Official Title: LCI-BRE-MTN-TPGC-001: A Phase II Trial of Trilaciclib, Pembrolizumab, Gemcitabine and Carboplatin in Metastatic Triple-Negative Breast Cancer.
NCT06027268
IRB-Approved Date: 2/11/2026

ATRIUM HEALTH
CONSENT TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Sponsor / Study Title:	**Atrium Health Wake Forest Baptist Comprehensive Cancer Center / "To**PC**our**T**: A Phase II Trial of **T**rilaciclib, **P**embrolizumab, Gemcitabine, and **C**arboplatin in Locally Advanced Unresectable or Metastatic **T**riple-Negative Breast Cancer**"**
Protocol Number:	**LCI-BRE-MTN-TPGC-001**
Principal Investigator: (Study Doctor)	**Antoinette R. Tan, MD, MHSc**
Telephone:	[redacted] **(24 Hours)** **(24 Hours)**
Address:	[redacted]
Contact Information for	[redacted] **Region**
Lead Investigator: (Study Doctor)	**Katherine C. Ansley**
Telephone:	[redacted]
Address:	**Hematology and Oncology Section** **Atrium Wake Forest Baptist Health** [redacted]

SUMMARY

You are invited to participate in a research study. The purpose of this research is to evaluate the anti-cancer efficacy (assess how well it works) of the combination of trilaciclib, pembrolizumab, gemcitabine, and carboplatin in participants with locally advanced unresectable or TNBC (triple-negative breast cancer). This study is also evaluating the safety and tolerability (how well your body can handle the treatment) of this combination of anti-cancer therapy. You are invited to be

Affix Participant Barcode Label Here

in this study because you have been diagnosed with triple-negative breast cancer (TNBC) that is either locally advanced and unresectable (the cancer is not able to be removed by surgery) or metastatic (cancer has spread to other parts of your body). Your participation in this research will continue until the study is complete, you decide to withdraw your consent to participate in the study, if the study doctor no longer feels it is in your best interest, or for other reasons described later in this consent.

Participation in this study will involve the combination of the drugs trilaciclib, pembrolizumab, gemcitabine, and carboplatin. All research studies involve some risks. Risks of participating in this study that you should be aware of are shortness of breath or difficulty breathing, itchy skin, rash, inflammation of many areas or organs of the body, swelling in areas of the body, fever, headache, confusion, and others. Additional information regarding the risks associated with this research study will be included in the "WHAT ARE THE RISKS OF THE STUDY?" section below.

You may or may not benefit from participation in this study. The possible benefits may include reduction in the side effects of chemotherapy, reduction in the symptoms from chemotherapy, reduction in tumor size, or slower progression of your cancer. It is possible that you may not benefit from the study drug, or it may harm you. We cannot guarantee that your participation in this study will help you. More information about the study drug that is obtained from your participation in this research study may help other people with the same disease in the future.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include other available therapies with known clinical benefit for your type of cancer including chemotherapy agents, immunotherapy, or another class of drugs called PARP inhibitors. Your study doctor can discuss the alternatives as well as the risks and benefits of these alternatives with you. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, please contact the study investigator using the contact information listed on the first page of this consent form.

If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Wake Forest University Health Sciences Research Subject Advocate at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies help scientist learn new information that may help other people in the future. You are being asked to be in this study because you

Affix Participant Barcode Label Here

have been diagnosed with triple-negative breast cancer that is either locally advanced and unresectable or metastatic. Please take your time in making your decision if you would like to join. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research is to evaluate the anti-cancer efficacy (assess how well it works) of the combination of trilaciclib, pembrolizumab, gemcitabine, and carboplatin in participants with locally advanced unresectable or TNBC (triple-negative breast cancer). This study is also evaluating the safety and tolerability (how well your body can handle the treatment) of this combination of anti-cancer therapy.

TNBC means that the three most common types of receptors (molecules [tiny parts] in a cell that respond specifically to a particular substance) known to fuel most breast cancer growth– estrogen, progesterone, and the HER-2 gene– are not present in the cancer tumor. Since the tumor cells lack these receptors, treatments like hormone therapy and drugs that target estrogen, progesterone, and HER-2 are ineffective. Therefore, chemotherapy treatments (chemical agents to treat cancer) have been the standard of care for TNBC. These are effective, but their long-term use often becomes limited by either toxicity (harmful effect of a drug) or resistance (no longer working against the cancer), leading to the cancer becoming more advanced.
Trilaciclib is an agent that helps protect your bone marrow (where your blood cells are made) from harmful side effects of chemotherapy. When given with standard chemotherapy, it may also enhance the anti-cancer treatment and improve overall survival. Trilaciclib has been approved for use in adult patients getting certain types of chemotherapy for advanced-stage small cell lung cancer; however, at this time, it has not been approved by the Food and Drug Administration (FDA) for patients with TNBC receiving chemotherapy. Adding trilaciclib to the other anti-cancer agents in this study is investigational.

Pembrolizumab is an immunotherapy agent approved by the FDA in combination with chemotherapy for the treatment of metastatic TNBC in patients who express PD-L1 (a protein found on some types of cancer cells). Immunotherapy is a type of cancer treatment that helps your own immune system fight cancer.

Gemcitabine and carboplatin are both chemotherapy agents commonly used in metastatic breast cancer patients.

This study is being carried out under the sponsorship of Atrium Health Wake Forest Baptist Comprehensive Cancer Center (AHWFBCCC). Pharmacosmos is providing funding and trilaciclib and Merck is providing funding and pembrolizumab, two of the treatments that will be used in this study.

Affix Participant Barcode Label Here

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
If you choose to participate, you will be one of up to 36 subjects taking part in this study. All subjects will be enrolled into the study over an approximately 30-month time period.

WHAT IS INVOLVED IN THE STUDY?

Before you begin the study (Screening):
To participate in this study, you will need to review, sign and date this consent form and provide authorization for the release of your medical records for research purposes. By doing so, you are giving us permission to determine if you are eligible to participate in this study.

You will need to have the following tests and procedures done to determine if you can be in the study. Some of 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. You will need to review, sign, and date this consent form prior to any study-related tests or procedures being done. Consent may also be obtained electronically.

- Documentation of your 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
- Documentation of any side effects that you may be experiencing from prior treatments
- 12-lead ECG (electrical recording that shows your heart rhythm)
- ECOG performance status (questions that assess how well you perform daily activities and how you are feeling)
- Blood work for blood counts, blood chemistry and clotting, and thyroid function
- Serum (blood) pregnancy test for women of childbearing potential
- Tumor imaging tests, including a CT scan with contrast dye (computed tomography – special type of x-ray that uses a computer to make pictures) and a bone scan (special x-ray where a small amount of a radiotracer [radioactive material] is injected into a vein) or MRI (magnetic resonance imaging – use of magnetic waves to look at the soft tissues of the body) to define the extent of your disease. A brain MRI will only be done if it is known that your cancer has spread to the brain or if you have concerning symptoms that may mean your disease has spread to the brain.
- For postmenopausal females: During screening, a blood test for FSH (follicle-stimulating hormone) will be done if you are under 45 years old and have not menstruated for over 12 months without a known medical reason, or an FSH test may be done if you have had less than 12 months of no menstruation. Women who show they are postmenopausal by this test will not be considered women of childbearing potential.
- **Tumor tissue for research (biopsy):** You will be asked to have a biopsy taken (removal of a small tissue sample from one of the areas where the cancer is in your body) before study treatment begins. If a new biopsy is not possible to obtain, we will request some of the tissue that was collected at the time of your diagnosis (archived), but only if it was collected within the past six months prior to starting treatment in this study. If tissue is

Affix Participant Barcode Label Here

not available or unable to be obtained within the required timeframe (i.e., either fresh or archived), you may still be eligible for the trial.

During the study (Intervention):

If the screening exams, tests, and procedures show that you can be in the study, and you choose to take part, you will begin study treatment as described below.

Your study treatment cycles will be 21 days in length.

You will be given the study treatment combination of trilaciclib, pembrolizumab, gemcitabine and carboplatin as follows:

- Trilaciclib, gemcitabine and carboplatin will be given on Day 1 and Day 8 of each cycle
- Pembrolizumab will be given on Day 1 of each cycle

Each of these treatment therapies are given to you intravenously (IV), which means given to you through a vein. It takes approximately 30 minutes to infuse each of these therapies. There may also be other medications given before or after these study treatment therapies to help prevent side effects, which will add to your time in the infusion center.

If you are having unfavorable side effects, the study treatment may be held for a while, or the dose of the study drug(s) 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(s).

You will need to have the following tests and exams during each cycle of treatment. Some are part of regular cancer care:

Day 1 of each cycle:

- Review of eligibility for study (cycle 1 only)
- Medical history (cycle 1 only)
- Physical examination including vital signs and weight measurements
- ECOG performance status
- Blood work for blood counts and blood chemistry
- Thyroid function (blood test) at odd cycles only, starting at cycle 3
- Serum (blood) or urine pregnancy test within 72 hours prior to Day 1 of each cycle for women of childbearing potential.
- *Blood for research purposes (not part of regular cancer care)*: blood samples will be collected prior to starting study treatment on Day 1 at Cycles 1, 2, and 3; also, at 3 and 6 months after beginning study treatment (if you are still receiving treatment).

Day 8 of each cycle:

- Vital signs prior to treatment
- Blood work for blood counts and blood chemistry

Throughout the study:

Affix Participant Barcode Label Here

- Tumor imaging- the CT or MRI scans that were done at screening will be repeated approximately every 9 weeks from Cycle 1, Day 1. If you are still on treatment after 12 months, the imaging frequency will change to approximately every 12 weeks from the previous scan or as needed per your doctor.
- Bone scan - if no cancer is found in the bones during the screening scan, the scan will only be repeated if clinically indicated (showing signs or symptoms of possible spread into the bones). If cancer is found in the bones at screening, a repeat bone scan will be done at the same time the tumor imaging is done throughout the study.
- Documentation of any medicines you are taking
- Documentation of any side effects that you are experiencing
- *Research biopsies (not part of regular cancer care)* Once on study, there are two other tumor tissue biopsies. One biopsy is required within 7 days prior to Cycle 3 of study treatment. The other biopsy is optional and will be collected if your disease progresses. This last, optional biopsy will be taken within 28 days of the imaging test which shows disease progression. Biopsies will not be taken if disease is found only in the bone or if there is a safety concern.

End of Treatment Visit

After you stop the treatment, this visit will occur approximately 30 days after your last treatment dose. During this visit, the following occurs:

- Physical examination including vital signs and weight measurements
- Documentation of any medicines you are taking
- Documentation of any side effects you are experiencing
- ECOG performance status
- Blood work for blood counts and blood chemistry
- Serum (blood) or urine pregnancy test for women of childbearing potential

Active Follow Up

If your cancer has not progressed and if you have not started a new anti-cancer treatment at the time your study treatment is discontinued, you will enter Active follow-up. You will be contacted about every 12 weeks to see how you are doing and whether you have begun new anti-cancer treatment. During Active follow-up, tumor evaluations (CT or MRI scans) will also be done about every 12 weeks. This follow-up will continue until your cancer progresses, you begin new anti-cancer therapy, or you withdraw your consent to participate.

Survival Follow Up

If your cancer progresses or you begin a new anti-cancer treatment, you will be contacted about every 12 weeks to see how you are doing. This follow-up will continue until the study has been completed for all subjects, you withdraw your consent to participate in the study, or death occurs. This follow-up may be done by phone contact.

Pseudo progression

Antoinette Tan, MD, MHSc

Some immunotherapy drugs, like pembrolizumab used in this study, may cause an initial appearance of an increase in the size of a tumor or number of tumors noted on imaging scans, called pseudo progression. With pseudo progression, the imaging scans will show an initial increase in size and/or number of tumors but in reality, the tumors may be stable or getting smaller or disappearing. This happens in a very small percentage of breast cancer patients. Your doctor treating your cancer will look at other symptoms and lab work to help diagnose pseudo progression or true progression of your cancer. If your treating doctor feels the appearance of increase in your cancer may be related to pseudo progression, you may be allowed to continue study treatment until a later scan, labs or symptoms show true progression of your cancer.

Your treating doctor must determine that there is evidence of clinical benefit for you to continue study treatment and there must not be any signs and symptoms of progression and/or clinical decline before each study treatment cycle for you to continue to receive study treatment.

If you continue study treatment after pseudo progression, you will continue treatment, scans, and all other study procedures required during study treatment per the usual study schedule until your study treatment is stopped. Then you will enter into Survival Follow-up (see section above).

Blood Samples for Research

You will have blood drawn from a vein, existing port access, or IV line. You will have approximately 1.5 tablespoons of blood withdrawn on Cycle 2, Day 1 and Cycle 3, Day 1. You will have approximately 3 tablespoons of blood withdrawn on Cycle 1, Day 1 and approximately 1.5 tablespoons at 3 and 6 months from your first study treatment. The total amount of blood withdrawn during the study will be approximately 9 tablespoons. Blood specimen collections will only occur if you are still active on the study.

Optional Tumor Biopsy

The study doctor and her associates (the investigators) are asking you to allow a biopsy of your tumor to be collected at a specific time point and used for the purposes of research. Your study doctor would like to collect an additional tumor biopsy at the time of disease progression, if your disease progresses. Regardless of your decision to allow an additional tumor biopsy to be taken at disease progression, 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 the additional biopsy.

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

Do you give permission to have an optional tumor biopsy at the time of disease progression for the purposes of research? Participation in this collection is optional and refusing to participate will not affect your eligibility for the study or the study treatment given.

Affix Participant Barcode Label Here

☐ **Yes** ☐ **No** **Initials** _____

YOUR ROLE IN THE STUDY
Taking part in a research study can be an inconvenience to your daily life. Please consider the study time commitments and responsibilities as a research subject when you are deciding to take part. Your responsibilities as a study subject include the following:

- Tell the truth about your medical history and current conditions.
- Tell the study doctor if you have been in a research study in the last 30 days or are in another research study now.
- Tell the study doctor about any problems you have during the study.
- The study doctor or study staff will talk to you about any medicines that you should not take while in this study.

HOW LONG WILL I BE IN THE STUDY?
You will remain in the study until the study has been completed.
You will continue to receive treatment until one of these events occurs:

- Your disease progresses (worsens)
- You experience unacceptable side effects
- You decide to withdraw (end your participation) from the study
- You have an illness which prevents you from continuing study treatment
- The study doctor feels the study treatment is no longer in your best interest
- You become pregnant

*Note: Pembrolizumab may only be given for 2 years i.e., a total of 35 cycles. The other study treatments may continue after this timepoint if they are still of benefit to you.

See "What is involved in the study?" section for details on Active and Survival follow up after you have discontinued the study treatment.

You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first. If you decide not to be in the study, that will not in any way harm your relations with your doctors or with Atrium Health.

WHAT ARE THE RISKS OF THE STUDY?
Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff.

Risks related to the study procedures in this study include:

Affix Participant Barcode Label Here

Radiation	If you participate in this study, you will be exposed to amounts of radiation above what you would normally receive in daily life. To be sure that you do not receive an unhealthy amount of radiation from your participation in this study, you should let your study doctor know if you have had, or are going to have, any other scans or x-rays as part of your medical or dental care. It is very important that you let your study doctor know if you already are participating in, or plan to participate in, any other research study that involves radiation exposure. This research study involves exposure to radiation from CT and bone scans. The risk of these procedures is small and is similar to that received from clinical x-ray and nuclear medicine studies. The amount of radiation exposure that you will receive from these procedures is at most equivalent to a uniform whole body exposure of 968 millirem. This is equal to 3.23 times the amount of background radiation that the average person in the United States receives each year (annual background = 300 millirem).
Contrast Dye with a "CAT" or CT scan (computed tomography scan-imaging technique used to gain detailed internal images of the body)	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 in 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.
MRI scan (Magnetic Resonance Imaging- a technique using strong magnetic fields to form pictures of internal body anatomy and processes)	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 build up over your lifetime, small doses from bone scans should not create a significant risk to your health. You will sign a separate consent form for this procedure.
Confidentiality and privacy	Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.
Blood draws	You may experience discomfort, bruising and/or bleeding where the needle is inserted. Occasionally some people become dizzy,

Affix Participant Barcode Label Here

	lightheaded or feel faint. Infection may occur on rare occasions.
ECG (electrocardiogram)	Small sticky pads will be stuck to your chest, shoulders and hips and a machine will measure the electrical activity of your heart. We may need to clip small patches of your hair in these areas. These sticky pads may cause some local irritation and may be uncomfortable to remove
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.

There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks to your health.

All drugs may have side effects. Most side effects are mild to moderate, but some may be serious and/or require treatment. Each subject's reaction to a study drug may be different. You may have a side effect or be at risk for symptoms, illnesses, and/or complications that could not be predicted by the study doctor or the Sponsor of this study. If such side effects occur, you must inform the study doctor immediately.

Risks and side effects related to the study treatment include:

Trilaciclib

At least 1166 people have taken at least 1 dose of trilaciclib. Some of those people did not have cancer (249 healthy subjects). The people with cancer received trilaciclib in combination with chemotherapy and usually received several doses.
Because trilaciclib is given with chemotherapy to cancer subjects, it is hard to know if the side effects experienced by those subjects are due to trilaciclib or chemotherapy.

Very common side effects of trilaciclib that occurred in at least 1 out of 10 subjects (greater than 10% of subjects) and occurred more frequently in subjects taking trilaciclib compared to subjects taking placebo (at least 2% more frequently in subjects taking trilaciclib) are listed below:

- Nausea
- Fatigue (feeling tired)
- Headache
- Shortness of breath
- Injection site reactions (itching, swelling, pain, redness, heat, or burning sensation at the site in the arm where trilaciclib flows into the vein)
- Cough

Affix Participant Barcode Label Here

- Low potassium levels in your bloodstream that can make your muscles weak, and really low levels can cause abnormal heart rhythms

Common side effects that occurred in 1 to 10 out of 100 subjects (1%–10% of subjects) and occurred more frequently in subjects taking trilaciclib compared to subjects taking placebo (at least 2% more frequently in subjects taking trilaciclib) include:

- Swelling of the legs
- Aches in your joints
- Skin rash
- Upper abdominal pain
- Irritation or inflammation of a vein (phlebitis or thrombophlebitis; when the irritation or inflammation is caused by a blood clot, it is called "thrombophlebitis")
- Increased liver enzymes that can cause fatigue and jaundice (yellowing of skin and eyes); usually mild and reversible, but can be serious
- Allergic type reactions to trilaciclib that can cause swelling in the face or tongue, hives, and/or itching
- Low levels of phosphate in your blood that can cause muscle weakness
- Pain in your muscles and bones including the muscles and bones of your chest
- Skin redness
- Bloating or distention (swelling) of your stomach
- Increase in weight
- Flatulence (gas)
- A flu-like illness
- Fluid between the lung and rib cage
- Restless leg syndrome (the urge to move your feet or legs when you are sitting still)

Approximately 3% of cancer patients that received trilaciclib prior to chemotherapy experienced a venous thromboembolic event (blood clot). Approximately 2% of patients receiving chemotherapy alone or with placebo (inactive therapy) reported a blood clot.

Other possible and potentially serious side effects (occurring in less than 1 out of 100 subjects [less than 1% of subjects] that received trilaciclib) include:

- In September 2019, the U.S. FDA issued a warning for oral (taken by mouth) CDK4/6 inhibitors, which are used in combination with other medicines to treat breast cancer. The FDA warned of a rare but serious and some cases fatal risk of lung injury called pneumonitis (inflammation of the lungs) or interstitial lung disease (ILD). Trilaciclib is a CDK4/6 inhibitor, however it is administered intravenously on an intermittent schedule. This is different from the oral CDK4/6 inhibitors that are usually given every day or almost every day. In subjects receiving trilaciclib, it was seen in less than 1 out of 1000 subjects (less than 0.1% of subjects). Symptoms may include:
    - Trouble breathing or discomfort with breathing

- Shortness of breath while at rest or with low activity
- Cough, fever or flu-like symptoms
- Any new or worsening breathing symptoms

If you develop any of the above symptoms, call your study doctor.

Pembrolizumab

Pembrolizumab works by helping your immune system to fight your cancer. However, pembrolizumab can also cause your immune system to attack normal organs and tissues in your body and can affect the way they work, which can result in side effects. These side effects may be serious (i.e., causing hospitalization or be life-threatening), may result in death, and/or may occur after you stop taking pembrolizumab. These side effects can affect more than one of your normal organs and tissues at the same time.

Very Common

Out of 100 people who receive pembrolizumab, 20 or more people may have the following:

- Itching of the skin
- Loose or watery stools
- Cough

Common

Out of 100 people who receive pembrolizumab, at least 5 but less than 20 people may have the following:

- Joint pain
- Rash
- Fever
- Back pain
- Pain in your belly
- Loss of skin color
- Not enough thyroid hormone, you may feel tired, gain weight, feel cold, or have infrequent or hard stools (hypothyroidism)
- Low levels of salt in the blood that may cause you to feel tired, feel confused, have a headache, have muscle cramps, and/or feel sick to your stomach (hyponatremia)

Uncommon

Out of 100 people who receive pembrolizumab, at least 1 but less than 5 people may have the following:

- Inflammation of the lungs, so you may feel short of breath and cough (pneumonitis)

Affix Participant Barcode Label Here

- Too much thyroid hormone, so you may feel anxious, feel angry, have trouble sleeping, feel weak, tremble, sweat, feel tired, have loose and watery stools (hyperthyroidism)
- Infusion reaction, where you may feel dizzy or faint, feel flushed, get a rash, have a fever, feel short of breath, experience a decrease in your blood pressure at the time of receiving your infusion (IV) or just after, or have pain at the site of infusion
- Inflammation of the bowels/gut, which may cause severe pain in your belly with loose or watery stools, and black, tarry, sticky stools or stools with blood or mucus (colitis)
- Inflammation of the skin so you may have peeling of the skin, itchiness, and/or skin redness. The skin inflammation (i.e., peeling, itching and redness) could also be widespread throughout your body. More severe skin reactions may involve the inside of your mouth, the surface of your eye and genital areas, and/or may cause the top layer of your skin to peel from all over your body which can cause severe infection (Severe skin reactions, including Stevens-Johnson syndrome or toxic epidermal necrolysis)

<u>Rare</u>
Out of 100 people who receive pembrolizumab, less than 1 person may have the following:

- Inflammation of the nerves that may cause pain, weakness, or tingling in your hands and feet, and may spread to your legs, arms, and upper body, leading to severe muscle weakness and possible temporary paralysis (Guillain-Barré syndrome)
- Inflammation of the muscles, so you may feel weak or have pain in your muscles (myositis)
- Inflammation of the pancreas (a gland in your abdomen that controls sugar levels), so you may have severe pain in the top part of your belly that may move to your back, feel sick to your stomach, and have vomiting that gets worse when you eat (pancreatitis)
- Inflammation of the eye, so you may have eye redness, blurred vision, sensitivity to light, eye pain, see floaters, or have headaches (uveitis)
- Inflammation of the liver that may make you feel sick to your stomach and vomit, feel like not eating, feel tired, have a mild fever, a pain in the right side of your belly, yellow eyes and skin, and dark urine (hepatitis)
- Inflammation of the pituitary gland (a gland in the head), which may cause you to feel sick to your stomach or have headaches, changes in your behavior, double vision, few to no menstrual cycles, weakness, vomiting and dizziness, or fainting (hypophysitis)
- Inflammation of the adrenal glands (glands on top of the kidneys) that may not make enough hormone, which could cause tiredness, weight loss, muscle weakness, feeling faint, having joint, muscle, and bellyaches, nausea, vomiting, loose or watery stools, fever, salt craving, and sometimes darkening of the skin like a suntan (adrenal insufficiency)
- Type 1 diabetes, a condition that can cause too much sugar in your blood, feeling thirstier than usual, frequent urination, and weight loss. You are likely to need regular insulin shots
- Inflammation of the kidney, so you may pass less urine or have cloudy or bloody urine, swelling, and low back pain (nephritis)

- Inflammation of the middle layer of your heart wall that may cause your heart to have difficulty pumping blood throughout your body, which can cause chest pain, shortness of breath, and swelling of the legs. You may experience a fast or irregular heartbeat that may cause dizziness or fainting (myocarditis)
- Inflammation of the thyroid gland, an organ that makes and stores thyroid hormones. This condition may lead to changes in your heart rate, blood pressure, body temperature, and the rate at which food is converted into energy (thyroiditis)
- A condition that may make you feel weak and tired and may cause drooping of the eyelids, blurred or double vision, difficulty swallowing, slurred speech, weakness in your arms and legs, or difficulty breathing (myasthenic syndrome/myasthenia gravis including exacerbation)
- The formation of small clusters of immune cells (called granulomas) in parts of your body such as your lymph nodes, eyes, skin, or lungs (sarcoidosis)
- Inflammation of the brain with confusion and fever. This may also include: disorientation, memory problems, seizures (fits), changes in personality and behavior, difficulty speaking, weakness or loss of movement in some parts of your body, and loss of consciousness (encephalitis)
- Inflammation of the spinal cord with pain, numbness, tingling, or weakness in the arms or legs, bladder or bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating, and constipation (myelitis)
- Inflammation of the blood vessels (vasculitis). Symptoms will depend on the particular blood vessels that are involved in the inflammatory process, for example; if it is your skin, you may get a rash. If your nerves are not getting enough blood, you could have numbness and weakness. You may also experience fever, weight loss, and fatigue.
- Low levels of parathyroid hormone (a hormone made by 4 tiny glands in your neck) which may result in low blood calcium and cause muscle cramps or spasms; fatigue or weakness; numbness, tingling or burning in your fingertips, toes or lips (hypoparathyroidism)
- Inflammation of the stomach (gastritis). You may have pain in your belly, feel full, or sick to your stomach. You may also experience nausea, vomiting or loss of appetite.
- Low number of red blood cells (cells that carry oxygen) due to destruction of red blood cells (hemolytic anemia). You may feel weak, tired, lightheaded, short of breath, or have a fast heartbeat. You may also experience difficulty with physical exercise, pale or yellow skin, dark urine, or fever.
- Not enough pancreatic enzymes (proteins that break down food) that leads to poor digestion of food (exocrine pancreatic insufficiency). You may have bloating, gas, discomfort in your belly, diarrhea, abnormal stool that is oily, or weight loss.
- Inflammation of the protective sac surrounding your heart (pericarditis) which can cause sharp chest pain and shortness of breath (especially when lying flat), fever, and a fast or irregular heartbeat. In severe cases, your heart may have difficulty pumping blood throughout your body.

Additionally, since pembrolizumab was approved in September 2014, the following side effects have been reported by people receiving pembrolizumab. These side effects were voluntarily reported from a group of people of unknown size. It is not possible to estimate the frequency of these side effects:

- Inflammation of the joints which may include joint pain, stiffness and/or swelling (arthritis)
- Severe responses of the immune system that cause the body to attack its own blood cells, spleen, liver, lymph nodes, skin and brain. This may include fever, rash, inflammation of the liver, yellowing of the skin, an enlarged liver and spleen, low blood counts, and enlarged lymph nodes. The nervous system may also be affected and cause confusion, seizures, and even coma (hemophagocytic lymphohistiocytosis)
- Changes in eyesight, eye pain, whitish patches on the skin and hearing loss (Vogt-Koyanagi-Harada syndrome)
- Inflammation and scarring of the bile ducts (tubes that carry digestive fluid that is made in the liver). This can cause symptoms similar to those seen with inflammation of the liver (hepatitis) such as pain in right side of your belly, yellow eyes and skin, feeling tired, and itching (sclerosing cholangitis).
- Inflammation or swelling of the nerve fibers of the eye which send visual information from your eye to your brain. This health condition often has a sudden onset of vision loss, loss of color vision, pain when moving your eyes, and/or loss of peripheral vision. It may affect one or both eyes at the same time (optic neuritis).
- Myocarditis-myositis-myasthenia gravis overlap syndrome is when the body's immune system attacks its own heart muscle (myocarditis), skeletal muscles (myositis), and the nerves that control muscles (myasthenia gravis) all at once. This may cause you to experience chest pain, swelling of the legs, fast or irregular heartbeat, dizziness, fainting, weakness, pain in your muscles, tiredness, drooping of the eyelids, blurred or double vision, difficulty swallowing, slurred speech, weakness in your arms and legs, and difficulty breathing.

If you have had an allogeneic stem cell transplant (a procedure in which a person receives blood-forming stem cells from a donor), you may experience graft versus host disease (GVHD), which may include diarrhea, skin rashes, and liver damage after receiving pembrolizumab. Sometimes this condition can lead to death.

If you have had a solid organ transplant (for example, if you have received a kidney or heart transplant), you may experience rejection of the transplanted organ. Your doctor will monitor you and should tell you what signs and symptoms you should report depending on the type of organ transplant that you have had.

Gemcitabine

Based on the studies of gemcitabine, the side effects below have been reported:

Very common side effects (occurring in at least 1 out of 10 people, or more than 10% of people)

- Fluid excess / swelling (which may go away when the drug is stopped)

Affix Participant Barcode Label Here

- Rash
- Hair loss
- Nausea and vomiting
- Proteins in your urine
- Blood in your urine
- Low red blood cell count (anemia), which can make you feel tired, dizzy or short of breath
- Low white blood cell count with increased risk of infection
- Low platelet count with increased risk of bleeding
- Impaired liver function / liver damage
- Difficulty in breathing
- Flu-like symptoms

Common side effects (occurring in 1 to 10 out of 100 patients, or 1 to 10% of patients)

- Fever
- Infections
- Headache
- Insomnia (trouble sleeping)
- Drowsiness/feeling sleepy
- Cough
- Runny nose, sneezing and/or stuffiness
- Diarrhea
- Constipation
- Inflammation and soreness in your mouth
- Increased liver enzymes that can cause fatigue and jaundice (yellowing of skin and eyes)
- Itching
- Sweating
- Back pain
- Muscle aches
- Chills
- Physical weakness or lack of energy

Some less common but possibly serious side effects for gemcitabine include:

- Severe allergic reaction, also known as Stevens-Johnson Syndrome, which can be life threatening.
- Severe skin reaction
- Capillary leak syndrome, which is characterized by sudden swelling, rapid drop in blood pressure, shock, lightheadedness, weakness, extreme tiredness, and nausea
- Posterior reversible encephalopathy syndrome, which is characterized by blindness, confusion, headache, high blood pressure, extreme tiredness, seizures, and other vision and nerve problems
- Heart failure or heart attack

Affix Participant Barcode Label Here

- Kidney failure
- Liver failure, which may result in death
- Inflammation or damage in the area where gemcitabine is given
- Sudden lung failure, also known as adult respiratory distress syndrome
- Damage to your lungs, including pneumonitis and fluid buildup
- Damage to your colon, which may cause pain

Carboplatin

Based on the studies of carboplatin, the side effects below have been reported:

Very common side effects (occurring in at least 1 out of 10 people, or more than 10% of people)

- Low white blood cell count with increased risk of infection
- Low platelet count with increased risk of bleeding
- Low red blood cell count (anemia), which can make you feel tired, dizzy, or short of breath
- Nausea and vomiting
- Abdominal pain
- Impaired kidney function
- Increased liver enzymes that can cause fatigue (feeling tired) and jaundice (yellowing of skin and eyes); usually mild and reversible, but can be serious
- Low levels of electrolytes in your blood (sodium, potassium, calcium, and/or magnesium)
- Fetal abnormalities if you get pregnant while taking this drug

Common side effects (occurring in 1 to 10 out of 100 people, or 1 to 10% of people)

- Infections; in some cases may be severe or fatal
- Bleeding; in some cases may be severe or fatal
- Allergic reaction (may include a rash, hives, fever, difficulty breathing, and low blood pressure)
- Loss of appetite
- Diarrhea
- Constipation
- Taste changes
- Ringing in the ears or hearing loss
- Hair loss or thinning of hair, including hair on the face and body
- Weakness, numbness, and pain from nerve damage, usually in the hands and feet.
- Sensations of pins and needles in hands and/or feet related to nerve irritation
- Decreased reflexes in your tendons
- Physical weakness or lack of energy
- Vision changes or vision loss (which improves after drug is stopped)
- Interstitial lung disease (injury to your lungs)
- Abnormal contraction of the smooth muscles in your airway resulting in narrowing and obstruction of your airway

Affix Participant Barcode Label Here

- Blistering of your mucous membranes (which may include the membranes of the mouth, eyes, nose, throat, genitalia, and/or anus)
- Temporary or permanent inability to have children

Some less common but possibly serious side effects for carboplatin include:

- Confusion
- Seizures
- Rash
- Severe allergic reaction which could be life-threatening
- Impaired kidney function / kidney damage (which may go away when drug is stopped) and kidney failure
- Impaired liver function / liver damage
- Dizziness
- Death due to allergic reaction, infection, or other causes

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
- 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.

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.

Data Safety Committee

A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study to identify possible safety issues to participants and to provide advice and recommendations on possible changes to the research study for the protection of participants.

REPRODUCTIVE RISKS AND OTHER ISSUES RELATED TO PARTICIPATING IN

Affix Participant Barcode Label Here

RESEARCH

Women Who Can Get Pregnant or Are Breastfeeding

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 you and the baby that are not known at this time. Women who can get pregnant will be tested for pregnancy during the study.

You must avoid getting pregnant in order to take part in this research study. You should not have sexual intercourse, or you should use a method of birth control that is acceptable to you and the study doctor. You should use this method of birth control during the length of your participation in this study and for at least 6 months after your last dose of trilaciclib and gemcitabine, and for 4 months after your last dose of pembrolizumab.

If you are a woman of childbearing potential, you must agree to use a highly effective method of contraception consistently during the study. Acceptable forms of birth control include:

- Surgically sterile (complete/partial hysterectomy, bilateral tubal ligation, or occlusion with surgery at least 6 months prior to starting treatment, or bilateral oophorectomy with surgery at least 2 months prior to dosing)
- Non-hormonal intrauterine device/system (IUD, IUS)
- Male partner who is sterilized prior to screening with post-vasectomy documentation
- True abstinence (not having sexual intercourse).

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.

Men

The effect of the study drugs on male sperm is unknown. In rare cases, drugs may damage sperm in ways that affect a child that is fathered. Affected sperm may be present in the semen for several months. Therefore, it is recommended to avoid donating sperm for 6 months after the last dose of trilaciclib and gemcitabine, and for 4 months after last dose of pembrolizumab.

You should not have sexual intercourse (abstinence) or you should use a male condom plus an acceptable method of birth control for at least 6 months after the last dose of trilaciclib and gemcitabine, and 4 months after the last dose of pembrolizumab if you have a partner of child-bearing potential. See list of birth control options in the women who can get pregnant section above. If you think that you have gotten a woman pregnant, you must tell the study doctor at once. If your partner gets pregnant during the study, you may be asked questions about the pregnancy and the baby.

Affix Participant Barcode Label Here

For men and women: If you are in a same-sex relationship, birth control requirements do not apply. If you are in a same-sex relationship at the time of signing this informed consent form but then you become engaged in a heterosexual relationship, you must agree to use birth control as described previously. If you are abstinent at the time of signing this consent form and later you become sexually active, you must agree to use birth control as described above.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
You may or may not receive any benefit from being in the study. The possible benefits may include reduction in the side effects of chemotherapy, reduction in the symptoms from chemotherapy, reduction in tumor size, or slower progression of your cancer. It is possible that you may not benefit from the study drug, or it may harm you. We cannot guarantee that your participation in this study will help you. More information about the study drug that is obtained from your participation in this research study may help other people with the same disease in the future.

WHAT OTHER CHOICES ARE THERE?
You do not need to take part in this research study to be treated for your cancer. There are other available therapies with known clinical benefit for your type of cancer which may include chemotherapy agents, immunotherapy, or PARP inhibitors. Your study doctor can discuss the alternatives as well as the risks and benefits of these alternatives with you.

WHAT ARE THE COSTS?
Study products or procedures related directly to the study will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility. Some medical insurance companies will not pay for regular medical care once they become aware that a patient is participating in a research study. Since we do not know what each individual insurance company will cover, you may wish to discuss coverage with your insurance company before agreeing to participate in this research study.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?
The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required or permitted by law, or necessary to protect the safety of yourself or others.

Your information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

TEXT MESSAGE COMMUNICATION. I give permission to Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including

Affix Participant Barcode Label Here

third-party agents if applicable) to contact me by text message at the number I provided to send information, reminders, and to communicate with me about the research study. I understand that I am responsible for the standard text message rate of my carrier. I also understand that text messaging is not a secure form of communication and I accept the risk that individuals not involved in the research study may be able to access the text messages. I also understand that texting is not to be used for emergency situations.

EMAIL COMMUNICATION. By providing my email address, I give permission for Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency situations.

WILL YOU BE PAID FOR PARTICIPATING?
You will receive no payment or other compensation for taking part in this study.

WHO IS FUNDING THIS STUDY?
This study is being funded by Pharmacosmos and Merck, Inc, under the sponsorship of AHWFBCCC. None of the doctors asking you to participate in this study have received or will receive money or other benefits for personal use from the study funding companies, Pharmacosmos and Merck, Inc, nor do they hold a direct financial interest in the sponsor or product being supplied. However, these funding companies 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.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?
Wake Forest University Baptist Medical Center maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of injuries or illnesses to some participants in certain research studies. To the extent research insurance coverage is available under this policy, the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. To the extent research coverage is not available, you or your insurance company may be charged for the costs of medical care. You may receive care at Wake Forest University Baptist Medical Center and/or Atrium Health.

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For

Affix Participant Barcode Label Here

more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury, contact the study investigator using the contact information listed on the first page of this consent form.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because

- Non-compliance with study participation, in the opinion of the study doctor
- You withdraw your consent to participate in the study
- You are no longer able to be reached for communication by the study team
- Your study doctor determines staying in the study is no longer of benefit to you
- Death
- Study is terminated early

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator using the contact information listed on the first page of this consent form.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chair of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

AUTHORIZATION TO USE AND DISCLOSE YOUR PROTECTED HEALTH INFORMATION

In this research study, any new information we collect from you and information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study may includes**:** 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.

If this research study involves the diagnosis or treatment of a medical condition, then Protected

Affix Participant Barcode Label Here

Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with the health care operations of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities.

We will take steps to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers, including Tempus and Discovery Life Sciences for analysis of your blood and tissue; the Institutional Review Board; representatives of Wake Forest University Health Sciences and Atrium Health Facilities; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs, videotapes, audiotapes or other recorded media which identify you unless we have your written authorization.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your medical record for verification of clinical trial procedures or data to the extent permitted by other applicable laws. These monitors, auditors, and other individuals are also required to maintain the confidentiality of your protected health information.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not

Affix Participant Barcode Label Here

expire.

Any research information entered into your medical record will be kept for as long as your medical record is kept by the Atrium Health. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Antoinette R. Tan that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Antoinette R. Tan, MD, MHSc
Levine Cancer
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Atrium Health, Wake Forest University Health Sciences, or their respective affiliated entities will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. Authorization to access this part of the medical record will only be available to people who have a need to know this information in order to perform their job-related duties. If you are not a patient of these health care facilities, a medical record will be created for you anyway to provide access to this important information to providers in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Laboratory test results and other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Atrium Health, Wake Forest University Health Sciences, and/or their respective affiliated entities. These results and reports will be kept secure in compliance with applicable laws, with permission to access this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A medical record will be created for all study participants seen on-site and if a medical record doesn't already exist. Information about your participation in the study will be placed in the

Affix Participant Barcode Label Here

medical record, along with any routine medical test results that were obtained as part of this study.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature:_ _____ Date: _____Time:_____ am pm

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 to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

Person Obtaining Consent (Printed):_____

Person Obtaining Consent Signature:_____ Date:_____
Time:_____ am pm

Affix Participant Barcode Label Here