Informed Consent Form

WINSHIP4517-18: A Phase II Study of Niraparib in Combination with EGFR Inhibitor Panitumumab in Patients with Advanced Colorectal Cancer

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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.

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

Title: Winship4517-18: A Phase II Study of Niraparib in Combination with EGFR Inhibitor Panitumumab in patients with advanced colorectal cancer

Principal Investigator: Olatunji B Alese, MD

Study-Supporter: Tesaro, which is now owned by GlaxoSmithKline

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?

This research study is a Phase II clinical trial. The purpose of this study is to define the safety and efficacy of combining two research drugs, Niraparib and Panitumumab (also known as Vectibix), in patients with advanced colon and rectal cancers. It may be that your cancer went away for a while but has grown back (relapsed) or it may be that it has never gone away (persistent or resistant tumor) after standard treatment. Panitumumab is approved by the U.S. Food and Drug Administration (FDA) for colon cancer and may be an appropriate treatment for you based on your physician's expert opinion. However, the combination of both medications has not been approved by the FDA for any cancer. Niraparib is approved by the FDA for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

What will I be asked to do?

If you choose to take part, you will be enrolled into this Phase II study. We expect to enroll approximately 26 patients in the study. We plan to enroll all subjects here at Emory.

Your participation will likely last for at least 8 weeks. However, you may continue in the study as long as your doctor feels you are benefiting from the therapy and your cancer is not getting worse. You can stop participating in the study at any time for any reason.

You will be seen about once every 2 weeks for the first few months of the study. If you are on the study longer than 2 months, it might be possible to space out the study visits. Most of these study visits will take just about the same amount of time as a regular doctor's visit.

How the Study Works – Eligibility and Enrollment

If you choose to participate in this research study, you will complete a "screening visit" that will consist of tests to find out if you meet the study requirements. The results of these tests will be used to decide whether you are eligible to participate in this study.

Some of the tests may have already been performed as part of the routine care you normally receive, while other required tests may be those that you wouldn't otherwise receive or would normally receive at a different time. The tests needed in order to complete the "screening visit" are described below:

- A medical history (questions about your health, current medications, and any allergies).
- A physical examination and evaluation of your ability to participate in the usual activities of daily living
- An assessment of your tumor by CT (Computerized Tomography) scan or MRI (Magnetic Resonance Imaging)
- Blood tests, including chemistry, clotting studies, lipid and cholesterol levels, and hematology, to measure disease status, determination of your kidney, thyroid and liver function, and tumor markers for pancreatic cancer (if applicable).
- Urine test (and Pregnancy test, if needed)

Your study doctor will discuss the results of the screening tests with you and will discuss whether you can participate in the study. You will stay on the trial until either your cancer gets worse (disease progression), you have significant side effects (toxicity) or withdrawal of your consent. Some of the common, less common and rare but significant side effects that may result from your participation on this trial are listed on pages 5 and 6 of this consent form.

Treatment Period – Day 1

Some of the tests and procedures to be done on the first day of treatment include

- A record of all medications you are currently on
- A medical history, physical examination and evaluation of your ability to participate in the usual activities of daily living
- Review of the Pill diary you will record as you take Niraparib
- Blood tests, including chemistry and hematology, to measure disease status, determination of your kidney and liver function, and tumor markers for colon or pancreatic cancer (if applicable).

You will receive Panitumumab intravenously as an infusion given over 60-90 minutes every 2 weeks, in combination with Niraparib pills which is taken once a day continuously. A pill diary will be completed for each dose of Niraparib taken.

Treatment Period – Day 8

- Blood tests, including hematology

Treatment Period – Day 15

- A record of all medications you are currently on
- A medical history, physical examination and evaluation of your ability to participate in the usual activities of daily living
- Review of the Pill diary you would have recorded as you take Niraparib
- Blood tests, including chemistry and hematology, to measure disease status, determination of your kidney, thyroid and liver function, and tumor markers for pancreatic cancer (if applicable).

Treatment Period – Day 22

- Blood tests, including hematology
- A punch biopsy of your skin: a small round piece of skin tissue about the size of a pencil eraser is removed using a sharp, hollow, circular instrument.

Treatment Period – Every 8 weeks

Every 2 cycles:

• Repeat cross sectional imaging (CT or MRI)

End of Treatment Visit

- A record of all medications you are currently on
- A medical history, physical examination and evaluation of your ability to participate in the usual activities of daily living
- Review of the Pill diary you will record as you take Niraparib
- Blood tests, including chemistry and hematology, to measure disease status, determination of your kidney and liver function, thyroid and tumor markers for pancreatic cancer (if applicable).

Safety Follow-Up Visit

You will be followed for at least 30 days after the last dose of study drug or until you start a new cancer treatment, whichever happens first.

After you complete the 30-day follow-up you will enter the post-treatment follow-up period. The study doctor or staff will discuss with you when and on which days to report to the clinic for the follow-up visits.

If you stop taking the study drug before your cancer gets worse you will continue to come in for a follow-up visit every 12 weeks with clinic visit and imaging until your cancer gets worse or you start a new treatment for your cancer. After 1 year. If at any time after you complete your treatment your cancer gets worse, or you start a new cancer treatment you will be contacted by telephone every 12 weeks for survival follow-up until the study ends.

Participants must not donate blood during the study or for 90 days after the last dose of study treatment. In addition, participants must not breast-feed while on study and for 180 days following the last dose of study treatment.

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 principal investigator, treating physician 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. As with all research studies, the study treatment and study procedures may involve unknown risks. Any medication can have temporary or permanent side effects that may or may not be expected.

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

Risk of **Blood Draw**: Blood draws can cause mild pain in the arm and may cause bruising, infection, and occasional fainting.

Risk of **Skin punch biopsy**: Punch biopsies can cause mild pain at the site and may cause bruising, infection, and occasional fainting.

Niraparib Side Effects

Your study doctor will explain the risks, side effects, and/or discomforts that may be experienced when taking the standard of care medications.

Niraparib has been studied in more than 1902 patients in TESARO clinical trials. Niraparib capsule is marketed as ZEJULA® and is approved to treat adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer in the United States and in Europe. Niraparib is currently being studied as a single medication and as a combination therapy within a variety of cancer clinical studies.

Niraparib Side effects experienced by patients taking niraparib as a single drug therapy:

Very Common occurrence (may affect more than 1 in 10 people)

- Decrease in the number of blood platelets (thrombocytopenia) that help blood to clot
- Decrease in the number of red blood cells (anaemia) that carry oxygen
- Decrease in the number of white blood cells (leukopenia) that fight infection
- Decrease in the number of neutrophils (neutropenia), a type of white blood cells (leukocytes) that fight infection
- High blood pressure (hypertension)

- Feeling like your heart is skipping beats or beating harder than usual (palpitations)
- Painful and frequent urination (urinary tract infection)
- Shortness of breath (dyspnoea)
- Runny or stuffy nose (nasopharyngitis)
- Cough
- Headache
- Dizziness
- Feeling weak (asthenia)
- Lack of energy (fatigue)Difficulty in sleeping (insomnia)
- Joint pain (arthralgia)
- Back pain
- Stomach pain (abdominal pain)
- Indigestion (dyspepsia)
- Feeling sick (nausea)
- Vomiting
- Frequent watery stools (diarrhoea)
- Difficulty passing stool (constipation)
- Decreased appetite

Common occurrence (may affect up to 1 in 10 people)

- Infection due to low white blood cell counts (neutropenic infection)
- An irritation or infection in the tubes that carry air in and out of the lungs, that causes a cough (bronchitis)
- Fast heart beat (tachycardia)
- Swelling of lower legs and feet (peripheral oedema)
- Muscle pain (myalgia)
- Rash
- Decrease in weight
- Feelings of sadness, depressed (depression)
- Feelings of worry, nervousness or unease (anxiety)
- Inflammation of the eye (conjunctivitis)
- Nose bleed (epistaxis)
- Sore, red mouth (stomatitis)
- Swelling or irritation of the lining of the mouth, throat, esophagus, stomach or intestines (mucosal inflammation/mucositis)
- Abnormal taste in mouth (dysgeusia)
- Dry mouth
- Increased sensitivity of the skin to sunlight (photosensitivity)
- Decrease in potassium in the blood (hypokalaemia)
- Increased level of creatinine in your blood (blood creatinine increase), which may be a sign of kidney damage
- Increased levels of substances in the blood produced by the liver, which may be a sign of liver injury (aspartate aminotransferase [AST] increased, alanine aminotransferase [ALT] increased, gamma-glutamyl transferase [GGT] increased)
- Other abnormal labs (alkaline phosphatase [ALP] increased)

Uncommon Occurrence (may affect up to 1 in 100 people)

- Fever with low white blood cell count (febrile neutropenia)
- Decrease in number of all types of blood cells (pancytopenia)

Rare Occurrence (may affect up to 1 in 1000 people):

- Severe life-threatening infection due to low white cell counts (associated with low blood pressure and possible organ failure (for example, heart, kidney and/or liver) (neutropenic sepsis)
- Severe increase in blood pressure (hypertensive crisis)
- A brain condition with symptoms including seizures, headache, confusion, and changes in vision (posterior reversible encephalopathy syndrome [PRES])

In addition to the above, the side effects below were reported by patients who were prescribed niraparib by their doctors:

- Allergic reaction (hypersensitivity, including anaphylaxis)
    - Life-threatening allergic reaction (such as difficulty breathing, rash, localised swelling, such as tongue, throat or lips) (anaphylaxis)
- Confusion (confusional state)
- Disorientation
- Seeing or hearing things that are not really there (hallucination)
- Impaired concentration, understanding, memory and thinking (cognitive impairment)
- Inflammation of the lungs which can cause shortness of breath and difficulty breathing (non-infectious pneumonitis)

Side Effects Requiring Immediate Medical Attention:

The side effects listed below require **IMMEDIATE MEDICAL ATTENTION OR ADVICE**.

Call the study doctor right away if you have any of these side effects:

- Allergic reactions can be life-threatening. Symptoms may include difficulty breathing, shortness of breath, low blood pressure (feeling lightheaded, dizziness), tingling around the mouth, rash.
- Low platelet counts may increase your risk of bleeding and bruising. Bleeding may require urgent medical attention, including a transfusion (receiving blood or blood products by vein).
- Low red blood cell counts may make you feel tired or short of breath and symptoms may require a blood transfusion.
- Low neutrophil counts may be associated with infection, sometimes severe and life-threatening.
    - Symptoms of severe life-threatening infection may include:
        - Fever, feeling of low blood pressure (lightheadedness, dizziness), decreased urination, rapid pulse, rapid breathing or shortness of breath
- High blood pressure (hypertension) including severe increase in blood pressure (hypertensive crisis) has been reported with the use of niraparib. If you have pre-existing hypertension, the physician will determine if your blood pressure is adequately controlled before starting niraparib treatment.
    - Symptoms of a severe increase in blood pressure may include:

- Blurry vision, headache, nausea, vomiting, confusion, passing out, seizures, weakness or numbness on one side of body or in one arm or leg and/or difficulty talking (symptoms of a stroke), trouble breathing, chest pain, pain in the upper or lower back, urine that is brown or bloody

- Posterior Reversible Encephalopathy Syndrome (PRES), a rare neurological side effect has been reported with niraparib treatment. If you have headache, vision changes, confusion or seizure with or without high blood pressure, please contact your doctor.

Class Effects:

Class effects are potential risks that are associated with a particular group of drugs. Niraparib belongs to the group known as poly (ADP-ribose) polymerase inhibitors (PARP) inhibitors. These class effects are potential risks for the group of drugs, but **have not yet been identified as side effects for niraparib**.

Myelodysplastic Syndrome (MDS)/Acute Myeloid Leukaemia (AML):

- **PARP inhibitors may cause blood cancers known as myelodysplastic syndrome (MDS) and acute myeloid leukaemia (AML).**
- MDS/AML, including cases with a fatal outcome with PARP inhibitors have been reported in a small number of patients who took niraparib or placebo (i.e., sugar pill).
- Your doctor may want to test your bone marrow for these problems.

Secondary Primary Malignancy:

- **PARP inhibitors may also cause a new primary cancer** (that is, a cancer other than the one for which you have been treated). In 2 studies comparing niraparib to placebo (sugar pill), new primary cancers were observed in a small number of patients who took niraparib was similar to those in patients who took placebo.

Safe Handling:
Niraparib may have adverse effects on an unborn baby. Wash your hands after handling the Study Drug. If a caregiver is giving the Study Drug to you, he or she should wear disposable gloves. Notify your Study Doctor if it appears that the Study Drug is damaged or defective in any way.

Contrast Agents
Your CT 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.

MRI
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 estimated radiation dose that you will receive is equal to or less than the annual radiation exposure limit allowed for persons who are occupationally exposed to radiation (for example, x-ray technologist, radiologist). The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. The risk for radiation-induced cancer from this study is minimal.

What about pregnancy and breastfeeding?

- Niraparib may have adverse effects on an unborn baby. You should not join this study if you are pregnant or planning to become pregnant. In addition, you should not get pregnant for 180 days after your last dose of Study Drug.
    - You should not join this study if you are breastfeeding.
- Effects of niraparib on fertility are unknown at this time. Animal studies in a drug similar to niraparib have been shown to cause a decrease in the number of cells that produce eggs in women's ovaries (reproductive organs).
- If you are a woman who can get pregnant, you will need to use high effective birth control while in this study and for 180 days after your last dose of Study Drug. You will have a pregnancy test before you can enter the study. Check with the study doctor about what kind of birth control methods to use and how long to use them. Some methods of birth control may not be allowed to be used during this study.
- Tell the study doctor if you are pregnant. If you get pregnant during the study, you will not receive any more niraparib, but you may remain in the study for follow-up. You must not breastfeed an infant (or store breastmilk for use) while taking the Study Drug and for 30 days after receiving final dose of Study Drug. We will follow-up until the delivery of the baby.

Male Participants

- To participate in the study, male study participants must adhere to a highly effective method of birth control
    - You must use a highly effective method of birth control and must not donate sperm during niraparib therapy and for 90 days after receiving the last dose.
- If you are sexually active with a woman who can become pregnant, you and your partner must use a highly effective method of birth control while you are participating in this study and for 90

days after your last dose of Study Drug. You must not donate sperm for 90 days after your last dose of Study Drug.

- Animal studies have shown that niraparib can cause a reversible decrease in sperm count. If you agree to participate in this study, you are expected to inform your female sexual partner(s) that you are participating in a clinical research study of an investigational drug, and that the effects of the drug on human sperm, an unborn baby and on a pregnant woman are unknown. You are also expected to provide your female sexual partner(s) with the information on the acceptable birth control methods described by your Study Doctor and to provide her with contact information for the Study Doctor for any additional questions. If your female partner becomes pregnant while you are participating in this study or within 90 days after your last dose of Study Drug, tell your Study Doctor right away as the Study Doctor is required to follow up and document the course and the outcome of all pregnancies. The Study Doctor may seek the pregnant woman's permission to review her medical records and the infant's medical records up to delivery, if applicable. The Study Doctor will share the information about your pregnant partner and the baby with the Sponsor to help understand the effects, if any, that the Study Drug may have on the pregnancy and/or the baby.

Will I benefit directly from the study?
This study is not designed to benefit you directly. Your colon cancer 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 the combination of Panitumumab and Niraparib. 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. The treating physician or 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, including your de-identified genetic information, may be shared with the research community at large to advance science and health. Data from this study 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.

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 skin biopsy 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.

Use of Your CT or MRI Scans in this Study

Your CT or MRI scans may be collected by the study sponsor for current and/or future research. Like key-coded data, these scans will be labeled with a unique code instead of your name. These scans and any information created from these scans will be treated as key-coded data and will be used and shared only as key-coded data may be used and shared as described in this consent.

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

Panitumumab and Niraparib will be free of charge.

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 will submit claims to your insurance for items and services that the sponsor 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 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 the sponsor 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 main study and for any optional studies in which you may choose to participate.

Main 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. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study.

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 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 research team and the Sponsor 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 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.
    - Government agencies that regulate the research including: Food and Drug Administration.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
    - Study-supporter: Tesaro, which is now owned by GlaxoSmithKline.
- 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 Studies: Future Research Studies, **New Biopsy during Treatment, and New Biopsy at Disease Progression**

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 research study.

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-C Clifton Road NE
Atlanta, GA 30322
Phone: 404-778-1900

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 main 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, MD 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.

ADDITIONAL STUDIES SECTION:

You will not get health benefits from any of these studies. The researchers leading this 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 will not know the results. You will not be billed for these studies.

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:

SAMPLES FOR FUTURE RESEARCH STUDIES

_____ I agree my samples and related information may be kept for use in future health research.

_____ 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.

OPTIONAL NEW BIOPSY DURING TREATMENT

_____ I agree to provide an optional new biopsy of the cancer sites during treatment.

OPTIONAL NEW BIOPSY AT DISEASE PROGRESSION

_____ I agree to provide an optional new biopsy of the cancer sites at disease progression.

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

_____ _____ ____:____ **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)**