Official Title: *LCI-GU-PRO-ADDE-001*: A Phase II Trial of Androgen Deprivation, Docetaxel and Enzalutamide in Patients With Metastatic Hormone Sensitive Prostate Cancer
NCT# 03246347
IRB-Approved Date: *06/06/2022*

ATRIUM HEALTH
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Sponsor / Study Title:	**Levine Cancer Institute/ "A PHASE II TRIAL OF ANDROGEN DEPRIVATION, DOCETAXEL AND ENZALUTAMIDE IN PATIENTS WITH METASTATIC HORMONE SENSITIVE PROSTATE CANCER"**
Protocol Number:	**LCI-GU-PRO-ADDE-001**
Principal Investigator: (Study Doctor)	**Earle Burgess, MD**
Telephone:	[redacted]
Address:	**Levine Cancer Institute** [redacted]

INTRODUCTION

Dr. Burgess and his associates (the investigators) are asking you to participate in a research study at Levine Cancer Institute (LCI) and Atrium Health with the combination of androgen deprivation therapy (ADT) and docetaxel with the addition of enzalutamide in the treatment of subjects with metastatic (cancer has spread) prostate cancer. The purpose of this study is to assess if ADT + docetaxel + enzalutamide is well tolerated and demonstrates improved efficacy (how well it works) compared to ADT + docetaxel. You are being asked to take part in this study because you have metastatic hormone sensitive prostate cancer.

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part in this study. You have also been told that you have the option not to participate. You may discuss your decision with your friends and family. You can also discuss it with your healthcare team. If you have any questions, you can ask your study doctor for more explanation.

This study is being carried out under the sponsorship of Levine Cancer Institute (LCI). Astellas Pharmaceuticals will be providing the drug enzalutamide (Xtandi) for this study.

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WHY IS THIS STUDY BEING DONE?

Prostate cancer is the most common cancer in men, and no curative therapies currently exist to treat advanced stages of this disease. The most commonly used treatment in patients with advanced disease is ADT (androgen deprivation therapy), but some patients with metastatic, untreated cancer benefit from also receiving treatment with docetaxel in combination with ADT.

This study assesses the effectiveness of adding enzalutamide to ADT and docetaxel in subjects with metastatic prostate cancer that is still responsive to ADT (considered "castrate-sensitive"). Enzalutamide is a drug taken by mouth that works by blocking the action of testosterone. Laboratory research suggests that ADT + enzalutamide + docetaxel may improve the effectiveness of anticancer therapy compared to docetaxel or enzalutamide alone. Although enzalutamide is currently approved by the Food and Drug Administration (FDA) for the treatment of prostate cancer after ADT has stopped working, the use of enzalutamide in combination with ADT and docetaxel in subjects with metastatic castrate sensitive disease is experimental, and potential benefits are not yet known.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

You will be one of the 39 subjects participating in this study at Levine Cancer Institute.

HOW THE STUDY WORKS

Before you begin the study (Baseline):

In order to participate in this study, you will need to:

- Review, sign, and date this informed consent form.
- Provide authorization for the release of your medical records for research purposes.

In order to check if you are eligible to participate:

- All of your medical history including history related to your current prostate cancer will be reviewed.
- If you had a diagnostic biopsy (to see how the tumor looks like under a microscope), we will review your lab report.
- Any medications (including but not limited to over-the-counter, supplements, vitamins) you are taking or have taken up to 14 days prior to signing and dating this consent form will be reviewed.
- You will have a doctor's appointment to conduct a physical exam and collect vital signs (like temperature, pulse rate, respiratory rate, blood pressure)
- Collect about two or three tablespoons of blood for laboratory tests. The labs will help to determine how well your kidneys, liver, and other organs function, and give us your blood cell counts.

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- If not already done within 42 days before signing consent for the study, you will have scans of the abdomen and pelvis, as well as scans or x-ray of the chest. Scans will be done using an x-ray machine that uses a computer to take pictures or computerized tomography (CT) scan. Also radionuclide bone scan will be used to check for cancer that may have spread to your bones. For this test, you will be injected with a small amount of radioactive material that is detected by a special camera at sites of cancer involvement in your skeleton.

During the study (Intervention):

This study treatment will be administered in an outpatient setting and consists of the following three treatment phases: Docetaxel Treatment Phase, Castrate Sensitive Enzalutamide Treatment Phase and Castrate Resistant Treatment Phase.

During the first phase (Docetaxel Treatment Phase), each 3 week period of time is considered a "cycle." Cycles are repeated every 21 days, unless study treatment delay is needed due to side effects, for a total of 6 cycles during this phase. During this phase, you will receive continuous ADT if you have not previously undergone surgical castration. ADT is usually administered as an injection into a muscle or under skin once every 3, 4 or 6 months. You will also receive docetaxel intravenously over a one-hour period every 21 days for up to six cycles. Approximately 12 and 3 hours prior to receiving docetaxel infusions, you will need to take a medication (dexamethasone) in order to reduce the risk of certain side effects of docetaxel, including allergic reactions and/or fluid retention. If you have a very low white blood cell count with or without a fever during this phase, your doctor may also recommend a medication be given as an injection under the skin with future treatments to lower your risk of future infections. On the first day of treatment, you will also begin treatment with enzalutamide, which is taken by mouth every day and will consist of 4 tablets, 40 mg each. If side effects or complications from study treatment occur, your study doctor may tell you to stop taking the study drug temporarily or to adjust the dose.

In addition to taking enzalutamide (4 tablets) once daily, you must also do the following:

- Swallow the tablets whole and not be broken or crushed or dissolved.
- Tablets can be taken with or without food
- Tablets can be taken any time during the day, but should be taken at the same time as consistently as possible
- If you miss a dose, you should take it as soon as possible unless the next dose is due within 12 hours.
- If vomiting occurs after taking a dose, an extra dose should not be taken.

Every 21 days, you will meet with your study doctor and/or clinical study staff prior to each docetaxel treatment. At these visits, we will check your vital signs and weight and ask about any side effects you may have. We will also take some blood (about 3 tablespoons) to ensure that your organs are functioning normally and blood levels are adequate to receive study treatment. We will also

check your prostate specific antigen (PSA) level to monitor treatment effectiveness. PSA is a protein made by prostate tissue and prostate cancer cells. On the first day of study treatment, we will also collect approximately 1 tablespoon of blood for research purposes to measure circulating tumor cells (CTCs), which are prostate cancer cells that can sometimes be detected in your bloodstream. All samples collected for research purposes will be labeled with a unique number that does not identify you by name.

Approximately 1 month after receiving your last docetaxel infusion, you will begin the second phase of study treatment (Castrate Sensitive Enzalutamide Treatment Phase). During this phase, each 2 month (56 days) period of time is considered a "cycle." Cycles are repeated every 56 days, unless study treatment delay is needed due to side effects or until your blood work suggests some prostate cancer cells may be growing by a rising PSA level. During this phase, you will continue to receive ADT and take enzalutamide as described above. Every 56 days, you will meet with your study doctor and/or clinical study staff. At these visits, we will check your vital signs and weight and ask about any side effects you may have. We will also take some blood (about 3 tablespoons) to ensure that your organs are functioning normally, blood levels are adequate to receive study treatment, as well as measure your PSA value to monitor treatment effectiveness. On the first day of this phase, we will again collect approximately 1 tablespoon of blood to measure CTCs for research purposes. Additionally, we will collect extra blood samples (1-2 tablespoons) at 26 weeks and 52 weeks from the day you initially began therapy to measure your PSA level to monitor treatment effectiveness. You will not receive any imaging during this phase unless you develop new symptoms of concern to your study doctor. Study treatment effectiveness will be measured by your PSA levels obtained from bloodwork.

If your blood work (rising PSA level) or symptoms suggest prostate cancer growth, you will begin the final phase of study treatment (Castrate Resistant Treatment Phase). During this phase, each 28-day period of time is considered a "cycle." At the beginning of this phase, you will have additional bloodwork collected (3-4 tablespoons) to measure your organ function, blood levels, PSA, testosterone, and CTC levels for research purposes. You will also undergo repeat x-ray tests that were obtained at the time of study entry including CT of the abdomen and pelvis, chest x-ray or CT of the chest and bone scan. During this phase, cycles are repeated every 28 days until the end of the study. You will continue to receive ADT and take enzalutamide as described above until your x-rays or CT and/or bone scans show detectable prostate cancer growth. Note that if a bone scan shows the development of two or more new lesions, a confirmatory bone scan will be performed a minimum of six weeks later and need to show development of two additional new lesions to be considered growth, which is a considered standard by prostate cancer experts.

During this phase, you will meet with your study doctor and/or clinical study staff every 28 days. At these visits, we will check your vital signs and weight and ask about any side effects you may have. We will also take some blood (about 3 tablespoons) to ensure that your organs are functioning normally, blood levels are adequate to receive study treatment, as well as measure your PSA value to monitor study treatment effectiveness. You will undergo repeat imaging with x-rays and scans as described above every 12 weeks. You will continue to receive the study treatment until cancer growth is confirmed by imaging.

You will continue to receive study treatment until cancer growth is detectable by imaging, side effects become unbearable even if they are being medically treated or you are too ill to continue. You also have the option to voluntarily discontinue study treatment and withdraw from the study at any time.

Your study doctor may also choose to withdraw you from the study for any reason.

After you complete the intervention (Follow-up):

Within 30 days of your last dose of study treatment, you will come in and meet with your study doctor and/or clinical study staff. At this visit, you will have blood drawn if necessary laboratory studies have not been obtained within the prior 14 days.

Following the visit, study staff may contact you approximately every 6 months for up to 7 years after you joined the study.

RISKS

Docetaxel and enzalutamide are both approved by the FDA for men with prostate cancer that has spread to other parts of the body and no longer responding to ADT. The risks of these drugs have been extensively studied in this clinical setting. While you are on this study, you are at risk for the side effects listed below. Most people do not experience all of the side effects listed. A side effect may get worse during the course of study treatment, or more side effects may develop as the study treatment goes on. Your study doctor will closely monitor and treat/prevent the side effects you might have through the study period.

The most common side effects of **enzalutamide** are listed below but this list may **not** contain all possible side effects:

- generalized weakness or feeling more tired than usual
- pain in your joints
- hot flashes
- decreased appetite
- headache
- high blood pressure
- a feeling that you or things around you are moving or spinning (vertigo)
- weight loss

Some other rare but serious risks from enzalutamide include but are not limited to:

- Seizure

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If you experience loss of consciousness, confusion, uncontrolled muscle shaking or twitching, abnormal sensations or known seizure activity, you must notify your study doctor immediately.

- Posterior Reversible Encephalopathy Syndrome (PRES)
  Symptoms of PRES can include seizure, headache, tiredness, confusion, blindness or other neurologic symptoms with or without elevated blood pressure. You must report these symptoms and inform your study doctor immediately.

- Allergic Reactions
  Allergic reactions have happened in people who take enzalutamide. Stop taking enzalutamide and get medical help right away if you develop swelling of the face, tongue, lips and/or throat.

- Ischemic Heart Disease
  Blockage of the arteries in the heart (ischemic heart disease) that can lead to death has happened in some people during treatment with enzalutamide. Your study doctor will monitor you for signs and symptoms of heart problems during treatment. Call your study doctor or go to the nearest emergency room right away if you get cause pain or discomfort at rest or with activity or shortness of breath during treatment with enzalutamide.

- Falls and Fractures
  Enzalutamide may increase your risk for falls and fractures. Falls were not caused by loss of consciousness (fainting) or seizures. Your study doctor will monitor your risks for falls and fractures during treatment with enzalutamide.

Common and/or serious risks associated with ADT include:

- hot flashes
- generalized weakness or feeling more tired than usual
- weight gain
- bone loss and osteoporosis
- depression and anxiety
- elevated blood sugar and diabetes
- heart disease and heart attacks
- loss of sexual drive and impotence
- slowed thinking and memory loss
- pain or bruising at injection site
- seizures

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- atrophy or shrinkage of testicles and penis

Common and/or serious risks associated with docetaxel include:

- allergic reaction, including life-threatening anaphylaxis (severe allergic reaction)
- lowered blood counts with associated increase risk of serious infection, bleeding, or anemia
- weakness and fatigue
- numbness, tingling, and/or pain
- hair loss
- swelling and fluid retention
- redness of skin and/or peeling
- damage and/or loss of finger/toenails
- visual loss and/or macular edema (swelling or thickening of the eye's macula, the part of your eye responsible for detailed, central vision).
- excessive tearing
- leukemia (cancer of the white blood cells)
- death

Other Risks

Computed Tomography (CT) Scan, Radionuclide Bone Scan and X-ray Risks
The CT scans, bone scans and x-rays will expose you to some radiation. Radiation levels are within acceptable limits. Ask the study doctor about the risk from these scans in this study. IV contrast dye given with a CT scan may cause an allergic reaction or kidney function abnormality.

Blood Drawing Risks
During this study, small amounts of blood will be drawn from a vein to perform tests that allow your study doctors to see how you are doing. Drawing blood may cause pain where the needle is inserted, and there is a small risk of bruising and/or infection at the place where the needle is inserted. Some people experience dizziness, upset stomach, or fainting when their blood is drawn.

Allergic Reaction Risks
As with taking any drug, there is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat, or eyes

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- A fast pulse
- Sweating

Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms, or any other side effects, during the study.

Reproductive Risks

Because of risks of fetal harm with enzalutamide and docetaxel, men on this study must use adequate forms of contraception while on study treatment and for at least 90 days after last taking study drug. If your partner becomes pregnant during the study, you must inform your study doctor immediately.

Highly effective methods

- Male sterilization (vasectomy).
- True abstinence

Effective methods

- Placement of intrauterine device or intrauterine system
- Condom with spermicidal foam/gel/film/cream/suppository
- Occlusive cap (diaphragm or cervical/vault caps) with spermicidal foam/gel/film/cream/ suppository
- Hormonal contraceptives

Unacceptable methods

- Abstinence at certain times of the cycle only, such as during the days of ovulation or after ovulation (based on symptoms or temperature)
- Pre-ejaculatory withdrawal

It is not known whether the study drug is secreted in breast milk. Women who are pregnant or breastfeeding should not handle or touch enzalutamide.

Unknown Risks

You might have side effects or discomforts that are not listed in this form. Some side effects may not be known yet. New ones could happen to you. Tell the study doctor or study staff right away if you have any problems.

WILL I BENEFIT FROM PARTICIPATING IN THIS STUDY?

If you agree to take part in this study, there may or may not be direct medical benefit to you. The use of combination of androgen deprivation therapy (ADT), docetaxel, and enzalutamide in the treatment of patients with metastatic prostate cancer is experimental and the potential benefits for its use are unknown. Other patients with metastatic prostate cancer may benefit in the future.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

You may choose not to participate in this study. Instead of being in this study, your options include but are not limited to:

- Other investigational drugs
- Treatment with other anticancer drugs
- No therapy with comfort care only. Comfort care, also called palliative care, helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible. If you think you might prefer comfort care, please discuss this with your family, friends and your doctor.

Please talk to your study doctor about these options and their potential benefits. Please ask any questions you may have and take as much time as you need to make your decision.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

You and/or your health plan/insurance will need to pay for all your routine care procedures, including treatment with ADT and docetaxel. Levine Cancer Institute will provide you with the study drug, enzalutamide, at no charge. There will be no cost for blood drawn for research. There is no additional cost to you to take part in this study. You and/or your health plan/insurance will not be charged for any lab studies or procedures obtained for research purposes only. Some health insurance plans may not cover certain procedures and medical treatments. You may wish to discuss coverage with your insurance company before agreeing to participate in this study.

You will not receive payment for taking part in this study.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's website at http://cancer.gov/clinicaltrials/understanding/insurance-coverage You can print a copy of the "Clinical Trials and Insurance Coverage" information from this website. Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

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STUDY STAFF PAYMENT/FINANCIAL DISCLOSURE

None of the doctors asking you to participate in this study has received or will receive money or other benefits for personal use from the company (Astellas) that is providing the enzalutamide (Xtandi) used in this study. The institution will receive some funding from Astellas to do the research.

COMPENSATION FOR INJURY

In the event that you are injured as a result of your participation in this study, we will provide or arrange for treatment as necessary. This treatment, as well as other medical expenses, will be billed to you or your insurance company in the usual manner. You will be responsible for deductibles, co-payments, and co-insurance. There are no plans to pay or give you other compensation for the injury. You do not waive any legal rights by signing this consent form.

If you become ill or are hurt while you are in the study, get the medical care that you need right away.

For insurance or other payment reporting purposes, we may need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because we may have to check to see if you receive Medicare and if you do, report the payment we make to Medicare.

In no way does signing this consent form waive your legal rights nor does it relieve the investigators, Sponsor or involved institutions from their legal and professional responsibilities.

WHAT IF I WANT TO QUIT THE STUDY LATER ON?

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, your decision will not in any way harm your relationship with your doctors or with Atrium Health or LCI, and there is no penalty or loss of benefits to you. You are free to stop being in the study if you change your mind after entering it. This would not harm your relationship with your doctors or with Atrium Health or LCI and there is no penalty or loss of benefits to you. If you choose to withdraw from the study, please notify the study doctor in writing at the address on the first page of this form.

Information already contributed to the study will remain in the study even if you choose to withdraw. If you leave the study for any reason, you will be asked to have the procedures completed for the final visit.

Your study doctor or Levine Cancer Institute can remove you for any reason at any time, from this study without your consent. Reasons include but are not limited to:

- The judgment that any condition or circumstance may jeopardize your welfare or the integrity of the study.

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- Your failure to follow the instructions of the study doctor.
- The study is stopped by Levine Cancer Institute.

Your study doctor will explain the reasons for your removal and will help arrange for your continued care, if needed.

CONFIDENTIALITY

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a patient. Your record for this study may, however, be reviewed and/or photocopied, by Astellas, Atrium Health, or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute.

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All of your study data will be kept in a secure location.

Results obtained for research purposes only, including circulating tumor cells, will not be provided to enrolled patients.

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.

AUTHORIZATION TO USE AND DISCLOSE YOUR PROTECTED HEALTH INFORMATION

If you wish to participate in this research study, you

_____

Printed Name of Research Subject

must sign this Authorization. By signing this Authorization, you give all healthcare providers, including Atrium Health, permission to use or disclose (release) your protected health information, both past and present, for the research study described here:

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"A PHASE II TRIAL OF ANDROGEN DEPRIVATION, DOCETAXEL AND ENZALUTAMIDE IN PATIENTS WITH METASTATIC HORMONE SENSITIVE PROSTATE CANCER"

The protected health information that we may use or disclose (release) for this research may include all information in your medical record, such as results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition.

The health information listed above may be used by and/or disclosed (released) to:

- Study investigator and research staff
- Study sponsor and/or its associated companies
- Regulatory or other governmental authorities of the United States or other countries based on this study
- Other persons or agents authorized by the study sponsor
- Atrium Health employees
- Other persons or agencies as required by law or allowed by federal regulations
- Data coordinating centers that will receive and process PHI; and/or;
- Advarra Institutional Review Board (Advarra IRB) or Data Safety and Monitoring Boards.

Atrium Health is required by law to protect your protected health information. By signing this Authorization, you authorize Atrium Health to use and/or disclose (release) your protected health information for this research study. Those persons who receive your protected health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your protected health information with others without your permission, if permitted by laws governing them. Your protected health information may then no longer be protected by the Privacy Rule.

Please note that you do not have to sign this Authorization, but if you do not, you may not receive research-related treatment through this study. However, Atrium Health may not condition (withhold or refuse) your other Atrium Health providers treating you on whether you sign this Authorization. You may change your mind and withdraw (take back) this Authorization at any time, except to the extent that Atrium Health or the Sponsor has already used or disclosed your protected health information based on this Authorization. To withdraw this Authorization, you must write to the Study Doctor at the address listed on the first page of this form

No publication or public presentation about the research described above will reveal your identity without another Authorization from you. If all protected health information that does or can identify you is removed, the remaining information will no longer be subject to this Authorization or federal rules (such as the Privacy Rule) and may be used or disclosed for other purposes.

When the research for which the use or disclosure is made involves treatment and is conducted by Atrium Health: To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete.

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At the conclusion of the research study and at your request, you generally will have access to your protected health information. Access to your protected health information in a medical record is described in the Notice of Privacy Practices provided to you by Atrium Health.

When conducting research, the data and results may be used or disclosed for further treatment outcomes research or to research a secondary result. This Authorization will remain in effect after the end of the current study, and any future related secondary study unless it is revoked by you in writing as described above.

_____

Signature of Research Subject

_____

Printed name of Research Subject

_____

Date

GETTING ANSWERS TO YOUR QUESTIONS OR CONCERNS ABOUT THIS STUDY

You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study). Questions may include:

- Who to contact in the case of a research-related injury or illness;
- Payment or compensation for taking part in this study, if any;
- Your responsibilities as a study subject;
- Eligibility to participate in the research;
- The study doctor's or study site's decision to exclude you from participation;
- Results of tests and/or procedures
- Other questions, concerns, complaints.

Contact the study staff or study doctor at Atrium Health, listed on the first page of this form, with any questions, concerns, or complaints.

GETTING ANSWERS TO YOUR QUESTIONS ABOUT YOUR RIGHTS AS A STUDY PARTICIPANT

This study has been reviewed by the Institutional Review Board (IRB). The IRB is a group of people who review the research to protect your rights. This committee reviewed this study to help ensure

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that your rights and welfare are protected and that the study is being carried out in an ethical manner. If you have questions about the conduct of this study or about your rights as a research subject, you may contact Advarra Institutional Review Board.

- By **mail**:
  Study Subject Adviser
  [redacted]
- or call **toll free**: [redacted]
- or by **email**: [redacted]

Please reference the following number when contacting the Study Subject Adviser: Pro00018087.

BEING A STUDY VOLUNTEER AND WITHDRAWING FROM THE STUDY

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, that will not harm in any way your relations with your doctors or with Atrium Health. You are free to stop being in the study if you change your mind after entering it. This would not harm your relations with your doctors or Atrium Health. If you choose to withdraw from the study, please notify the study doctor in writing at the address on page 1 of this form.

- You may always say no. You do not have to take part in the study.
- If you start a study, you may stop at any time. You do not need to give a reason.
- If you do not want to be in a study or you stop the study at a later time, you will not be penalized or lose any benefits.
- If you stop, you should tell the study staff and follow the instructions they may give you.

Your part in the research may stop at any time for any reason, such as:

- The sponsor decides to stop the study
- The sponsor or the study doctor decides to stop your part in the study for your safety.
- You need additional treatment.
- You do not follow the study rules.
- You have a new injury or illness.
- You decide to stop.

You may be asked to stop the study even if you do not want to stop. Your study doctor will explain the reasons for doing so and will help arrange for your continued care, if needed.

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NEW INFORMATION ABOUT THE STUDY

You will be told about any new information found during the study that may affect whether you want to continue to take part.

STATEMENT OF CONSENT

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____ _____
Signature of Research Subject Date Time

_____
Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____ ____/____/____ _____
Signature of Person Explaining Consent Date Time

_____
Printed Name of Person Explaining Consent

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