3/1/2023

Study of TGF-β Receptor Inhibitor Galunisertib (LY2157299) and Enzalutamide in Metastatic Castration-resistant Prostate Cancer

NCT02452008

If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Overcoming drug resistance in metastatic castration-resistant prostate cancer with novel combination of TGF-β receptor inhibitor LY2157299 and enzalutamide: a randomized multi-site phase II study**

Application No.: **IRB00065746**

Principal Investigator: **Channing Paller**
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Fax: 410-614-8160

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- Biospecimens will be collected in this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.

- 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.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

2. Why is this research being done?

This research is being done to test the effectiveness (anti-tumor activity) and safety of combining enzalutamide with LY2157299 for the treatment of men with advanced castrate resistant prostate cancer.

What is enzalutamide?

Enzalutamide blocks testosterone production in your body to slow or stop the growth of prostate cancer cells. Enzalutamide (Xtandi®) is approved by the FDA for the treatment of patients with advanced castrate resistant prostate cancer who have received chemotherapy. The FDA is allowing the use of enzalutamide in combination with LY2157299 in this research study. Enzalutamide is made by Catalent Pharma Solutions and is marketed by Astellas Pharma US and Medivation.

What is LY2157299?

LY2157299 is an investigational drug that inhibits a growth factor that is believed to play a role in the spread of the cancer. The use of LY2157299 in this research study is investigational. The word "investigational" means that LY2157299 is not approved for marketing by the Food and Drug Administration (FDA). The FDA is allowing the use of enzalutamide in combination with LY2157299 in this research study. To date, LY2157299 has either been administered alone or in combination with other drugs to over 400 patients.

Men with advanced castrate resistant prostate cancer may join this study.

How many people will be in this study?

About 66 men will take part in this study. About 45 people are expected to take part at Johns Hopkins and Sibley Memorial Hospital.

3. What will happen if you join this study?

The study will consist of the following parts:

- Screening evaluation
- Dosing period and response assessments
- Office visit after last dose
- Post-study follow-up

If you agree to be in this study, we will ask you to do the following things:

Screening Visit

Sign this consent form after all of your questions are answered. Tests outlines below will be done during the screening visits to confirm that you qualify to take part in the study. These tests and procedures are likely to be part of regular cancer care and may be done even if it turns out that you do not take part in the research study. If you have had some of these tests or procedures recently, they may or may not have to be repeated. The screening visit will be performed within 28 days of the first study drug administration visit.

The following tests will be performed:

- A complete medical history, physical exam, including vital signs (temperature, blood pressure, heart rate, height, and weight) and an assessment of your overall general health (performance status).
- You will be asked to list your medications
- A computed tomography (CT) or magnetic resonance imaging (MRI) scan will be done to check the size of your tumor(s) during the study. A bone scan of your skeleton will also be done.
- Blood tests (about 2 tablespoons): testing for a tumor marker, testosterone, blood counts, the clotting properties of your blood, and evaluation of your heart, liver, and kidney function.
- Urine testing
- Two tests will be done to examine the condition of your heart (heart rhythm and function). You will have an EKG and a Doppler echocardiogram. An ECG or EKG is a tracing of the electrical activity of the heart. A Doppler echocardiogram is a picture of the heart and the large heart vessels obtained by using ultrasound.

The study team will check the results of these screening tests to see if you qualify to continue to take part in the study. If you wish to continue to participate in the study, you must also agree to the following:

- You will agree to comply with the visit schedule and procedures.
- You will agree to use an acceptable method of highly effective contraception to prevent pregnancy (for example, birth control pills, condoms with spermicide, or hormone implants) for the duration of the study. Regardless of method used, both males and females must agree to use a barrier contraceptive method (a condom, for example) to prevent transfer of fluids during the study and for 6 months after receiving last dose of the study drug.

If you are eligible to participate in this study based on the screening tests (described above), you will be randomly assigned (like flipping a coin) to one of 2 treatment groups in order to determine if one treatment regimen is better than the other. Thirty six people will be assigned to Treatment Arm 1 and twenty four people will be assigned to Treatment Arm 2. The two treatment groups are:

Arm	Number of People	Treatment Assigned
1	**36**	**Enzalutamide and LY2157299**
2	**24**	**Enzalutamide alone**

If you are eligible to participate in this study based on the screening, the following evaluations will be performed:

- Research blood sample (about 2 tablespoons) before starting treatment on the study and prior to Cycle 4.
- If you have a tumor that is accessible for biopsy, you will undergo a biopsy of the tumor to obtain tissue before starting treatment on the study and prior to Cycle 4.

Dosing Visits

If you meet the study requirements during the screening period, you will then begin the dosing phase of this trial. Each cycle of treatment is 28 days long. You will receive the following regimen:

- Treatment Arm 1: Enzalutamide will be taken orally once a day at a dose of 160mg for 28 days. LY2157299 will be taken orally twice a day for a total dose of 300mg on Days 1-14.

- Treatment Arm 2: Enzalutamide will be taken orally once a day at a dose of 160mg for 28 days.

The following evaluations and tests will be performed prior to dosing on Day 1 of each Cycle:

- A complete medical history, physical exam, including vital signs (temperature, blood pressure, heart rate, and weight) and an assessment of your overall general health (performance status).
- A review of any medications you are taking or have taken since your last visit.
- A review of any side effects or other medical problems you have had since your last visit.
- Blood tests (about 2 tablespoons): testing for blood counts and evaluation of your heart, liver, and kidney function.
- If you are enrolled on Treatment Arm 1: You will have a Doppler echocardiogram on Day 1 of Cycle 3, and every 6 months therafter, while you remain on study (for example Cycles 3, 9, 15).
- A computed tomography (CT) or magnetic resonance imaging (MRI) scan and bone scan will be done to check the size of your tumor(s) every three Cycle while you remain on study (for example Cycles 4, 7, 10).

The physician will review the results of your physical exam and blood tests and decide if you should receive either enzalutamide and LY2157299 or enzalutamide alone.

The following evaluations and tests will be performed prior to dosing on Cycle 1 Day 1, Cycle 1 Day 14 or 15, Day 1 of Cycles 1, 2, 3, 4, 7, 10, 12 and every 3 Cycles after Cycle 12:

- Blood tests (about 1 teaspoon): testing for a tumor marker
- Research blood sample (about 3.5 tablespoons).

If you have a side effect that requires a procedure as part of your medical care, we will collect the tissue or cell samples to evaluate your cancer and your body's response to enzalutamide and LY2157299 or enzalutamide alone.

Follow-Up Visit

The following evaluations will be performed during a clinic visit after your last dose (about 30 days after last dose of enzalutamide or LY2157299):

- A complete medical history, physical exam, including vital signs (temperature, blood pressure, heart rate, and weight) and an assessment of your overall general health (performance status).
- A check of your vital signs (heart rate, temperature, blood pressure, weight).
- A review of any medications you are taking or have taken since your last visit.
- A review of any side effects or other medical problems you have had since your last visit.
- Blood tests (about 2 tablespoons): testing for blood counts and evaluation of your heart, liver, and kidney function.
- You will have a Doppler echocardiogram

Post-study follow-up

After the follow-up visit, the study staff will continue to ask about your health, medications, and CT scan results every 6 months.

Incidental Findings

The imaging tests you are having as part of this research study will be reviewed by a qualified person just as it would be if you were having the imaging tests as part of your routine medical care.

There is a possibility that while reviewing your imaging tests we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding."

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by mail or by phone. In the case of a potential serious emergency, someone may go to your home.

A qualified person (usually a member of the research team) will talk to you if there is an incidental finding. You do not have an option to decline information about an incidental finding.
If you want, we will give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious.
- Since an incidental finding will be part of your medical record, it may affect your current or future life or health insurance coverage. This risk will vary depending on the type of insurance plan involved.

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

Request to collect and store biospecimens for future research

As part of this research study, we would like to ask you to let us store your biospecimens (blood and serum) and health information for future research. Tests include looking at immune responses and biomarkers and seeing how they may be related to drug responses. This research could include other diseases and involve research tools such as gene sequencing or the creation of cell lines.

- Gene sequencing of your DNA provides researchers with the code to your genetic material.
- Cell lines are living tissue samples that can be grown in a laboratory. A cell line can provide an unlimited supply of cells in the future without requiring more samples from you. Each cell contains your complete DNA.

These samples will not identify you by name but by a unique number, and may be stored indefinitely. Only authorized personnel with permission from the principal investigator will have access to them. Your identity will remain strictly confidential. Should future testing lead to the development of a commercial product; there are no plans to provide you with financial compensation. At this time, there are no benefits for you associated with this testing and you will not receive any results from it.

The Genetic Information Nondiscrimination Act (GINA) may help protect you from health insurance or employment discrimination based on genetic information.

The law provides that health insurance companies and group health plans

- may not ask for genetic information from this research and
- may not use genetic information when making decision about eligibility or premiums

The law will not stop health insurance companies from using genetic information to decide whether to pay claims. The law also will not help you get other types of insurance (such as: life, disability or long term care).

The study doctor can provide you with additional information if you have questions. Also, further information about our use of your biospecimens can be found in this consent document under the heading *What happens to Data and Biospecimens that are collected in the study?*.

Will you allow us (Johns Hopkins, Dr. Channing Paller, Eli Lilly and Company, and other collaborators) to store the biospecimens we collect for this study for use in future research*?*

YES _____
Signature of Participant

NO _____
Signature of Participant

How long will you be in the study?
You will be in the study about as long as your disease is not getting worse or you do not have bad side effects.

Future Contact
We would also like your permission to contact you about other studies that you may be eligible for in the future.

YES __ _____
Signature of Participant

NO __ _____
Signature of Participant

4. What are the risks or discomforts of the study?

Participation in this study may involve risks or discomforts. While you are on this study, you may experience the side effects listed below. You should tell your doctor about any side effects even if they are not listed here and you may receive treatment for some of these side effects. Many of the side effects go away shortly after the study drug is stopped, but in some cases, side effects may be serious, long-lasting, and may even cause death.

Enzalutamide Risks
The most common side effects reported with enzalutamide use are weakness or feeling more tired than usual, back pain, diarrhea, joint pain, hot flushes, swelling in your hands, arms, legs or feet, muscle or bone pain, headache, nose, airway or lung infection (respiratory infection), muscle weakness, dizziness, trouble falling or staying asleep (insomnia), trouble breathing (pneumonia), back pain with nerve problems in the lower body, including leg numbness or weakness, blood in the urine (hematuria), sensation of tingling, burning, pricking, or numbness of the skin (paresthesia), nervousness (anxiety), and high blood pressure (hypertension).

A small number of patients had convulsions (seizures) on enzalutamide in clinical trials. There are potential interactions between enzalutamide and other medications. Tell your study doctor about all medications you are taking so interactions are avoided.

LY2157299
The most common risks and discomforts reported by patients who received LY2157299 are weakness, tiredness (fatigue), nausea, and vomiting. Other risks and discomforts reported by people who have received LY2157299 include headache, a decrease in the part of the blood that carries oxygen (low red blood cells), a decrease in the part of the blood that prevent bleeding (low platelets), a decrease in the part of the blood that prevents infection (low white blood cells), inflammation of the anus, loose stool, dry mouth, upset stomach, swollen ankles, dizziness, shortness of breath, itching, constipation, loss of appetite, high creatinine phosphokinase in the blood, and protein in the urine.

Eighteen patients had serious effects associated with LY2157299 monotherapy. Some of these effects led to hospitalization. These events included low red blood cells, low platelets, low white blood cells, loose stools, bleeding in the gastrointestinal tract, blockage in an artery in the lung, stroke, belly pain, high bilirubin in the blood, confusion, decreased consciousness or coma due to liver failure, skin infection caused by bacteria, lower respiratory tract infection, heart attack, pneumonia, shock, inflammation of the pancreas, weakness, thirst, bleeding in the upper GI tract, fluid in the lungs, fluid in the belly tissue, cancer progression, accumulation of blood in the tissues behind the belly and its supporting tissues, and nausea.

Two deaths that may be associated with the drug have occurred in patients taking LY2157299 monotherapy. However, these deaths are still being investigated.

You may feel discomfort during some of these tests or may experience some inconveniences. Some may also have risks, which may include:

- **Blood samples:** drawing blood from your arm may cause pain, bruising, lightheadedness, and rarely, infection.
- **CT and Bone Scans:** A Computerized Tomography or CT scan provides multiple detailed pictures of the inside of the body. Bone scans provide detailed pictures of your bones. CT and bone scans use radiation, similar to an X-ray, in order to take these pictures. These scans are considered standard of care for men with castrate resistant prostate cancer and would be done to assess your disease even if you were being treated with standard Care.
- **Contrast dye for CT and Bone scans**: Contrast dye is usually administered when you get a CT or bone scan. Some people may develop hives and itching or other allergic symptoms from this dye. In addition, if you have low kidney function, this dye can temporarily or permanently decrease your kidney function.
- **Magnetic Resonance Imaging (MRI):** A MRI scan involves a strong magnetic field so please tell your doctor if you have a pacemaker (the magnetic field can cause your pacemaker to malfunction), metal dental work or a metal prosthesis (implant) in your body or any large tattoos that use an iron-base dye (as this can interfere with the image and cause pain during the assessment). Risks of MRI include claustrophobia, discomfort due to lying still for a prolonged period of time, and other factors which will be described to you and discussed with you at the MRI center.
- **Possible Risks Related to Radiation** This research study includes exposure to radiation from x-rays or gamma rays. This radiation exposure is for research purposes only and is not part of your medical care. X-rays and gamma rays from natural or medical sources can damage the genetic material (DNA) in your cells. At low doses, the body is usually able to repair the damage.

  The radiation exposure that you will get in this research study is up to 2.0 rem (a rem is a unit of absorbed radiation). This is more than the 0.3 rem that the average person in the United States gets each year from natural sources like the sun, outer space, air, food and soil. It is less than the 5 rems of radiation that is allowed each year for people who are exposed to radiation in their jobs.

  The radiation exposure described here is what you will get from this research study only. It does not include any exposure you may have received or will receive from other tests outside of this study that are a part of your medical care. Radiation risk builds up with each exposure. You should think about your own history of radiation exposure from tests (like x-rays or CT scans) in deciding about the radiation in this study. If you have questions about the total amount of radiation you will be receiving, you should ask your doctor.

- **Tumor Biopsy:** Your doctor will discuss the risks associated with obtaining tissue samples. Having biopsies performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling and/or infection at the site of the biopsy. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy site.

Are there any other risks?
Other less common side effects have been reported with the use of the drugs in this study. The study doctor or staff can discuss these with you.

Despite the GINA protections and the best efforts of the research team, there may still be a risk if information about you were to become known to people outside of this study.

There may be other side effects or risks that are not known at this time.

5. Are there risks related to pregnancy?

Participating in this study may involve unforeseen risks on sperm. To avoid this risk, you should use adequate methods of birth control throughout your participation in this study. Acceptable methods of birth control may include abstinence or a double-barrier method such as condom with spermicide starting with the first study visit up to 6 months after the last dose of study drug.

The following birth control methods are allowed during the study:

- Barrier methods:
  - Diaphragm
  - Condom (by the partner)
  - Copper IUD
  - Sponge
  - Spermicide
- Hormonal method:
  - Hormonal contraceptives (such as the birth control pill)
- Abstinence (no sex)

If your partner becomes pregnant during the study you must notify the study doctor right away. The pregnancy will be reported to the Sponsor. You must also agree to not donate sperm during the study and for a period of 6 months after your last dose of study drug.

This research may hurt an embryo or fetus in ways we do not currently know.

6. Are there benefits to being in the study?

You may or may not benefit from being in this study. If the drug works, you may have some benefit. If the drug does not work, you may not benefit. If you take part in this study, you may help others in the future.

7. What are your options if you do not want to be in the study?

If you decide not to join this study, other options are available. You do not have to join this study to get treatment. Other options available to you include standard of care treatment with enzalutamide.

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet).

This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).

- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

9. Will you be paid if you join this study?

No.

10. Can you leave the study early?

Your decision to participate in this study is voluntary.

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities**.**

11. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities**.**

12. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health problems treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

13. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

- You will be asked to give us a list of other health care providers that you use.

14. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form you will not give up any rights you have to seek compensation for injury.

15. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.
When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Paller at 410-955-8893. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

If you are taking part at Sibley Memorial Hospital, call Dr. Channing Paller at 202 660-6500 or 202 841-2707 for the Sibley Memorial Research Office.

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call Dr. Channing Paller at 410-955-8239 in Baltimore or 202-660-6500 in DC at Sibley during regular office hours.

If you have an urgent medical problem related to your taking part in this study, Dr. Channing Paller at 410-955-8239 in Baltimore or 202-660-6500 in DC at Sibley during regular office hours or the medical oncologist on call at 410-955-4331 during regular office hours, after hours, and on weekends.

If you are taking part at Sibley Memorial Hospital and you have a medical problem related to your taking part in this study, call Dr. Channing Paller 202 660-6500. If this doctor is not available, the operator will page the “on call physician.”

d. What happens to Data and Biospecimens that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The biospecimens and/or data you provide are important to this effort.

If you join this study, you should understand that you will not own your biospecimens or data, and should researchers use them to create a new product or idea, you will not benefit financially.

With appropriate protections for privacy, Johns Hopkins may share your biospecimens and information with our research sponsors and partners.

16. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

Signature of Participant, LAR or Parent/Guardian	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider	(Print Name)	Date/Time

Signature of Participant	(Print Name)	Date/Time

Signature of Witness to Consent Procedures (optional unless IRB or Sponsor required)	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

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