# Informed Consent Form

WINSHIP5079-20: Paricalcitol and Hydroxychloroquine (PH) Combination with Gemcitabine and Nab-Paclitaxel in Advanced Pancreatic Cancer

NCT Number: NCT04524702

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# You Are Being Asked to Be in a Research Study
## Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 21 people who are being studied, at Emory and elsewhere.

### Why is this study being done?
This study is being done to determine if a combination of study drugs (called Paricalcitol and Hydroxychloroquine) is safe and effective against your tumor. The two drugs have different mechanisms of action: Paricalcitol (a form of vitamin D) works by blocking a signal in the cancer cells that leads to growth and spreading of the tumor; and hydroxychloroquine (an autophagy inhibitor) enhances the activity of standard chemotherapy on cancer cells and prevent them to utilize energy to grow. You are being asked to be in this research study because you have advanced pancreatic cancer.

### Do you have to be in the study?
It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

### What do I have to do if I choose to participate in this study?
If you are eligible and want to be part of the study, you will participate until your disease gets worse, or the side effects of the study drugs become unacceptable, or your doctor believes the study is not in your best interest anymore, or you withdraw consent for any reason. The researchers will ask you to do the following: go over your current condition, your medical history and any medications you may be taking; undergo physical examination, blood samples drawn, tissue biopsy, scans (MRI/CT), electrocardiograms (EKG or ECG). You will undergo pregnancy test if you are a woman of childbearing potential. You will receive study treatment (a combination of two drugs called Paricalcitol and hydroxychloroquine) along with standard chemotherapy used for your cancer.

Some of these procedures will be paid for by the study. Standard of care procedures will be billed to your insurance.

### How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. Given this is an investigational treatment, there is no guarantee that you will derive benefit if you choose to participate in this study.

## What are the risks or discomforts I should know about before making a decision?

The study will take time. The drugs that is being tested may not work any better than regular care, and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include: high calcium level in your blood, nausea, vomiting, diarrhea, decreased appetite, abdominal pain, edema fatigue, retinopathy, lower number of normal red blood cells, white blood cells, and platelets in the blood and bone marrow (called chemotherapy-induced myelosuppression), hearth complications: cardiomyopathy, Torsade de pointes (experienced by the patient as dizziness, palpitations, syncope, or seizures). Other risks are low sugar level in your blood (hypoglycemia), peripheral neuropathy, alopecia, rash, dehydration, increased aspartate aminotransferase (AST), increased alanine aminotransferase (ALT), increased alkaline phosphatase, amounts of protein and/or blood in the urine (proteinuria and/or hematuria ), fever and difficult breathing.

Other risks include loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the “What are the possible risks and discomforts?” section of this document.

## Alternatives to Joining This Study

If you decide not to enter this study, there is care available to you outside of this research study. Your doctor will discuss alternative options with you. You do not have to be in this study to be treated for your cancer. Instead of being in this study, you have these options:

1. Treatment with other drugs, not on study
2. Other experimental therapies

## Costs

Study related cost will be paid by the study. You WILL have to pay for some of the standard of care procedures, if those are not covered by your medical insurance. The study team can help you work out how much you might have to pay. There is more information in the cost section below.

## What Should I Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts of these are research and which are standard care that you would have even if you did not join the study. Take time to consider this, and talk about it with your family and friends.

**Emory University and Saint Joseph's Hospital**
**Consent to be a Research Subject / HIPAA Authorization**

**Title:** Paricalcitol and hydroxychloroquine (PH) combination with gemcitabine and nab-paclitaxel in advanced pancreatic cancer

**Principal Investigator:** Olatunji Alese, MD

**Study-Supporter:** Morningside Center for Innovative and Affordable Medicine

## 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?

You have been invited to participate in this research study because you have cancer in your pancreas. This study will help study doctors find out if combining two drugs (called Paricalcitol and Hydroxychloroquine) is a better way to treat your pancreatic cancer. The study doctors hope to learn whether the study drug combination will be safe and will enable you to live longer.

The two experimental study drugs are thought to work by inhibiting two different possible ways in which a cancer cell can grow and spread:

- **Paricalcitol** (a form of vitamin D) helps break through the pancreatic tumor's protective layer (stroma) produced by pancreatic satellite cells that are particularly activated in pancreatic cancer. These satellite cells have high levels of Vitamin D receptors and the blocking of these receptors by Paricalcitol inactivates the stromal production.

- **Hydroxychloroquine** is a relatively inexpensive drug currently available for the treatment of malaria and autoimmune diseases. Hydroxychloroquine has been shown to inhibit autophagy. Autophagy is a process of self-cannibalization in which injured cancer cells ingest pieces of themselves, such as organelles and macromolecules, to conserve energy, and, therefore, thrive. Additionally, autophagy helps rid the cancer cells of toxic substances and free radicals, such as hydrogen peroxide and superoxide. When combining chemotherapy with autophagy inhibition, damaged cancer cells are unable to conserve the needed energy to survive.

The combination of the two experimental drugs will be given concomitantly to a standard chemotherapy treatment (the chemotherapy drugs you will received are called gemcitabine and nab-paclitaxel).

It is not known if giving the study drugs at the same time will affect your cancer and survival the same as giving each of the drugs on its own, although the combination could be potentially effective in patients with pancreatic cancer.

**What will I be asked to do?**
This study asks you to do several things, most of them would be done as standard of care if you were not on this study.

First, once all your questions have been answered and you feel comfortable that you understand what this study involves, you will need to sign this informed consent.

**Screening**
To find out if you can take part in this study, you will go through a **Screening process**. In this process, you will be asked about your general health and your medical history. You will also be asked about medicines, prescriptions and any over-the-counter drugs and supplements you are taking right now or have taken within 28 days prior to the first dose of study drug.

If any of the tests required at screening were performed prior to signing consent, as part of your routine care, and if they fall within the time allowed by the study, they may be used and need not be repeated.
This screening evaluation process may take up to a maximum of 28 days prior to starting the study and will include the following:

- Review your current condition, your medical history, and any medications you may be taking.
- A physical examination (including Performance assessment, vitals, obtaining your height and weight)
- Obtaining an electrocardiogram (to record the rhythms and electrical activity of your heart).
- Approximately one tablespoon of blood will be drawn for blood tests (electrolytes, kidney function, liver function), for a complete blood count (white blood cells, red blood cells, and platelets), for coagulation and other cancer specific testing (CA19-9 and G6PD).
- Urinalysis and urine protein to creatinine ratio to assess for any protein in your urine.
- 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.
- Undergo eye examination.

- Radiologic imaging studies to evaluate tumor status: Have a PET/CT or computerized tomography (CT) scan or magnetic resonance imaging (MRI) or bone scan to see tumor. CT stands for computed tomography. A CT scanner is used to take a series of X-rays of your body at slightly different angles. A computer puts these together to produce a very detailed picture of the inside of your body. Magnetic resonance imaging (MRI) uses a strong magnetic field and radio waves to produce detailed pictures of the inside of your body. The pictures produced by the CT scans and the MRIs provide doctors with information to help them assess the extent of your cancer. CTs will be performed with oral and intravenous (IV) contrast; MRIs will be performed with IV contrast. This means that you may have to drink a special solution or receive a special dye by injection into a vein that will highlight areas of disease involvement more easily for a doctor who is reviewing your scans.
- Ask you for tissue samples of your tumor and a blood samples for research purposes.

**Treatment schedule**

If you are found to be eligible for the study, and agree to participate, you will be started on for the first treatment.

- At the start of your study treatment (Day -14) you will receive **Paricalcitol** three times a week (25 mcg will be administered into the vein of your arm or in the chemotherapy port), and **Hydroxychloroquine** (orally: 800 mg (400 mg twice a day) for the first week daily, 1200 mg (600 mg twice a day) afterwards. Each dose should be taken with a meal or a glass of milk. The patient will be requested to maintain a diary for each dose of medication. Patient must stop taking vitamin D or calcium containing supplements after signing of consent and until end of the study.
- After two weeks (corresponding to Day 1 of Cycle 1) you will start the **chemotherapy** per standard of care with Gemcitabine and nab Paclitaxel: both drugs will be administered into the vein of your arm or chemotherapy port on Day 1, 8 and 15 of every cycle. 1 Cycle last 28 days (4 weeks).
- Research biopsy will be performed prior to starting on the trial. The biopsy is for research purposes and is not part of your standard clinical care.

On Day 1 of every cycle (and at the time of discontinuation of study treatment), you will go through the following assessments:

- Review medications you may be taking.
- Perform a physical exam and take your vital signs and weight.
- Collect blood samples for blood cell counts, blood sugar, organs functions, cancer specific testing.
  Collect research blood sample. Your blood samples will be used to study cells, genes and proteins present in the liquid portion of the blood (serum). This study will attempt to find differences in the blood between patients and before and after treatment. It might help us understand changes in biomarkers induced by the treatment. Samples will be collected at Baseline, at Cycle 1 Day 1, 8, 15; at Cycle 2 and Cycle 3 Day 1 and one last sample will be collected at the end of treatment period (study discontinuation).

On Days 8 and 15 of every cycle

- Collect blood samples for blood cell counts, blood sugar, organs functions

- Tumor biopsy for research purposes
- Biopsy of your tumor will be performed prior to starting the study
- Collect a second research tumor biopsy on Day 21 +/- 2 days. The biopsy is for research purposes and is not part of your standard clinical care.

Electrocardiogram (ECG) Obtaining an electrocardiogram (to record the rhythms and electrical activity of your heart).

- ECG prior to study start
- ECG will be performed 2 to 4, 48 and 96 hours after first dose of hydroxychloroquine
- ECG will be repeated 48 hours after second dose of hydroxychloroquine
- ECG will be performed on day 1 of first and second cycle

Imaging studies (CT or MRI) Computed tomography (CT) or magnetic resonance imaging (MRI) of the chest/abdomen/pelvis.

- Baseline imaging studies must be performed within 8 weeks of study start
- Radiologic imaging studies every two cycles (between day 21 and 28 of that cycle) to evaluate your tumor status.

Eye exam

- Prior to study start
- Every 6 months while on the study
- Any time there are new change in vision while on the study

At every clinic visit, we will be assessing for side effects. 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.

**How will my medicine be provided?**

The 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 study doctor or study nurse. You may also call the medical team at (404) 778-1900 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 this two-drug combination or procedures that are not known at this time.

**General Risks**

If you choose to take part in this study, there is a risk that the study approach may not be as good as the usual approach for your cancer at shrinking or stabilizing your cancer.

You also may have the following discomforts:

- Spend more time in the hospital or doctor's office
- Be asked sensitive or private questions about things you normally do not discuss.

The drugs used in this study could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. It is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study and after you have completed the study.

The drugs used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will test your blood and let you know if changes occur that may affect your health.

There is also a risk that you could have other side effects from the study drugs.

Here are important things to know about side effects:

- The study doctors do not know who will or will not have side effects
- Some side effects may go away soon, some may last a long time, and some may never go away
- Some side effects may be mild, serious, and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect
- Your study doctor will work with you to treat your side effects
- Your study doctor may adjust the study drugs to try to reduce side effects.

**Drug Risks**

**Risk associated with paricalcitol**

In terms of safety, paricalcitol is less likely to produce elevations in calcium and phosphorus levels compared to other forms of vitamin D, primarily due to its decreased effect on intestinal absorption of calcium and phosphorus.

Taking too much vitamin D or taking it for a long time can cause very high calcium or vitamin D levels which may cause serious health problems and the need for emergency medical care. Signs of high calcium include feeling tired, difficulty thinking clearly, loss of appetite, nausea, vomiting, constipation, increased thirst, increased urination, and weight loss. Tell your doctor if you are having any of these signs.

The risk may be increased when paricalcitol is used concomitantly with high dose calcium preparations, thiazide diuretics, or vitamin D compounds.

The most common risks and discomforts expected in this study are:

The most common side effects with the use of paricalcitol include diarrhea, inflammation of the nose and throat, dizziness, vomiting, high blood pressure, allergic reaction, nausea, and swelling.

**Risk associated with hydroxychloroquine**

Blood Glucose
It has been shown to cause severe hypoglycemia (low blood sugar levels) including loss of consciousness that could be life threatening in patients treated with and without antidiabetic medications.

Less serious side effects
- Nausea
- Vomiting
- Diarrhea
- Abdominal cramps
- Loss of appetite
- Muscle weakness
- Dizziness
- Ringing in the ears
- Headache
- Nervousness
- Skin rash and itching
- Hair loss

If you already have psoriasis, you are more likely to experience skin reactions than other people when taking hydroxychloroquine.

Rare but serious side effects
- Visual disturbances- blurred vision and/ or decreased vision including visual loss and blindness
- Any hearing loss
- Suicidal behavior
- Frequent fevers, severe chills, bruising, sore throat or mouth ulcers (these may be signs of blood reactions)
- More severe symptoms of low blood sugar (hypoglycemia), including:
  - disorientation
  - seizures, fits or convulsions
  - loss of consciousness
- Fast or irregular heartbeat. These are serious side effects. You may need urgent medical attention. Serious side effects are rare.
- Hydroxychloroquine may cause the heart muscle to take longer than usual to make another beat. This is called QT prolongation. QT prolongation is determined by an electrocardiogram (ECG). This prolongation could predispose patients to develop symptoms such as fainting (syncope) or an arrhythmia (a disturbance in your heart rate) which can potentially be fatal. While taking part in this study, your doctor may request additional electrocardiograms (ECG, EKG) to monitor your heart rate and rhythm.

**Risk associated with chemotherapy**

The most common (≥ 20%) adverse reactions of nab-paclitaxel in adenocarcinoma of the pancreas are low white blood cells (neutropenia), fatigue, peripheral neuropathy, nausea, alopecia, peripheral edema, diarrhea, fever, vomiting, decreased appetite, rash, and dehydration.

The most common adverse reactions for the single agent (≥20%) are nausea/vomiting, anemia, increased aspartate aminotransferase (AST), increased alanine aminotransferase (ALT), neutropenia, increased alkaline phosphatase, fever, rash, amounts of protein and/or blood in the urine (proteinuria and/or hematuria ) and difficult breathing.

**What effects could the tests have on me?**
You may feel discomfort during some of these tests or may experience some inconvenience. Some may also have risks, which may include:

**Blood samples:** drawing blood from your arm may cause pain, bruising, lightheadedness, and rarely infection.

**IV line (inside the vein):** may cause discomfort, irritation, mild bruising, bleeding, leakage of drug solution, and rarely infection, nausea, and lightheadedness.

**Contrast Agent Risks:** Your CT or MRI procedure will require the use of a “contrast agent.” The contrast agent is a substance that helps the radiologist interpret the images. The contrast agent will be injected by either a hand-held needle or a machine that does the injection. Most contrast agents stay in your body for only a few minutes, but some of them can remain for a few hours or days without any harm to you or anyone near you. Contrast agents are generally quite safe, but any injection involves some risks. The injection could harm a nerve, artery or vein, or cause infection. The contrast agent could affect kidney function or cause an allergic reaction, though these outcomes are rare. The contrast agent could also leak from your veins a little causing swelling and discomfort, that is typically treated with ice packs.

**Magnetic resonance imaging (MRI) Risks:** MRI exams use powerful magnets to create images of the body. In addition to the possible reactions to contrast materials, you may feel claustrophobic while in the magnet, and will hear loud beeping or hammering noises. If you have tattoos or any metal items in your body such as implants, pacemakers, clips or shrapnel, we will do special screening to make sure your MRI scan is done safely.

**Radiation-Related Risks**: You will be exposed to radiation from CT scans. These procedures are necessary for your medical care and will occur even if you do not participate 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 biopsies: Both biopsies are for research purposes and will not impact your clinical care.** Having biopsies performed may cause pain, bruising, bleeding, redness, low blood pressure,

swelling and/or infection at the site of the biopsy, perforation of gastric wall/esophagus and rarely, death. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy site. Other potential risks will be described to you and discussed with you by physicians who conduct these biopsies.

**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. These risks 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 prior to study entry . 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.

Tell the study doctor if you are pregnant. If you get pregnant during the study, you will not receive any more study drug, but you may remain in the study for follow-up.

**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 1 month 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?**

This study is not designed to benefit you directly. 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 pancreatic cancer. 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 including the standard chemotherapy regimen (gemcitabine and nab paclitaxel). 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**

De-identified data from this study (data that has been stripped of all information that can identify you), including your de-identified genetic information, may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data and specimens from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your de-identified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

We will use your sample and data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial cell line, a medical or genetic test, a drug, or other commercial product) that could be sold by a company. You will not receive money from the sale of any such product.

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

**How is my Genetic Information Protected? What are the Risks?**

The Genetic Information Nondiscrimination Act (GINA) is a federal law that generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

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

Be aware that GINA does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, and does not apply to employers with less than 15 employees.

In addition to GINA, the State of Georgia has laws that prohibit insurers from using genetic testing information for any non-treatment purpose. However, like GINA, this state law protection has exclusions: life insurance policies, disability income policies, accidental death or dismemberment policies, Medicare supplement policies, long-term care insurance policies, credit insurance policies, specified disease policies, hospital indemnity policies, blanket accident and sickness policies, franchise policies issued on an insurance policy written as a part of workers' compensation equivalent coverage, or other similar limited accident and sickness policies.

**Privilege**
In the State of Georgia, in some circumstances your genetic information has may have special legal protections called "privilege." This means that the information cannot be used as evidence in a court. By allowing us to use and disclose your genetic information for this research study along with other information about you that genetic information used in the research may no longer have that legal protection. Other protections described in this form will still apply. There are also other confidentiality protections for research data in general under Georgia state law

**Medical Record**
If you have been an Emory and Saint Joseph's Hospital patient before, then you already have an Emory and Saint Joseph's Hospital medical record. If you have never been an Emory and Saint Joseph's Hospital patient, you do not have one. An Emory and Saint Joseph's Hospital medical record will be made for you if an Emory and Saint Joseph's Hospital 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 and Saint Joseph's Hospital medical record you have now or any time during the study.

Emory and Saint Joseph's Hospital 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 and Saint Joseph's Hospital 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: results on the correlative blood samples and results on the analysis of tumor biopsy specimens.

Tests and procedures done at non-Emory and Saint Joseph's Hospital places may not become part of your Emory and Saint Joseph's Hospital 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 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.

If you get ill or injured from being in the study, Emory and Saint Joseph's Hospital will help you to get medical treatment. Emory and Saint Joseph's Hospital will not pay for your medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory and Saint Joseph's Hospital have not, however, set aside any money to pay you if you are injured as a result of being in this study or to pay for this medical treatment. For Emory and Saint Joseph's Hospital, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory or Saint Joseph's Hospital employee. "Negligence" is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

**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 sponsor does not pay. The sponsor will not pay for your regular medical care. If you have insurance, Emory and Saint Joseph's Hospital will submit claims to your insurance for items and services that the sponsor does not cover. Emory and Saint Joseph's Hospital will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor 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 Saint Joseph's Hospital 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 and Saint Joseph's Hospital 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.

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.

**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. If you do not sign this form, 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 and Saint Joseph's Hospital 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.

- The following people and groups will use your PHI to make sure the research is done correctly and safely:
  - Emory and Saint Joseph's Hospital 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.
  - Other researchers and centers that are a part of this study.
  - Government agencies that regulate the research including: Food and Drug Administration.
  - Public health agencies.
  - Research monitors and reviewer.
  - Accreditation agencies.
  - Morningside Center for Innovative and Affordable Medicine.
- 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.

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

**Revoking Your Authorization**
If you sign study revocation 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-C 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. The Sponsor, and people and companies working with the Sponsor on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

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 Dr. Olatunji Alese at [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**

***TO BE FILLED OUT BY SUBJECT ONLY***

Please **print** your name, **sign**, and **date** below if you agree to be in this research study, and any optional studies you initialed above. 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**

_____ _____ ____:____ **am / pm**
**Signature of Subject (18 or older and able to consent)** **Date** **Time (please circle)**

***TO BE FILLED OUT BY STUDY TEAM ONLY***

_____
**Name of Person Conducting Informed Consent Discussion**

_____ _____ ____:____ **am / pm**
**Signature of Person Conducting Informed Consent Discussion** **Date** **Time (please circle)**