorized agents and/or any company to which Novartis transfers its right to the study drug or rights and responsibilities as Drug Manufacturer
- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will do its best to protect the privacy of your records, but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by federal law.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. 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.

F. You have the right to review and correct certain PHI. However, during the study, access to the PHI may be limited to protect the integrity of the study. You may have access to your PHI at the end of the study.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE
A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT