Official Title: *LCI-BRE-H2N-ANPA-001*: Pilot Trial of Anastrozole and Palbociclib as First-Line Therapy and as Maintenance Therapy After First Line Chemotherapy in Hormone Receptor Positive, HER2-Negative Postmenopausal Metastatic Breast Cancer
NCT# 02942355
IRB-Approved Date: *08/17/2022*

**ATRIUM HEALTH**
**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

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| **Sponsor / Study Title:** | **Levine Cancer Institute, Pilot Trial of Anastrozole and Palbociclib as First-Line Therapy and as Maintenance Therapy after First-Line Chemotherapy in Hormone Receptor-Positive, HER2-Negative Postmenopausal Metastatic Breast Cancer** |
| **Protocol Number:** | **LCI-BRE-H2N-ANPA-001** |
| **Principal Investigator: (Study Doctor)** | **Antoinette Tan, MD** |
| **Telephone:** | [redacted] |
| **Address:** | **Levine Cancer Institute** [redacted] |

## INTRODUCTION

Dr. Tan and her associates (the investigators) are asking you to participate in a research study at Levine Cancer Institute (LCI) and Atrium Health (AH) of anastrozole and palbociclib as first-line therapy and as maintenance therapy after first-line chemotherapy in hormone receptor (HR)-positive, HER2 (human epidermal growth factor receptor)-negative postmenopausal metastatic breast cancer. Hormone receptor-positive breast cancer means that your breast cancer cells have a receptor protein that binds the hormones. Cancer cells that are hormone receptor-positive may need hormone to grow and may stop growing or die when treated with substances that block the binding and actions of hormones, such as aromatase inhibitors (for example, anastrozole).

You are being asked to take part in this study because you have HR-positive, HER2-negative postmenopausal metastatic breast cancer. This study will be offered as first-line treatment for metastatic breast cancer to patients who have not yet received treatment for metastatic breast cancer or as maintenance therapy for patients who have previously started first-line chemotherapy and have had a good response for at least 6 months. If you are pre- or perimenopausal with HR-positive, HER2-negative metastatic breast cancer, you can participate if you agree to receive monthly LHRH (luteinizing hormone releasing hormone) agonist injections that decrease estrogen (hormone) production from your ovaries, which make you postmenopausal until you stop the injections.




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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. 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 health care 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). Pfizer is the company supplying the drug (palbociclib) that will be used in this study.

**WHY IS THIS STUDY BEING DONE?**

The purpose of this study is to determine if the study drug, palbociclib, is safe to use when it is combined with the aromatase inhibitor anastrozole. Other goals in this study are to learn about the effect of palbociclib and anastrozole on the white blood cell count, to learn about the effect of both study drugs on tumor growth in subjects who have not received prior therapy for their metastatic disease and in subjects who receive this combination after chemotherapy, and to learn how the DNA (genetic material) and proteins in the blood and tumor may predict or show an effect from palbociclib.

This study will evaluate giving palbociclib and anastrozole together as first-line therapy (Group A) and as maintenance therapy after being treated with first-line chemotherapy (Group B). Your study doctor will decide which group you will be placed in based on your situation.

Maintenance therapy is the treatment of cancer with medication, typically following an initial round of treatment. Maintenance therapy in this study is described as slowing the growth of advanced cancer after initial treatment. In this situation, maintenance therapy is not used to cure the cancer, but it can lengthen a person's life. In rare instances, maintenance therapy can avoid or slow the cancer's return.

Palbociclib (Ibrance®) is a drug that has been approved by the Food and Drug Administration (FDA) in the United States for the treatment of advanced breast cancer. It is used along with the aromatase inhibitor letrozole for the treatment of postmenopausal women with HR-positive, HER2-negative advanced breast cancer as the first hormone-based therapy for their metastatic disease.

Palbociclib is in a new class of drugs called CDK (cyclin-dependent kinase) 4/6 inhibitors that work to stop the proteins CDK 4 and CDK 6 from signaling. By stopping these proteins, palbociclib slows cell growth and division in healthy and cancer cells.

Anastrozole (Arimidex®) is an endocrine (hormonal) agent called an aromatase inhibitor that blocks the enzyme that makes estrogen and is used for the treatment of postmenopausal women with hormone receptor-positive breast cancer that has spread to other sites in the body or as a treatment after first-line therapy. It has been FDA approved for these uses. Many breast cancer tumors grow in response to hormones in the body. This medicine blocks the effects of the estrogen hormone in the body. As a result, the amount of estrogen that the tumor is exposed to is reduced, limiting the growth of the tumor. The combination of palbociclib and anastrozole has been approved by the FDA for the treatment of metastatic breast cancer.

## HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

You will be one of about 40 subjects participating in this study. Approximately 25 subjects will be enrolled in Group A and 15 subjects will be enrolled in Group B. Your participation in the study may last up to 66 months (5 and ½ years). However, if you or other subjects are still on study treatment after 66 months, we will continue to follow you until at least 30 days after all subjects have discontinued study treatment.

## HOW THE STUDY WORKS

**Before you begin the study (Baseline):**
You will need to have the following tests and procedures done to determine if you can be in the study. These exams, tests, and procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- Medical history
- Physical examination; including vital signs (heart rate, blood pressure, breathing rate, temperature) and height/weight measurements.
- Documentation of any medicines you are taking.
- You will be asked about the extent of your physical activity and how you are generally feeling.
- Electrocardiogram (ECG), a paper tracing of the electrical activity of your heart.
- Imaging tests, such as a CT (computed tomography – a special type of x-ray) scan with contrast dye or MRI (magnetic resonance imaging – use of magnetic waves to look at the soft tissues of the body) and a bone scan (a procedure in which a small amount of a radiotracer (radioactive material) is injected into a vein prior to the special x-ray).
- Documentation of any side effects you are experiencing.
- Pregnancy test if you are of childbearing potential. If you are not post-menopausal and have not yet started LHRH agonist injections, you will have a pregnancy test before starting the LHRH agonist. The pregnancy test will be repeated within 14 days of starting study treatment.
- Blood work for estrogen and other hormone levels to confirm postmenopausal status if you are less than age 60.
- Blood work for blood counts and blood chemistry (electrolytes [salts or chemicals in the blood] and kidney and liver functions) and tumor markers (substances in the cells that indicate disease).

The following tests and procedures will be done specifically for this study and are not part of your regular cancer care:

- Blood work to check for circulating tumor DNA (ctDNA)- fragments of DNA [genetic material] from cancer cells in the blood).
- You will be asked to have a biopsy (removal of a small tissue sample from the area where your disease is) taken before the study treatment is started for the purposes of research. This sample

is optional. If you do not agree to this additional sample, you may still take part in this study. This procedure will not be done if the study doctor does not consider it safe to biopsy the tumor. You will be given the opportunity at the end of this consent form to indicate whether or not you agree to this procedure.

- Optional blood draw for future research. You will be given the opportunity at the end of this consent form to indicate whether or not you agree to this procedure.

**During the study (Intervention):**
If the exams, tests, and procedures show that you can be in the study, and you choose to take part, then you will begin study treatment as described below:

- Postmenopausal women - you will take 1 mg anastrozole by mouth once daily on Day 1 through Day 28 of each 28-day cycle. You will also take palbociclib by mouth once daily on Day 1 through Day 21 of each 28-day cycle (3 weeks on/1 week off).

- Pre- or perimenopausal women - you will take 1 mg anastrozole by mouth once daily on Day 1 through Day 28 of each 28-day cycle. You will also take palbociclib by mouth once daily on Day 1 through Day 21 of each 28-day cycle (3 weeks on/1 week off). In addition, you will be given an LHRH agonist injection as prescribed by your study doctor.

You will be given study treatment on 28-day cycles until the time your disease progresses. If you are having unfavorable side effects, the study treatment may be stopped for a while, or the dose of the study drug may be reduced. Your study doctor will also discuss with you whether it is in your best interest to continue the study treatment with the study drug.

Anastrozole may be taken with or without food. You should take your dose of anastrozole at approximately the same time each day. You will be given a Medication Diary to record your doses and you will be asked to bring the diary with you to each appointment.

You will be provided palbociclib in blister packs (3 weekly blister packs of 7 tablets each). Palbociclib should be taken at approximately the same time each day with or without food. Do not eat grapefruit or drink grapefruit juice while taking palbociclib. Do not begin any herbal medicines while taking palbociclib without first speaking with your study doctor. You should swallow palbociclib tablets whole and not chew them prior to swallowing. The palbociclib tablets should not be removed from the blister pack and placed in a pill caddy/pill box. You will be given a Medication Diary to record your doses and you will be asked to bring the diary with you to each appointment. If you miss a day's dose or vomit any time after taking a dose, skip the dose and do not make it up the next day. If you inadvertently take an extra dose during a day, you must skip the next day's dose. If you are experiencing side effects from palbociclib that are not tolerable, the study doctor may reduce the dose you are taking.

You may experience risks or discomforts when taking part in this study, which include some that are common such as low blood cell counts, infections, gastrointestinal (stomach and intestines) symptoms, fever, and fatigue, some that are rare, such as life-threatening infections and sepsis, and

some that are unknown at this time. This is not a complete list of risks or discomforts. A comprehensive list of risks and discomforts is provided later in this consent document.

During the study, you will need the following exams, tests, and procedures. They are part of regular cancer care.

- Medical history and physical exam including vital signs
- Documentation of any side effects you are experiencing
- You will be asked about the extent of your physical activity and how you are generally feeling.
- Blood work for blood counts, blood chemistry, and tumor markers. The blood counts will be collected once a week for approximately 12 weeks (until 3 cycles have been completed). After 12 weeks, the blood counts will be collected once a month.
- Imaging tests approximately every 8 weeks from your first study treatment and at time of follow-up, such as a CT scan or MRI. A bone scan will be done for all patients at screening and then approximately every 8 weeks during treatment if bone metastasis is present at screening. Imaging tests (CT scan or MRI and bone scan for patients with bone metastasis present at screening) will then be done approximately every 12 weeks after you have been on the study for 12 months. A bone scan may also be done if new bone pain is present.

The following tests and procedures will be done specifically for this study and are not part of your regular cancer care:

- Blood work to check for circulating tumor DNA within a week prior to treatment on Cycle 3 Day 1
- You will be asked to have an optional biopsy taken prior to Cycle 3 Day 1 of treatment if your study doctor considers it safe to biopsy. These samples are optional. If you do not agree to these additional samples, you may still take part in this study.
- A portion of all tissue collected while on study including tissue collected from previous biopsies or surgery and/or fresh biopsies will be banked for future research if you agree. You will be given the opportunity below to indicate whether or not you agree to this.

**After you complete the intervention (End of Treatment; one visit):**
When your study doctor discontinues your study treatment, you will return for your End of Study Treatment visit. During this visit, the following procedures and tests will be done:

- Medical history and physical exam including vital signs.
- Documentation of any side effects you are experiencing.
- You will be asked about the extent of your physical activity and how you are generally feeling.
- Blood work for blood counts and blood chemistry.
- You will be asked to have an optional biopsy taken at disease progression if your study doctor considers it safe to biopsy. These samples are optional. If you do not agree to these additional samples, you may still take part in this study.

The following tests and procedures will be done specifically for this study and are not part of your regular cancer care:

- Blood work to check for circulating tumor DNA.

**Follow-Up**
The following tests and procedures will be done as part of your follow-up care after you have completed study intervention and the End of Treatment visit. These tests and procedures will continue until you have experienced disease progression (your cancer has gotten worse), you start new anti-cancer treatment, you choose to withdraw consent and stop participation in the study, or death; whichever comes first

- Your study doctor will ask that you continue to have imaging tests performed as part of your standard care after you have completed study intervention and enter study follow-up. The frequency of the imaging tests may occur every 8-12 weeks, or as determined by your study doctor.
- Your study doctor may ask that you continue to have blood taken for tumor marker assessment as part of your standard care if they feel it is appropriate to do so for the treatment of your cancer. The frequency of the tumor marker assessment may occur every 12 weeks, or as determined by your study doctor.

**Survival Follow-Up**
- You will be contacted every 6 months by telephone, in writing, or during a clinic visit for collection of follow-up information and to see how you are doing.

**RISKS**

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, study doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the drugs. In some, cases, side effects can be serious, long-lasting, or may never go away. A severe side effect rarely may be life-threatening. You should tell your study doctor immediately if you experience any side effects.

This study has several risks. First, it is possible that you will get the new study treatment but do less well than you have been doing. Second, because the study treatment is new, we may not yet know all the side effects and something unexpected could happen. The following known side effects of anastrozole and palbociclib are listed below.

**<u>Palbociclib</u>:**
Palbociclib has been given to approximately 1699 patients with breast cancer who received palbociclib together with hormonal treatment in Pfizer-sponsored clinical trials.

The following side effects have been reported:

**Side effects seen in 30% or more of patients:**

- Decreases in neutrophils (may increase the risk of infection)
- Decreases in white blood cells (infection fighting cells)
- Infections
- Fatigue (tiredness)

**Side effects seen in 10% to less than 30% of patients:**

- Decreases in hemoglobin (substance in the red blood cells that carries oxygen to the body) that may cause weakness
- Diarrhea
- Nausea
- Vomiting
- Decreases in platelets that may cause bleeding and/or bruising
- Decrease in appetite
- Constipation
- Inflammation of the mouth
- Joint pain
- Back pain
- Pain in hands and feet
- Hair loss
- Rash
- Cough
- Shortness of breath
- Headache
- Dizziness
- Hot flush
- Insomnia (inability to sleep)
- Fever
- Common Cold

**Reported in between 5 to less than 10% of patients:**

- Swelling of hands and feet
- Nosebleed
- Muscle cramps
- Dry mouth
- Abdominal pain
- Indigestion
- Asthenia (general weakness)
- Irritation or sores in the lining of hollow organs like the mouth, throat, stomach, and bowels

- Pain
- Influenza (flu) like illness
- Muscle pain
- Pain in the muscles and bone including around the chest and neck
- Increases in blood liver markers that may indicate liver damage
- Dry skin
- Itching
- Mouth/throat pain
- Impaired sense of taste
- Depression
- Fall
- Anxiety
- Increased blood pressure
- Acid reflux (heartburn)
- Increased creatinine level (may indicate abnormal kidney function)

**The following have been reported in less than 5% of patients, but are still deemed important:**

- Fever associated with dangerously low levels of a type of white blood cell (neutrophils)
- Blurred vision
- Increased tearing
- Dry eye
- In addition, interstitial lung disease (ILD)/pneumonitis may occur during treatment. ILD is inflammation of the lungs, and can be severe or life-threatening and may lead to death. Tell your study doctor right away if you have any new or worsening symptoms, including:
    - Trouble breathing or shortness of breath
    - Cough with or without mucus
    - Chest pain

Serious and life-threatening infections have been observed in some patients treated with palbociclib.

**<u>Anastrozole</u>:**

The **most common side effects** are:

- Hot flashes/flushes
- Weakness or decreased energy
- Increased sweating
- Increased cholesterol levels
- Swelling in the hands or feet
- Joint pain/stiffness
- Constipation

- Dizziness
- Headache
- Chest pain
- Hair loss or thinning
- Back pain
- Bone pain
- Cough
- Shortness of breath

Other **less common side effects** are:

- Difficulty sleeping
- Depression
- Increased blood pressure
- Diarrhea
- Nausea
- Loss of appetite
- Abdominal pain
- Bone fracture
- Osteoporosis, or bone thinning, a disease that can affect postmenopausal women. The study drug may increase your chance of developing osteoporosis and may slightly increase your risk for bone fractures caused by osteoporosis. Talk with your study doctor or study nurse about your risk of developing osteoporosis, about tests that can detect osteoporosis, and about ways to prevent osteoporosis and fractures.
- Drowsiness
- Muscle aches
- Vaginal bleeding
- Vaginal dryness

**LHRH agonists**

You will only take an LHRH agonist by monthly injection if you have not reached menopause. Leuprolide and goserelin are specific examples of drugs that cause you to become postmenopausal to decrease the estrogen production from your ovaries, which may help to treat your breast cancer. Stopping of menstrual periods and the inability to have children while receiving the injections are desired effects of these medications. Side effects include:

- Hot flashes
- Weight gain
- Tiredness
- Loss of muscle mass

**Pregnancy Precautions**

You may not take part in this study if you are breastfeeding, are pregnant, think that you may be pregnant, or are trying to get pregnant. If you are pregnant or breastfeeding, there may be risks to



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you and the baby that are not known at this time. Women of childbearing potential will be tested for pregnancy during the study. You must avoid getting pregnant in order to take part in this research study.

It is important for you to tell the study doctor at once if you get pregnant or think that you might be pregnant while you are in the research study. If this happens, the study doctor will discuss with you what you should do. If you get pregnant, you will be asked to stop taking part in the study. You may also be asked questions about your pregnancy and the baby.

**Other Side Effects/Risks:**

**Blood Drawing**
You may have pain or bruising at the site where the blood is drawn. You may feel faint. An infection at the site of the blood draw is possible.

**CT Scan/MRI**
A CT scan exposes you to a small dose of radiation. Although all radiation you receive builds up over your lifetime, this amount of radiation should not create a significant risk to your health. Contrast dye is usually injected when you get a CT scan. The contrast dye may cause pain or burning when it is injected and may worsen kidney function in people who already have kidney disease or who are dehydrated (have not had enough liquids that day). The contrast dye may also cause an allergic reaction, which could be severe and life-threatening.

There are risks from an MRI if you are pregnant or have one of the following: an artificial heart valve, pacemaker, metal plate, pin, or other metallic objects in your body (including gunshot or shrapnel). You may also become anxious from lying in a tight space without moving. The MRI scan does not cause any pain and does not expose you to x-ray radiation.

**Bone Scan**
A bone scan exposes you to a small dose of radiation. Although all radiation you receive builds up over your lifetime, small doses from bone scans should not create a significant risk to your health.

**ECG**
The risks from an ECG can include skin irritation and a rash from the gel that is used or from wearing or removing the patches.

**Tumor Biopsy**
The risks of a biopsy can include bleeding, pain, and infection. To reduce these risks, the site of the biopsy will be numbed and sterile techniques will be used. You will sign a separate consent for this procedure.

**Allergic Reaction**
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; a fast pulse; and/or sweating.

**Specimen Confidentiality**
There is a small risk that your protected health information may be released during the processing of your specimens for research. Everything possible will be done to ensure your privacy and confidentiality is maintained. Your specimens will be labeled with a code that does not identify you. Only your study doctor and a small number of study staff will know your identity.

**Privacy Risks of Genetic Testing**
If your genetic research data are shared with unauthorized users, you may be at risk of loss of the privacy of your health data. This risk is minimized by protections described in the Confidentiality section below.

## EXCLUSION CRITERIA

There may be reasons why you are not allowed to take part in this study. Some of these reasons include:

- You are unable to swallow pills.
- You have received a CDK inhibitor before.
- You have known active or symptomatic central nervous system (brain) tumor and/or carcinomatous meningitis.
- You have had anti-cancer therapies, surgery, or radiation within at least 3 weeks prior to Day 1 of the study.
- You have another type of cancer that has been treated during the last 3 years.
- You have a serious or significant medical problem, within the past 6 months which may make it dangerous for you to receive this study treatment, for example, a heart condition known as congestive heart failure, where your heart fails to pump blood, or pulmonary embolism, which is blockage of blood vessels in the lung.
- You had prior hematopoietic stem cell (cells that produce all other blood cells) or bone marrow (soft tissue inside bone) transplantation.
- You have known human immunodeficiency virus (HIV) infection.
- You are currently participating and receiving study therapy or have participated in another research study within 4 weeks of the first dose of study treatment.



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## WILL I BENEFIT FROM PARTICIPATING IN THIS STUDY?

This study may or may not improve your condition. The information gained from your participation may benefit others with your condition.

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

Your study doctor is willing to discuss the benefits and side effects of other forms of treatment other than this study that are available. These include:

- Other usual chemotherapy for your type of cancer.
- Other investigational research studies with chemotherapy, hormones, radiation therapy, or new anti-cancer agents that may be available for your disease.
- Choosing no further treatment. If you choose no further treatment, you will be given care and medicines to help you feel more comfortable. This is called "comfort care", also called palliative care. This type of 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.

## WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

Some of the tests or treatments used in this study may be part of your standard care used to maintain your health even if you did not take part in this study. You and/or your health plan/insurance will need to pay for some or all of the costs related to your standard treatment. The study drug palbociclib and tests that would not be done (including tumor biopsies done for research purposes) unless you are participating in this study will be provided at no cost to you.

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 web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this web site. 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.

You may wish to discuss coverage with your insurance company before agreeing to participate in this research study.

## WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

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

In the event that you are harmed as a result of your participation in this study, inform your study doctor immediately so you can access medical treatment. You and/or your health plan will be



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charged for this treatment in the usual manner. The study will not pay for standard medical treatment.

You still have the right to make a claim through the legal system even if you sign this form, accept medical care, or accept payment for medical expenses.

## 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 to not participate will not in any way harm your relationship 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 relationship with your doctors or Atrium Health (AH). Information contributed to the study will remain in the study even if you choose to withdraw. If you choose to withdraw from the study, please notify the study doctor in writing at the address listed on the first page of this consent document.

The study doctor may choose to involuntarily withdraw you from the study for any reason.

We will tell you about new medical findings that may affect your willingness to continue in the study.

If you stop taking part in the study, any specimens which may have already been collected and processed will remain de-identified and part of the study. Any specimens which may have been collected, but have not yet been processed may be destroyed upon your written request. No specimens will be returned to you.

## WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

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 Atrium Health, Pfizer (funding company), 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.

Your de-identified specimens for research (with only your unique ID number) and associated data will be stored in a biospecimen repository (a "bank" of specimens and data) at Atrium Health.

Your specimens for research may be used to determine the sequence of some or all of your genes (DNA – traits passed in families). However, this study is not intended to identify disease causing mutations that can affect the health of close family members (such as your parents, siblings or children).



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A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information.

This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that the sponsor will get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that the sponsor will get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans and all employers with 15 or more people must follow this law.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance or long-term care insurance.

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:

**LCI-BRE-H2N-ANPA-001: Levine Cancer Institute, Pilot Trial of Anastrozole and Palbociclib as First-Line Therapy and as Maintenance Therapy after First-Line Chemotherapy in Hormone Receptor-Positive, HER2-Negative Postmenopausal Metastatic Breast 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



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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.

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**

**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 (Pfizer) that developed the drug palbociclib used in this study. However, Pfizer will give money or other benefits to a research fund, foundation, educational institution, or other organization with which the doctor or study staff is associated.

**QUESTIONS**

The researchers doing the study at Atrium Health are Dr. Tan and her associates. You may ask them any questions you have now. If you have questions later, you may contact them at the address and/or phone number listed on the first page of this consent document.



Affix Participant Barcode Label Here

## WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- 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: Pro00017766.

## OPTIONAL AND FUTURE STUDIES – BIOSPECIMEN COLLECTION

The study doctor and her associates (the investigators) are asking you to allow your blood and tissue to be collected and used for the purposes of research. All information for the main study's informed consent form still applies to this part of the informed consent. Your study doctor would like to collect blood samples and tissue from you for future, currently unplanned research. Regardless of your decision to participate in this optional blood collection, you may still participate in the main study, if you choose to. However, you must participate in the main study in order to be eligible for participation in this optional blood and tissue collection.

If you agree to participate in the optional and future research - blood collection, we will ask to collect approximately 20 mL or about a tablespoon and a half of blood. We would like to collect blood on the first day of treatment on this study prior to treatment.

If you agree to participate in the optional and future research – tissue collection, we will ask to collect and store tissue from you collected during the course of the study.

If you agree to participate in the optional tissue biopsies, we will ask to collect a biopsy at the following time-point(s): before study treatment starts, prior to Cycle 3 Day 1, and at disease progression. The biopsies will only be collected if your study doctor has determined that it is safe to do.



Affix Participant Barcode Label Here

If you agree to donate samples, they will be stored at the Levine Cancer Institute Bio Specimen Repository, a place where human samples are securely stored and where any of your remaining archived and/or freshly collected samples will be stored.

If you decide at a later date to withdraw your consent for any reason, you have the option not to allow Levine Cancer Institute to use your blood samples and tissue collected for testing by contacting the study doctor at the telephone number or address listed on the first page of this form. Blood and tissue samples will be destroyed only if they have not already been tested.

Participation in this collection is optional, and refusing to participate will not affect your eligibility for the main study or the study treatment given.

1. **Do you give permission to have an optional blood sample collected to be stored for future research?**

   Yes_____ No_____ Initials_____

2. **Do you give permission to have tissue previously taken from you and during the course of the study to be stored for future research?**

   Yes_____ No_____ Initials_____

3. **Do you give permission to have an optional tissue biopsy at the following time points for the purposes of research if your study doctor determines it is safe: Before study treatment starts, before Cycle 3 Day 1 and/or at the time of disease progression?**

   Yes_____ No_____ Initials_____



Affix Participant Barcode Label Here

**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



Affix Participant Barcode Label Here