Informed Consent Form

WINSHIP3263-16: A Phase 1 Study of Palbociclib in Combination with Cisplatin or Carboplatin in Advanced Solid Malignancies

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EMORY | WINSHIP CANCER INSTITUTE
A Cancer Center Designated by the National Cancer Institute

You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

Consent to be a Research Subject / HIPAA Authorization

Title: **Winship 3263-16: A phase 1 study of palbociclib in combination with cisplatin or carboplatin in advanced solid malignancies**

Principal Investigator:
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Department of Hematology and Medical Oncology

Study-Supporter:
Pfizer Inc.

Introduction
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you. Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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.

What is the purpose of this study?
The purpose of this study is to study the combination of two anticancer drugs, palbociclib and platinum (cisplatin or carboplatin) in patients whose cancer is no longer responding to standard treatment or patients who are unable to tolerate the standard treatment for their cancer. We seek to establish the safety of taking these two medications together and to determine the appropriate doses of the two drugs when given together as well as identify potential side effects when the drugs are administered together. We will also test the benefit of the two drugs in a smaller group of patients with lung, pancreas and breast cancer after we have determined the appropriate doses of the two drugs when taken together.

Another purpose of this study is to find out if the medication works for your kind of cancer and side effects of the combination of palbociclib and platinum (carboplatin or cisplatin) by looking at your response to the treatment. We want to find out what effects, good or bad, the drugs have on your cancer.
This study will also look at specific substances called biomarkers in your blood and in the tumor tissue which are involved in the growth of tumor cells and determine if the levels of these biomarkers are related to your response to treatment or development of side effects.

Palbocilib, also known by the brand name, Ibrance®, is a biologic drug approved by the Food and Drug Administration (FDA) for the treatment of advanced breast cancer after failure of hormonal treatments. It comes as a capsule that is taken by mouth.

Cisplatin is a chemotherapy drug that is approved by the FDA for the treatment of various types of cancer including bladder cancer, cancer of the ovary and testis. It is usually given as an intravenous infusion into the blood.

Carboplatin is a chemotherapy drug that is approved by the FDA for the treatment of ovarian cancer and is also a component of the usual standard treatment for breast and lung cancer. It is usually administered to patients as an intravenous infusion into the blood.
We expect a total of about 90 study participants to take part in this study in order to test different doses of palbociclib together with cisplatin or carboplatin.

What will I be asked to do?
Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there are some extra exams, tests, and/or procedures that you will need to have if you take part in this study. If you agree to participate in this study the following procedures will be performed.

Screening before you begin the study (up to 4 weeks prior to treatment)
You will first undergo some testing to determine whether or not you are fit to participate in the study. Some of these exams, tests or 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.
These procedures will include detailed questions about your cancer, previous treatment and side effects. You will also have a CT scan or MRI to determine the extent of your disease. Finally you will have blood and urine tests to ensure that it is safe to for you to receive the intended treatment. If it is determined that you are eligible to participate in the study, you will proceed to the next stage of the study.

At an initial "screening" visit, you will be asked about your current condition, your medical history, and any medications you may be taking. You will undergo a series of tests to evaluate your disease. These include:

- A physical examination
- Measurement of your blood pressure, heart rate, and temperature
- Obtaining your height and weight
- Blood tests (about 3 teaspoons of blood will be taken from your vein)
- CT (computed tomography) or MRI (Magnetic Resonance Imaging) scan will be done if you have not had one recently. The CT or MRI will find and measure the location of your disease. Both are painless procedures which produce a picture inside of your body.
- Evaluation of your ability to carry out daily activities
- For women able to have children, a pregnancy test
- An evaluation of your ability to chew and swallow
- A hearing test
- You will be asked about your diet, eating, and speech.

You will need to have the following extra tests, and/or procedures to find out if you can be in the study:

- We will perform a pregnancy test if you are a woman who could have children. You must not be pregnant, breastfeeding, or planning to have children (male patients included) in order to join the study.
- Blood sample to test for pregnancy in women of childbearing age to be collected before every new cycle while on treatment
- Electrocardiogram to check the electrical activity of your heart

- Archival tumor samples and blood samples will be collected from each patient enrolled on the study. This sample is required in order for you to take part in this study because the research on the sample is an important part of the study. Samples will be analyzed for genes and proteins that may affect how these therapies will work. Any leftover specimen will be stored for biobanking and may be used for additional research in the future. This will be discussed in greater detail in the section on optional studies below.

If you meet the "entry criteria" from testing at your screening visit, we will give you a time to come back usually within one to two weeks. At that next visit we will formally enter you in the study. If your screening visit was more than 7 days ago, we will have to repeat many of the same tests. These would include measuring your weight, temperature, blood pressure, and heart rate. If your imaging scan was done more than 4 weeks earlier, we will need to repeat them. We will also need samples of your blood for laboratory testing. We will use these results as your baseline readings. We will also use them to verify that it is safe for you to start taking study treatment.

During the study:
If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures. They are part of regular cancer care.

If you are found to be eligible for the study, and agree to participate, you will be assigned to receive study drugs palbociclib and cisplatin or palbociclib and carboplatin. The chemotherapy drugs, carboplatin or cisplatin will be administered once every 28 days. You will take the palbociclib pills you will take every day. Depending on your type of cancer and medical history, you will be assigned to Arm A or Arm B of the study. Patients in Arm A will receive palbociclib along with cisplatin. Patients in Arm B will be treated with palbociclib and carboplatin.

Cycle 1
Day 1: At the start of your study treatment (day 1 of cycle 1), your doctor will perform a physical exam and take your vital signs, weight, and temperature. You will have routine blood tests performed. You will also have a skin punch biopsy if not performed during the screening period. You will receive the infusion of cisplatin (Arm A) or carboplatin (Arm B). Just before and after the infusion of the chemotherapy, we will collect blood samples at specific times before the infusion, and then at half hour, one hour, 2 hours and 4 hours after end of infusion for patients in Arm A. Blood samples for carboplatin will be collected just before infusion, at 5 minutes before the end of infusion and then at 1 hour and 4 hours after the end of the infusion.

Days 2 through 22: You will receive a specified dose of palbociclib to be taken once daily. The instruction on how to take the drugs will be written on the bottles and you will be given a special diary to write down when you take the medications. The specified doses that you will take will be determined by the experience of other patients who have participated in the study before you. In the event that you belong to one of the first group of patients to go on the study, you will be given a dose that is felt to be safe and not likely to cause undue harm based on previous experience of patients taking these drugs. The drugs will be taken continuously for 21 days followed by a break of 1 week (this 28-day period is referred to as a cycle). Do not throw away your pill bottles. Bring them to the clinic each time you visit. Your study nurse or coordinator will need to collect all pill bottles that have been given to you. It is recommended to take the pill around the same time every day and preferably in the morning

Day 8: You will return to the clinic for the study team to check you out for any side effects arising from the treatment and also to have your blood drawn for standard testing.

Day 15: You will come to the clinic for the study team to check you out for any side effects arising from the treatment and also to have your blood drawn for standard testing and to collect additional blood samples to measure the amount of palbociclib in your blood. Remember to bring your pill with you to the clinic on this day and not to take the pill until you have been seen in the clinic.

Day 22: You will return to the clinic for the study team to check you for any side effects and also to have blood drawn. You should remember to bring your pill to the clinic on this day. You will take your palbociclib pill in the clinic after the study team has collected blood sample and another skin punch biopsy. In addition, you will undergo a biopsy of your tumor to be performed in the radiology department under CT scan guide. You will take your palbociclib pill only after the skin and tumor biopsy samples have been collected.

Cycle 2

Day 1: Before receiving your study treatment on day 1 of cycle 2, your doctor will perform a physical exam and take your vital signs, weight, and temperature. You will have routine blood tests performed. You will first take your palbociclib dose followed by the infusion of cisplatin (Arm A) or carboplatin (Arm B). Just before and after the infusion of the chemotherapy, blood samples will be collected again at specific times before the infusion, and then at half hour, one hour, 2 hours and 4 hours from the end of infusion for patients in Arm A. Blood samples for carboplatin will be collected just before infusion, at 5 minutes before the end of infusion and then at 1 hour and 4 hours after the end of the infusion.

Days 2 -21: You will continue to take your specified dose of palbociclib once daily at home according to the instruction written on the bottles and you will be given a special diary to write down when you take the medications. The specified doses that you will take will be determined by your experience during cycle 1. Palbociclib will be taken continuously for 21 days followed by a break of 1 week (this 28-day period is referred to as a cycle). Do not throw away your pill bottles. Bring them to the clinic each time you visit. Your study nurse or coordinator will need to collect all pill bottles that have been given to you. It is recommended to take the pill around the same time every day and preferably in the morning

Cycle 3 and beyond: On Day 1 of each new cycle and before the next dose of study therapy can be given, a physical examination will be performed. Blood pressure and heart rate (your "vital signs"), temperature, and weight will be measured. The same standard blood tests will be collected as with the first cycle. The dose and timing of your therapy may be changed based upon test results or due to any serious side effect you may be experiencing. If delays in treatment do occur, it may also result in extra visits to the clinic. If the side effects are severe and do not come under control, you may be withdrawn from the study if the study doctor feels this is in your best interests. If the study therapy is delayed by more than four weeks due to side effects, then you will be withdrawn from the study.

We will repeat CT or MRI scans after every 2 cycles of therapy i.e. every 8 weeks for the first 6 months and thereafter, we will obtain scans after every 3 cycles or every 12 weeks. This is to determine whether or not your cancer is responding to the treatment. In addition, we will obtain 2 tablespoon full of blood after every 2 cycles on therapy so as to better study how the drugs are working.

We will also like to collect additional tumor biopsy at the time that your cancer stops responding to the treatment it had previously responded well to the treatment. This will enable us to better understand how and why cancer cells become resistant to this treatment.

How long will I be in this study?

You will receive the treatment for as long as you are benefiting and you do not have bad side effects. It is estimated that patients on average will receive approximately four to six cycle of the combination of palbociclib and chemotherapy. Further treatment beyond six cycles with the combination or with palbociclib will be allowed if you continue to derive benefit.

How will my medicine be provided?

The study medicine that you will take will be dispensed by the pharmacy and delivered to the principal investigator or study team member. The principal investigator or health care providers on his/her research team will provide the

medicine to you. If you have questions about the medicine, you should ask the principal investigator or study nurse. You may also call the pharmacy if you have questions about the medicine. The number for the pharmacy is included on your medicine package.

Who owns my study information and samples?

If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study.

What are the possible risks and discomforts?

There may be side effects from the study drug or procedures that are not known at this time. Your condition may not get better, and it may even get worse, as a result of your being in this study. You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, 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 the 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.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Risks of Palbociclib

The most common risks and discomforts (>10% of patients)	**The less common risks and discomforts (5 to <10%)**	**Rare but possible risks (<5%)**
• Infections • Low white blood cell count • Decreases in neutrophil • Reduced platelets • Decreased appetite • Stomatitis (mouth sores) • Nausea • Diarrhea • Constipation • Vomiting • Rash • Alopecia (hair loss) • Fatigue • Joint pain • Back pain • Pain in hands and feet • Cough • Shortness of breath • Headache and dizziness • Hot flush • Inability to sleep (insomnia) • Fever • Common cold • Decreased hemoglobin	• Nose bleed • Dry skin • Change in taste • Abdominal Pain • Indigestion • Dry mouth • General weakness (asthenia) • Swelling of hands and feet • Irritation or sores in the lining of hollow organs like mouth, throat, stomach, bowels • Pain in muscles and bone including around the chest and neck • Influenza (flu) like illness • Muscle cramps • Increases in blood liver markers that may indicate liver damage • Itching • Mouth/throat pain • High blood pressure • Depression • Fall	• Febrile neutropenia (fever and low white count) • Blurred vision • Increased tearing • Dry eye • Pneumonitis (inflammation of lung tissue)

	• Anxiety • Acid Reflux (Heartburn) • Increased Creatinine level that may indicate abnormal kidney function • Pain • Muscle pain	

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

In a rat study where palbociclib was administered for the lifespan of the rat, microglial cell (a type of cell located in the central nervous system) tumors were seen at blood concentrations higher than those used to treat humans. It is currently unknown what these findings observed only in male rats mean for patients treated with palbociclib over time.

Male reproductive organ effects were seen in some of the rats and dogs that were given palbociclib for at least 3 weeks. These effects include decay of seminiferous tubule structure (tubes in the testes where sperm is produced) and a decrease in semen fluid secretion (ability of semen to flow). These effects on male reproductive organs were minimal to severe, depending on the dose given. These toxicities were observed at drug levels that are used in clinical research studies. Partial to completer reversal of these effects were seen at least 4 weeks after palbociclib dosing stopped. It is currently unknown what these findings mean for patients treated with palbociclib over time. If you are a male patient and want to have children at a later time, it is recommended that you preserve your sperm prior to beginning therapy.

Risks of Cisplatin

The most common risks and discomforts (>20% of patients)	**The less common risks and discomforts (4-20%)**	**Rare but possible risks (<4%)**
• Nausea, vomiting • Infection, especially when white blood cell count is low • Anemia, which may cause tiredness, or may require blood transfusions • Bruising, bleeding • Kidney damage, which may cause swelling • Hearing decrease, • Ringing in ears • Change in taste	• Allergic reaction, which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Confusion • Difficulty with balance • Numbness in the fingers and toes • Low blood pressure • Low magnesium, which may cause heart beat irregularities that are possible life threatening	• Cancer of bone marrow later in life caused by chemotherapy • Seizure

Risks of Carboplatin

The most common risks and discomforts (>20% of patients)	The less common risks and discomforts (4-20%)	Rare but possible risks (<4%)
• Anemia • Decreased Blood Platelets • Decreased Function of Bone Marrow • Decreased Neutrophils a Type of White Blood Cell • Decreased White Blood Cells • Hemorrhage • Infection • Signs and Symptoms at Injection Site • Feel Like Throwing Up • Feeling Weak • Hair Loss • Low Amount of Calcium in the Blood • Low Amount of Magnesium in the Blood • Low Amount of Potassium in the Blood • Low Amount of Sodium in the Blood • Numbness, Tingling or Pain of Hands or Feet • Pain • Stomach Cramps • Throwing Up	• Bronchospasm • Inflammation of Skin caused by an Allergy • Itching • Rash • Toxic Effect on Brain or Spinal Cord Function • Toxicity to Organs of Hearing • Trouble Breathing • Abnormal Liver Function Tests • Diarrhea • Incomplete or Infrequent Bowel Movements • Problems with Eyesight	• Hepatic Veno-Occlusive Disease (liver injury) • Life Threatening Allergic Reaction • Painful, Red or Swollen Mouth • Poor Vision • High Blood Pressure • Loss of Appetite

Other risks and inconveniences:
Injections: There are risks associated with the use of needles. Obtaining blood samples may cause some discomfort, bruising, bleeding from the site of sampling, formation of a blood clot, and in rare cases, infection or fainting. Every effort will be made to minimize discomfort.

The blood pressure cuff may also cause discomfort or bruising to the upper arm.

Risks of having biopsies of your cancer:
Biopsies of your cancer may cause side-effects and/or complications. These include the possibility of infection and bleeding. Depending on which part of your body the biopsy is performed, there may be other possible side-effects or complications. Your doctor will explain the risks of any biopsies with you in detail, and you will be asked to sign a separate consent form. Your biopsy may be performed under X-ray guidance by a radiologist.

Risks of having CT scans:
This research study involves exposure to radiation from CT scans (x-rays). These procedures are routinely used for medical purposes. This radiation dose is necessary for your medical care and will not occur only as a result of your participation in this study. The radiation dose estimate that you will receive is equal to or less than the radiation exposure allowed to be received by a radiation worker for 2 years. The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. Although the risk from radiation is cumulative it is not expected to adversely affect your condition or treatment. The Emory University Radiation Safety Committee has reviewed and approved the use of radiation in this research study.

Risks of having MRI scans:
Some people may feel frightened by the cramped space inside the machine or by the loud, repeated sounds the machine makes. The greatest risk of having an MRI is the chance of metal objects flying through the air toward the magnet and hitting you. To reduce this risk, all people giving and getting the MRI scan are asked to remove all metal from their clothing and all metal objects from their pockets. Please inform the study doctor if you have metal in your body from an operation. If you do, you may not be able to have a MRI scan. Also, if you have a pacemaker, you should not have a MRI scan.

Reproductive risks:
If you are a woman: to protect against possible side effects of the study drug, women who are pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus and there may also be other risks that are not yet known. If you are a woman of childbearing ability, you and the study doctor must agree on a method of birth control to use throughout the study. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant women will be taken out of the study.

If you are a man: the effect of the study drug on sperm is not known. To protect against possible side effects, if you are a man you should not get a sexual partner pregnant while taking the study drug and for up to six months after the last dose. You and the study doctor should agree on a method of birth control to use throughout the study.

If you will be taking the study drug home, keep it out of the reach of children or anyone else who may not be able to read or understand the label. Do not let anyone else take the study drug besides you.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?
Your [condition] may improve while you are in this study but it may not, and it may even get worse. This study is designed to learn more about palbociclib when combined with carboplatin or cisplatin. The study results may be used to help others in the future.

Will I be compensated for my time and effort?
You will not be offered compensation for being in this study.

What are my other options?
If you decide not to enter this study, there is care available to you outside of this research study. You do not have to be in this study to be treated for your cancer. Instead of being in this study, you may have these options depending on what type of therapies you received in the past:

1. Supportive care (care to help you feel more comfortable, including hospice care)

2. Treatment with other drugs (chemotherapy, biologic agent).
3. Radiation therapy
4. Surgery
5. Other experimental therapy

The study doctor will discuss these with you. You do not have to be in this study to be treated for your cancer. Taking part in this study, however, may make you unable to participate in some other research studies, if they exclude people who have taken certain treatments. You should discuss this with the researchers if you have concerns. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

How will you protect my private information that you collect in this study?
Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information
Your samples, genomic data and health information will be stored and shared with other researchers. The samples and information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may have come from.

Medical Record
If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory Healthcare medical record you have now or any time during the study.

Emory Healthcare may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory Healthcare medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include:

Tests and procedures done at non-Emory places may not become part of your Emory medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury
If you get ill or injured from being in the study, Emory will help you get medical treatment. Emory and the study supporter have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory or study supporter employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Olatunji Alese at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

Costs
The study supporter will pay for certain items and services that you may receive if you take part in this study.

You will have to pay for the items or services for which the study supporter does not pay. The study supporter will not pay for your regular medical care. If you have insurance, Emory will submit claims to your insurance for items and services that the study supporter does not cover. Emory will send in only those claims for items and services that it reasonably believes your insurance will pay and that the study supporter has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and the study supporter will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

Withdrawal from the Study
You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study and for any optional studies in which you may choose to participate.

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- Pfizer as a study supporter may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The supporter may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The research team and the supporter may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
- Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Food and Drug Administration.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
    - Pfizer or its agents

- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Optional Study/Storage of Data/Specimens for Future Research:

This section is about optional studies you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The researchers leading this optional study hope the results will help other people with cancer in the future.

The results will not be added to your medical records and you or your study doctor will not know the results.

You will not be billed for these optional studies. You can still take part in the main study even if you say "no" to any or all of these studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

Circle and or initial your choice of "yes" or "no" for each of the following studies.

Optional Sample Collections for Laboratory Studies and/or Biobanking for Possible Future Studies

Researchers are trying to learn more about cancer, diabetes, and other health problems. Much of this research is done using samples from your tissue, blood, urine, or other fluids. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems.

Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment.

If you choose to take part in this study, the study doctor for the main study would like to collect samples of your tumor for research on genetic tests likely to predict the benefit from treatment with palbociclib and other similar drugs.
If you choose to take part, a sample of tissue from your previous biopsy or if unavailable, a new tumor biopsy will be collected. The researchers ask your permission to store and use your samples and related health information (for example, your response to cancer treatment, results of study tests and medicines you are given) for medical research. The research that may be done is unknown at this time. Storing samples for future studies is called "biobanking". The Biobank is being run by the study PI.

WHAT IS INVOLVED?

If you agree to take part, here is what will happen next:

1) Tissue sample from that was collected at the time of your original biopsy to diagnose your cancer will be sent to the Biobank.
2) Your sample and some related health information may be stored in the Biobank, along with samples and information from other people who take part. The samples will be kept until they are used up. Information from your medical record will be updated from time to time.
3) Qualified researchers can submit a request to use the materials stored in the Biobanks. A science committee at the clinical trials organization, will review each request. There will also be an ethics review to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you.
4) Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.
5) Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.

WHAT ARE THE POSSIBLE RISKS?

1) The most common risks related to drawing blood from your arm are brief pain and possibly a bruise.
2) There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
3) There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.
4) In some cases, this information could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. There can also be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

Your privacy is very important to the researchers and they will make every effort to protect it. Here are just a few of the steps they will take:

1) When your sample(s) is sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.
2) The list that links the unique code to your name will be kept separate from your sample and health information. Any Biobank and *study* staff with access to the list must sign an agreement to keep your identity confidential.
3) Researchers to whom *study staff* sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
4) Information that identifies you will not be given to anyone, unless required by law.
5) If research results are published, your name and other personal information will not be used.

WHAT ARE THE POSSIBLE BENEFITS?

You will not benefit from taking part.
The researchers, using the samples from you and others, might make discoveries that could help people in the future.

ARE THERE ANY COSTS OR PAYMENTS?

There are no costs to you or your insurance. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

WHAT IF I CHANGE MY MIND?

If you decide you no longer want your samples to be used, you can call the study doctor, Olatunji Alese, MD, at [redacted] who will let the researchers know. Then, any sample that remains in the bank will no longer be used and related health information will no longer be collected. Samples or related information that have already been given to or used by researchers will not be returned. You may request to destroy your specimens in the future if you desire so.

WHAT IF I HAVE MORE QUESTIONS?

If you have questions about the use of your samples for research, contact the study doctor, Olatunji Alese, MD, at [redacted].

Please circle your answer to show whether or not you would like to take part in each option (*include only applicable questions)*:

SAMPLES FOR THE LABORATORY STUDIES:

I agree to have my specimen collected and I agree that my specimen sample(s) and related information may be used for the laboratory study(ies) described above.

YES …… NO …….

I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to learn about results from this(ese) study(ies).

YES …… NO …….

SAMPLES FOR FUTURE RESEARCH STUDIES:
My samples and related information may be kept in a Biobank for use in future health research.

YES …… NO …….

I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to participate in other research in the future.

YES …… NO …….

PHI That Will be Used/Disclosed for Optional Study:
The PHI that we will use and/or disclose (share) for the optional research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for which your PHI will be Used/Disclosed for Optional Study:
We will use and disclose your PHI for the conduct and oversight of the optional storage and future research use of your PHI.

Authorization for This Use of PHI is Required to Participate in Optional Study, but Not in Main Study:
You do not have to authorize the use and disclosure of your PHI. If you do not authorize the use and disclosure of your PHI for the optional study, then you may not participate in the optional research study. You can still be in the main research study even if you don't participate in the optional study.

People Who Will Use/Disclose Your PHI for Optional Study:
The following people and groups will use and disclose your PHI in connection with the optional research study:

- The same people and groups who will use and disclose your PHI for the Main Study will also do so in connection with the optional research study/storage of PHI for future research.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

Olatunji Alese, MD
Winship Cancer Institute
Emory University
1365 Clifton Road NE
Atlanta, GA 30322

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information
Contact Colleen Lewis, NP [redacted] or Dr. Olatunji Alese [redacted].

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at [redacted]:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

Consent and HIPAA Authorization for Optional Study/Studies:

Please initial below if you opt to participate in and authorize use and disclosure of your PHI in the optional study/studies previously described:

[Tumor Biopsy at baseline] _____Initials

[Tumor Biopsy at progression] _____Initials

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in the main study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

_____ _____

Signature of Legally Authorized Representative **Date** **Time**

_____

Authority of Legally Authorized Representative or Relationship to Subject

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**