Informed Consent Form

Lenvatinib in Recurrent Hepatocellular Carcinoma After Liver Transplantation

NCT Number: NCT05103904

Document IRB Approval Date: 6/25/24

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 17 people who are being studied, at Emory and elsewhere.

Why is this study being done?

This study is being done to determine if the study drug, lenvatinib, is safe and effective to reduce the size of your tumor. You are being asked to be in this research study because you have recurrent hepatocellular carcinoma after liver transplantation. Hepatocellular carcinoma is the most common type of liver 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, up to 2 years, or death, or the side effects of the study drug become unacceptable, or your doctor believes the study is not in your best interest anymore, or you withdraw your 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, have blood samples drawn, scans (MRI/CT), electrocardiograms (EKG or ECG), radiation (if it will apply to your treatment plan). You will undergo a pregnancy test if you are a woman of childbearing potential. 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 study drug, lenvatinib, 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: nausea, hypertension (high elevation of blood pressure), fatigue, low blood cell count, anemia (decrease in the number of red blood cells that carry oxygen), hand-foot syndrome (developing redness and pain in palms and soles with peeling of skin), mouth sores, joint pain, losing protein in the urine, hair loss, hemorrhage, respiratory problems, diarrhea, headache, skin rash (itchy skin), 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

The study drug lenvatinib will be provided at no cost to you. 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.

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 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: Winship5381-21: Lenvatinib in Recurrent Hepatocellular Carcinoma After Liver Transplantation

IRB #: STUDY00003060

Principal Investigator: Olumide Gbolahan, M.D.

Investigator-Sponsor: Olumide Gbolahan, M.D.

Study-Supporter: Eisai

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 liver and a history of liver transplantation. This study will help study doctors find out if the study drug, lenvatinib, is a better way to treat your liver cancer. The study doctors hope to learn whether the study drug will be safe and will reduce your cancer and enable you to live longer. Lenvatinib is an FDA-approved drug for patients who have liver cancer with no prior history of liver transplantation. Lenvatinib is not FDA approved for patients with recurrent liver cancer after liver transplant. The study drug is thought to work by inhibiting blood vessel formation by cancer cells, growth and spread of cancer cells. It is not known if giving the study drug will affect your cancer and survival although it could be potentially effective in patients with liver cancer and history of liver transplantation.

The main purpose of this study is to first determine whether lenvatinib causes the size of your cancer to shrink. The secondary purposes of this study are to see how long any effect on your cancer lasts, how long you live, any side effects that you may experience during the study.

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.
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 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 hepatitis virus testing, thyroid function and coagulation .
- 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.
- 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 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 cycle.

At the start of your study treatment (Day 1 of Cycle 1) and during the study participation, your doctor will:

- 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, coagulation, pancreas, liver and kidney functions.
- Perform urinalysis
- Urine or serum pregnancy test if you are a women of childbearing potential within 72h of starting study drug and every 4 weeks.
- Research blood sample for biomarker analysis. A biomarker is a measurement that is used to evaluate health or make a diagnosis of disease. 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 help us understand the cause of unintended side effects from the study treatment and changes in biomarkers induced by the treatment.
- First dose of lenvatinib will be administered by mouth and you will continue to take lenvatinib daily by mouth. You will receive the study drug for 8 weeks before the first radiographic imaging studies are performed.

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 you having to attend extra visits. 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 you remain on treatment, you will have radiographic imaging performed every 8 weeks. Radiographic imaging will continue to be performed until disease progression is identified by your physician.

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 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.

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

Side effects of lenvatinib, Some May be Serious

Very Common (affects more than 1 in 10 people and up to 8 in 10 people)
High or low blood pressure
Loss of appetite or weight loss
Nausea (feeling sick) and vomiting (being sick), constipation, diarrhea, abdominal pain, indigestion
Feeling very tired or weak
Dry, sore, or inflamed mouth or throat
High levels of protein in the urine
Hoarse voice
Headache
Hand-foot syndrome (redness, soreness and swelling of the skin on the hands and feet)
Joint pains
Cough
Low level of platelets in the blood, which may lead to bruising
Musculoskeletal, muscle, limb, or back pain
Swelling of the legs
Underactive thyroid and change in blood test result for thyroid stimulating hormone (high) - may result in fatigue, weakness, dry skin, hair loss, intolerance to cold
Rash
Feeling dizzy
Bleeding (most commonly nose bleeds, but may include bleeding from other sites, such as blood in the urine, bruising, bleeding from the gums, coughing up blood)
Odd taste sensation
Trouble sleeping
Hair loss
Urinary infections (increased frequency in urination and pain in passing urine)
Changes in blood test results for potassium levels (low) and calcium levels (low) – may increase the chance of having an abnormal heart rhythm

Common (may affect 1 in 100 up to 1 in 10 people)
Loss of body fluids (dehydration)
Dry skin, thickening and itching of the skin
Feeling bloated or having gas in the bowel
Malaise (feeling unwell)
Inflammation of the gallbladder
Changes in blood test results for liver
Changes in blood test results for magnesium (low) – may increase the chance of having an abnormal heart rhythm
Changes in blood test results for kidney function
Changes in white blood cells (low) which may increase risk of infections
Changes in blood test results (high) for lipase and amylase
Changes in blood test results for cholesterol (high)

Uncommon (may affect 1 in 1000 up to 1 in 100 people)
Painful infection or irritation near the anus
Splenic infarction (severe pain in the upper left part of the belly (abdomen), which may be associated with fever, chills, nausea, and vomiting)
Inflammation of the pancreas, which may cause severe pain in the abdomen or back
Impaired healing – wounds may take longer to heal.

Serious side effects of lenvatinib:

Common (may affect between 1 in 100 up to 1 in 10 people)

- Stroke, mini-stroke, or bleeding in the brain – may result in numbness or weakness on one side of the body
- Blood clot in the legs or lungs (pulmonary embolism) – may cause swelling of the calf associated with warmth or tenderness, sudden onset of shortness of breath, rapid breathing, tightening of chest or chest pain, cough or coughing up blood, rapid heart rate, and a blue tinge to the lips
- Heart problems, heart palpitations or heart attack – may cause chest pain or pressure, pain in the arms, back, neck, or jaw, shortness of breath, rapid or irregular heart rate, coughing, bluish colour to lips or fingers, feeling very tired.
- Fistula formation or bowel perforation – abnormal connections between different organs in the body or between an organ and another part of the body such as the skin or windpipe, or formation of a hole in the wall of the gut, which can cause severe abdominal pain
- Bleeding inside the body particularly from the gut – may cause black, tarry, or bloody stools
- Dehydration and kidney failure – may result from diarrhea and vomiting (being sick) which are very common side effects
- Heart failure – a decreased pumping ability of the heart, which may cause severe shortness of breath
- Liver damage or failure – may cause yellowing of the skin or eyes (jaundice), tiredness or sickness, loss of appetite, abdominal pain, or high temperature.
- Hepatic encephalopathy – may result in confusion, drowsiness, poor concentration, or loss of consciousness.

Uncommon (may affect between 1 in 1000 up to 1 in 100 people)

- Posterior reversible encephalopathy syndrome (PRES) is a potentially fatal condition that may have the following symptoms: headache, confusion, convulsions, and vision disturbance. An MRI scan may be required to diagnose this condition.
- Pneumothorax – a leak of air from the lung into the chest so the lung cannot inflate. This may cause sudden chest pain or sudden shortness of breath. There may be a higher chance of this occurring if cancer has spread to the lungs or if treatment is for solid tumor cancers, such as osteosarcoma or soft tissue sarcoma, or in patients under the age of 25.
- Aortic dissection – tearing in the wall of the aorta (a large artery), which may cause severe pain in the back, chest, or abdomen and internal bleeding
- Osteonecrosis of the jaw (ONJ)- rare but serious condition in which cells in the jawbone starts to die. It can cause severe pain in the jaw. Invasive dental procedures are an identified risk for the development of osteonecrosis of the jaw. A dental examination and appropriate preventive dentistry should be considered prior to starting lenvatinib. Periodic dental examinations and oral hygiene are important while you take lenvatinib. If you have planned dental procedures,

notify your dentist and oral surgeon that you are taking lenvatinib. Do not start medications without first discussing this with the trial doctor.

Contrast Agent:
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.

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 Risk:
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 4 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.

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 an adequate method of birth control or abstinence for the duration of the study and for 60 days after last dose. 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 60 days after the last dose. You and the study doctor should agree on an adequate method of birth control or abstinence for the duration of 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 effect of lenvatinib on liver cancer in patients with prior liver transplant. 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 study doctor will discuss these with you. You do not have to be in this study to be treated for your liver 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 deidentified 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.

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 of the research blood samples for correlative analysis.

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

The study-supporter may choose not to pay for Subject Injury Costs for any subject, no matter if the subject is insured, or how he/she is insured.

If you believe you have become ill or injured from this research, you should contact Dr. Gbolahan at telephone number 404-778-1900. 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 will help you to get medical treatment. Neither Emory, Saint Joseph's nor the study-supporter have set aside money to pay for this 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.

For Emory and Saint Joseph's, 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 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-supporter does not pay. The study-supporter 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 study-supporter 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 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 Saint Joseph's Hospital and the study-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 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.

- Dr. Olumide Gbolahan is the Sponsor of the study. The Sponsor 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 Sponsor 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 Study-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 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 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.
    - Study supporter: Eisai
- 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 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:

Olumide Gbolahan, M.D.
[redacted]

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 the Principal Investigator, Dr. Gbolahan, 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, or concerns 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 complaints about the research or an issue you rather discuss with someone outside the research team.

You may also let the IRB know about your experience as a research participant through our Research Participant Survey at **https://tinyurl.com/ycewqkke**.

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.. 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)**