Informed Consent/Authorization for Participation in Research

Title of Research Study: Phase II study of REPotrectinib with or without fulvestrant in patients with hormone receptor-positive human epidermal growth factor 2-negative metastatic invasive LObular carcinoma who received a prior endocrine Therapy in combination with cyclin-dependent kinase 4 and 6 inhibitor (REPLOT Trial)

Study Number: 2024-0099

Principal Investigator: Jason Mouabbi, M.D.

_____ _____
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 a certain type of invasive lobular carcinoma (breast cancer) that is metastatic (has spread to other parts of the body).

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 find out if the drug repotrectinib, given alone or in combination with fulvestrant, can control the disease in patients with metastatic invasive lobular carcinoma. The safety of this drug and combination will also be studied.

The study drugs are FDA approved to treat other types of cancer, including other types of breast cancer. Their use in treating metastatic invasive lobular carcinoma is considered investigational. The study doctor can explain how the drugs are 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 as long as the doctor thinks you are benefiting.

You will be asked to come to the clinic for study visits at least 1-2 times a month. During these visits, you will complete certain tests and procedures, including physical exams, blood tests, tissue biopsies, and imaging scans.

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?

Early studies with repotrectinib showed a good side effect profile with most side effects being mild. Side effects of this treatment may include dizziness, taste changes, and numbness.

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?

Treatment with the study combination may help to control the disease. It cannot be promised that there will be any benefits to you or others from your taking part in this research. However, future patients may benefit from what is learned on this study.

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, your choices may include fulvestrant in combination with capivasertib, alpelisib, or everolimus. These alternative treatments have risks and benefits that may be the same or different than those in this research study. The study doctor can discuss these alternative treatments, including their risks and benefits, with you.

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 713-792-2817.

This research has been reviewed and approved by an 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 58 people at MD Anderson 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 be performed within 28 days before your first scheduled dose of therapy to help the doctor decide if you are eligible:

- You will have a physical exam. In this study, physical exams may also included recording of your ability to perform everyday activities (your performance status) and measurement of your vital signs (such as heart rate, blood pressure, and temperature).
- Blood (about 2 teaspoons) will be drawn for routine safety tests.
- If you can become pregnant, urine will be collected for a pregnancy test. In order to take part in the study, you must not be pregnant.
- You will have CT scans of the chest, abdomen, and pelvis, as well as x-rays of your bones (bone scan).
- Leftover tissue from an earlier procedure will be used for research testing, including immune system testing and genetic research testing. If leftover tissue is not available, a fresh tissue biopsy may be collected for this testing. The study team can explain this in more detail.

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 Groups

If you are found to be eligible to take part in this study, you will be assigned to a study group based on when you enroll in the study and what earlier therapies you have had.

Safety Run-in

The first 6 participants will be part of a safety run-in group. These participants will receive 1 study cycle of repotrectinib plus fulvestrant. If no serious side effects are seen during that first cycle, the study will open to enrollment to both Cohort 1 and Cohort 2. These first 6 patients will be part of Cohort 1 and continue receiving the study drug combination.

Cohort 1

Cohort 1 will include participants who have either never received fulvestrant or who previously received fulvestrant in combination with another agent but stopped receiving it for reasons other than the disease getting worse. The first 15 participants enrolled in Cohort 1 will receive the study drug combination starting on Day 1 of their first treatment cycle. The next 14 participants enrolled in Cohort 1 will begin with fulvestrant alone for at least 12 days and then start repotrectinib sometime between Days 13 and 20 (depending on when their Cycle 1 biopsy is performed). This is done in order to use the biopsy results to study the effects of fulvestrant alone in these patients.

Cohort 2

Cohort 2 will begin enrolling up to 29 participants who have received fulvestrant in earlier treatments. Participants in Cohort 2 will receive repotrectinib alone.

Study Drug Administration

- **Fulvestrant** is given as an injection into the muscle on Day 1 and 15 of Cycle 1 and Day 1 of every cycle after that.
- **Repotrectinib** is taken by mouth in capsule form 1 time every day. If the drug is well tolerated, your dose may be increased to 2 times a day, starting at Day 15 of Cycle 1. The study team can discuss this with you as needed.

If needed for your safety, Repotrectinib may be taken with or without food. Repotrectinib should be swallowed whole (not chewed or cracked). Do not take a repotrectinib capsule if it is broken, cracked, or otherwise not intact. Repotrectinib should be taken at the same time each day, and you should not take more than the prescribed dose at any time. If you miss taking your scheduled dose by at least 12 hours or if you vomit after taking your dose, do not try to make it up or take extra the next time; just take your next scheduled dose as prescribed.

The study staff will give you a drug diary to write down when you take each dose of repotrectinib, as well as any missed or vomited doses. You will be asked to bring your drug diary, as well as any unused doses and your pill bottles, to each clinic visit.

Study Visits
Each study cycle is 28 days.

At **most study visits**, you will have procedures that would be done as part of your routine care doctor visits. These may include recording your performance status, measuring your vital signs, and/or being asked about the drugs or medications you are taking and the side effects you may be having.

Up to **2 weeks before Day 1 of Cycle 1**, you will have an image-guided core biopsy of tumor tissue. To perform an image-guided biopsy, a needle is inserted into the affected area using imaging such as CT, ultrasound, or MRI to collect cells or tissue from an organ, lymph node, or suspected tumor mass. The doctor will use the imaging to guide the needle into the area. To perform a core biopsy, a sample of tissue is removed using a hollow core needle that has a cutting edge. This biopsy is performed for biomarker research testing (including genetic biomarker research). Biomarkers are found in the blood/tissue and may be related to your reaction to the study drug.

On **Day 1 of Cycle 1**:
- You will have a physical exam.
- Blood (about 4 teaspoons) will be drawn for routine safety tests, tests to measure the amount of circulating tumor DNA (ctDNA) in your blood, tumor marker testing, and immune system research testing. ctDNA testing measures the amount of free-floating genetic material from tumor cells in your blood. Tumor markers may be related to the status of the disease.

On **Day 15 of Cycle 1**:
- You will have a physical exam.
- Blood (about 4 teaspoons) will be drawn for ctDNA testing, immune system testing, and tumor marker testing.
- You will have an image-guided core tumor biopsy performed for biomarker research testing.

On **Day 1 of Cycles 2 and beyond**:
- You will have a physical exam.
- Blood (about 2 teaspoons) will be drawn for routine safety tests.

On **Day 1 of Cycles 2, 4, 6, and then every 3 cycles after that**, you will have imaging scans (CT and bone scans) to check the status of the disease. If your cycles are delayed for any reason, you will still have these scans every 8 weeks for the first 24 weeks, and then every 12 weeks after that.

End-of-Treatment Visit
- Blood (about 3 teaspoons) will be drawn for routine safety tests, ctDNA testing, and tumor marker testing.

Follow-up

You will be followed for 30 days after you leave the study. If you leave the study due to intolerable side effects, you will be followed closely until the side effect resolves. Your health status will be checked by the study team every 12 weeks through in-person contact at routine clinic visits and/or checks of your medical record.

Other Instructions

- You should tell the study team what other drugs, over-the-counter medications, and herbal or dietary supplements you are taking while you are receiving this treatment. Some drugs and substances may interact with the study treatment or prevent it from working, while others may cause interactions that may be serious or life-threatening.
- You should not eat grapefruit, Seville oranges, pomelos, or star fruit, or consume any products with these fruits, because they can interact with the study drug.

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

If you take part in this research, you will be responsible for telling the study team about any symptoms or side effects you have, following study directions, and coming to all study appointments (or contacting the study team to reschedule).

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.

If you decide to leave the research, contact the study doctor so that the study doctor can help you stop study treatment safely. If you withdraw from this study, you can still choose to be treated at MD Anderson.

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.

Fulvestrant Side Effects

Common (occurring in more than 20% of patients)

• fatigue • nausea • diarrhea	• low blood cell counts (red, white)	• abnormal liver tests (possible liver damage) • infection

Fulvestrant may cause low blood cell counts (red blood cells and/or white blood cells):

- A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood 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)

• swelling (arm/leg) • hot flash • headache • dizziness • fever • hair loss (partial or total) • skin rash • itching • low blood sugar	• low blood levels of albumin (possible swelling, weakness, and/or fatigue) • low blood levels of phosphate (possible bone damage) • loss of appetite • vomiting • constipation • mouth blisters/sores (possible difficulty swallowing)	• abnormal taste • abdominal pain • low blood cell count (platelets) • pain • weakness • cough • difficulty breathing • injection site pain

Fulvestrant may cause a low platelet cell count. 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.

Frequency Unknown

• blood clots in a vein (possible pain, swelling, and/or redness) • pain shooting from the lower back to the thighs	• uterine and/or vaginal bleeding • liver damage • nerve damage (possible numbness, pain, and/or loss of motor function)	• liver failure • nerve pain • abnormal kidney test (possible kidney damage)

Repotrectinib Side Effects

Common (occurring in more than 20% of patients)

• difficulty walking • mental status change (such as memory loss and impaired thinking) • inability to speak • confusion • delirium (loss of contact with reality) • difficulty concentrating • hallucinations (seeing or hearing things that are not there) • memory loss	• dizziness • fatigue • headache • muscle weakness • nerve damage (possible numbness, pain, and/or loss of motor function) • low blood sugar • high blood sugar (possible diabetes) • high blood levels of sodium (possible weakness and/or swelling)	• high blood levels of uric acid (possible painful joints and/or kidney failure) • constipation • abnormal taste • increased risk of bleeding • abnormal liver test (possible liver damage) • muscle damage and/or muscle breakdown • difficulty breathing

Repotrectinib may cause low blood cell counts (white blood cells and red blood cells).

- 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.
- A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood transfusion.

Occasional (occurring in 3-20% of patients)

• swelling • fever • weight gain • diarrhea	• nausea/vomiting • falling • muscle pain • visual disturbance	• low oxygen level in the blood (possible lightheadedness) • build-up of fluid around the lungs • cough

Using the study drugs together may cause side effects that are not seen when each is given alone. The study drug combination may also increase the frequency and/or severity of the side effects listed above.

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 **biopsies** 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.

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.

X-rays send a small amount of radiation though the body. All radiation adds up over a lifetime and may increase the risk of a new cancer forming.

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 or breastfeeding baby, so you should not become pregnant, breastfeed a baby, or father a child while on this study. You must use birth control during the study and for at least 7 months after your last dose of the study drugs, if you are sexually active.

Birth Control Specifications: If you can become pregnant (or you are male and your female sexual partner can become pregnant, you should use highly effective birth control during the study and 7-month post-treatment period. Please note, female participants who are currently using hormonal birth control must use a second method of birth control as well, since the study treatment may change the effectiveness of hormonal birth control.

Approved birth control methods include:

- Intrauterine device/system (IUD/IUS),
- Surgical sterility for participant and/or partner (successful tubal ligation [tubes tied] or hysterectomy for females, vasectomy for males)
- Barrier method (condom plus spermicide)
- Hormonal birth control (female partner of male participants only), such as pills, injection, implant, patch, and/or inserts like a vaginal ring – must have been started at least 7 days before the male participant begins therapy

You do not need to use birth control if you are over the age of 55 and/or are post-menopausal, have a history of surgical sterilization, or have confirmed ovarian failure (due to radiation therapy or some other medical reason).

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away.

Getting pregnant will result in your removal from this study.

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy.

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

You will receive repotrectinib at no cost to you while on study. You and/or your insurance provider will be responsible for the cost of fulvestrant while you are on 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 will include the cost of collecting the research biopsies before and during treatment, the cost of research testing on biopsy samples, some of the blood draws performed for ctDNA testing, and the urine pregnancy test performed at screening.

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). This includes the CT scans and bone scans, some of the tumor marker blood tests, and the costs of collecting the research tissue biopsy that may be collected if the disease gets worse. 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 Turning Point Therapeutics, Inc. (the study sponsor), the MD Anderson 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 Turning Point Therapeutics, Inc., 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.

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 if the disease gets worse, certain side effects occur, you need treatment that is not allowed on study, you are unable to follow study directions, the study is stopped by the sponsor, or your doctor thinks it is in your best interest to leave the study.

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

If you get sick or hurt and it is related to your participation in this study, you will be given care at MD Anderson (if you are at the clinic when you are sick or hurt). If you get hurt or sick 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 or show them your participant card)
- call the study doctor (Dr. Mouabbi, at 713-792-7676) or 713-792-2121 (24 hours)

You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. Costs of treatment received because you were hurt or sick 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 Turning Point Therapeutics, Inc. (a wholly owned subsidiary of Bristol Myers Squibb Company).

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. If the researchers return genetic test results to

you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

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.

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 the disease responded to treatment or was stable for at least 6 months, and then got worse, you may be asked to allow a tumor tissue biopsy to be collected for tests to help researchers understand why some cancers become resistant to the treatment at the cellular and molecular levels, which could guide future treatments for others in a similar situation.

Optional Procedure Risks: Having **biopsies** 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.

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

Optional Procedure #1: If the disease gets worse, do you agree to allow a tumor tissue biopsy to be collected for research testing?

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)
   - The IRB and officials of MD Anderson
   - Turning Point Therapeutics, Inc. (a wholly owned subsidiary of Bristol Myers Squibb Company), who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study, and/or licensees of the study technology
   - 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.

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