Informed Consent Form

Title: IMPACT-TB*: A Phase II Clinical Trial of the Safety, Pharmacokinetics and Hematologic Effects of Imatinib on Myelopoiesis in Adults when Given With and Without Isoniazid and Rifabutin
*Imatinib mesylate per oral as a clinical therapeutic for TB

NCT Number: NCT03891901

IRB Approval Date: May 4, 2023

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 48 volunteers who are being studied at Emory.

Why is this study being done?
This study is being done to answer the question: can a drug called imatinib (which is approved for use in certain types of leukemia) be used to increase cells in the blood that fight bacterial infection? This is part of a larger research plan to test whether imatinib can be used in the treatment of tuberculosis (TB). An important purpose of the research is to determine the safety of different doses of imatinib in adults.

Do I 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. 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 for about 50 days (9 study visits). The researchers will ask you to do the following: answer questions about your health, complete brief physical exams, take heart rhythm tests (ECGs), provide small amounts of blood and urine for laboratory tests, and take imatinib tablets as instructed. On day 14 of the study, we will ask you to provide several small blood samples during the course of the day, so it will be necessary to remain at the clinical site on that day. All of these procedures will be paid for by the study.

How is this study going to help me?
This study is not designed to benefit you directly. If you are in the study, you will be helping the researchers answer the study question.

What are the risks or discomforts I should know about before making a decision?
The study will take time. The drug that is being tested may cause side effects. 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 possible side effects of imatinib, some of which include low blood cell counts, anemia, nausea and vomiting,

fluid retention, diarrhea, fever, headache, blurred vision, and liver and kidney problems. Other serious risks are possible, such as 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

Since this is not a treatment study, the alternative is not to participate.

Costs

You WILL NOT have to pay for any of the study procedures.

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.) This is a volunteer study, and it is your decision whether to participate. Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: IMPACT-TB*: A Phase II Clinical Trial of the Safety, Pharmacokinetics and Hematologic Effects of Imatinib on Myelopoiesis in Adults when Given With and Without Isoniazid and Rifabutin
*Imatinib mesylate per oral as a clinical therapeutic for TB

Study Arm: Imatinib dosing only

Principal Investigator: Edmund K. Waller, MD, PhD

Co-Investigators: Daniel Kalman, PhD; Cynthia Giver, PhD; R. Donald Harvey, III, PharmD; Colleen Kraft, MD; Aneesh Mehta, MD

Study Sponsor: National Institutes of Health (NIH) / National Institute of Allergy and Infectious Diseases (NIAID) / Division of AIDS (DAIDS)

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.

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.

Please note that any student currently enrolled in an Emory course taught by the Principal Investigator or a Co-Investigator on this study is exempt from enrolling in this study. Similarly, any Emory employee currently working under the supervision of any investigator on this study is exempt from enrolling.

What is the purpose of this study?
The purpose of this volunteer research study is to test whether a drug called imatinib (which is approved for use in certain types of leukemia) can also be used to increase cells in the blood that

fight bacterial infection. The results may help us develop improved methods for treating tuberculosis (TB). The duration of this study is 43 - 50 days, including 9 visits to the study site. Participants will take imatinib. During the study visits, we will examine your medical history, collect and review your vital signs, perform a physical exam, take an electrocardiogram (ECG) of your heartbeat, collect blood and urine samples, test your eyesight, and assess any possible signs and symptom from the study drug. Common side effects of the study drug include edema (swelling affecting the face, hands, lower legs and feet), rash, fever, upset stomach, low blood cell counts, muscle cramps and bone pain. Some less common side effects are, headaches, tiredness, and blurred vision. Rare but serious risks include liver problems and kidney damage. The study is not designed to directly benefit you, but your participation may help improve TB treatment for people around the world. The alternative to participating in this study is simply not to participate – it is your choice whether or not to participate.

We are interested in using the drug imatinib in the treatment of tuberculosis (TB). Imatinib is already U.S. Food and Drug Administration (FDA)-approved and commonly used to treat patients with several malignancies, including leukemia, at doses of 400 – 800 mg/day. Studies have been done in animals that show that this drug can also help treat TB. Imatinib has been taken by thousands of patients. We think that imatinib, at doses lower than or equal to the doses used in cancer, might help patients with TB. However, we must first test the safety and effects of imatinib in healthy people to find the doses that can be used in patients to treat TB. In this arm of the study, we will test the effects of imatinib when it is given alone (not in combination with antibiotics). We will determine the effects of imatinib on white blood cell formation (known as myelopoiesis) in adults. We will also use your blood samples in research tests to determine the effects of imatinib on the ability of immune cells to kill bacteria. Each subject will be assigned to receive one of three different dose levels (100mg, 200mg or 400mg per day for 28 days). In every case, the dose of imatinib is equal to or below doses approved for use in patients with leukemia. Once we know how imatinib works on the immune system in healthy people, we can plan new studies combining imatinib with antibiotics, and later test its effects in people who are sick with drug-resistant TB.

What will I be asked to do?

At the screening visit, we will ask you questions about your health, review your medical records, complete a brief physical exam, perform a test of your heart rhythm, and take a small amount of blood and urine for laboratory tests to see if you qualify for the study. These will include tests for infection with human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV). If you do qualify and you consent to be in the study, you will be assigned to one of three different doses of imatinib. The doses of imatinib that we will test are lower than or equal to those used in leukemia patients, who typically take 400 mg imatinib per day long-term. Volunteer subjects will take 100, 200, or 400 mg imatinib per day. We will begin enrolling volunteers at the lower doses and assign volunteers to the higher doses as we continue the study. We will ask you to take 28 days of imatinib.

If you qualify to participate in the study after the screening visit, we will ask you to complete 8 more study visits over 42 days, at the Georgia Clinical & Translational Science Alliance (Georgia CTSA) Clinical Research Center site in Emory University Hospital (GCRC). You will receive a container of study drug at Visit 1, within a week of the screening visit. Visit 1 (Day 1) will require a blood sample before you take the first dose of study drug in the presence of the study nurse or staff. The total length of your involvement will be 43-50 days, depending on how many days are between your screening visit and Visit 1. Most of the visits will take approximately 30 minutes, but Visit 4 (on Day 14) will require you to stay at (or close by) the study clinic for about 8 hours (see below). It may be

possible to substitute tele-medicine visits for some of the shorter appointments if there are unforeseen difficulties with scheduling. Any such arrangements must be made with the study team in advance.

The types of things we will do during the study visits include:

- Ask about symptoms, review your medical history and medical records if you have them, and ask about possible adverse effects of the medications
- Perform a brief physical exam, including vital signs
- Collect a sample of your urine
- Perform a heart rhythm test, called an ECG
- Test your eyesight using a wall chart
- Draw blood for blood counts, electrolytes, measures of kidney and liver function, and research tests.
- Blood volumes will range from 1 teaspoon to 3 tablespoons depending on the visit, except for visit 4 will require more blood as described below:
- At visit 4, we will insert a small plastic tube (catheter) into a vein in your hand or arm and monitor your blood drug levels by 6 blood draws done over a time period of 8 hours. The catheter is left in the vein during this period of time in order to avoid having to repeatedly stick a needle into your vein. The total blood volume that will be removed for this intensive study visit will be about 5 Tablespoons. During this time you will be given food and refreshments.

All of these procedures are experimental parts of the research project and none are needed for your medical care.

Human Biological Samples
While you are in this study, you will have blood (serum/plasma) samples collected to be used for the current study analysis, including re-running study tests, if necessary, and storing samples for future research. The purpose of storing these samples is to make them available to scientists who are trying to develop new tests, treatments, and ways to prevent diseases. We hope that these samples will provide information that will help researchers in the future. The samples will be labeled with an identification code. Your samples will never be labeled with your name and will remain separate from the files linked to your name. These de-identified samples, as well as your de-identified information and records relevant to the study, may be used by other investigators in future studies without obtaining additional informed consent from you. This research study will not include whole genome sequencing (WGS).

Successful research using the samples or other parts of the samples could result in a commercial or therapeutic product with significant value, such as a product for the medical treatment or diagnosis of tuberculosis or other diseases. You will not share in any financial benefits of these uses.

Your samples will only be used for research and will not be sold. These samples may be utilized by Emory for further or additional analyses to answer scientific or medical questions, but if your samples are given to other researchers (other than Emory) your de-identified samples and study information would only be given to researchers who have had their research reviewed by an Institutional Review Board (IRB), which is a committee that protects the rights and privacy of study subjects.

How will the study drug be provided?

The imatinib that you will take come in tablet form. The medication will be ordered by the study doctor, dispensed by the pharmacy and picked up by a study team member. The study team member or a GCRC research nurse will provide the study drug to you. If you have questions about the study drug, you should ask the principal investigator, study team member, or study nurse. You may also call the pharmacy at (404) 712-4718 if you have questions about the medication. The number for the pharmacy is included on your study drug package. We will provide you with a pill diary to keep track of your imatinib, which you will review with the GCRC staff at each visit.

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?

Side effects and risks associated with study drug:

>>> Please report any symptoms or side effects that you experience to the study team.

Imatinib Risks

The most common side effects while taking imatinib are:

- Low blood counts. Your white and red blood cells and platelets may temporarily decrease. This can put you at increased risk for infection, anemia and/or bleeding.
- Nausea and vomiting
- Edema (fluid retention: swelling of the face, hands, lower legs, feet)
- Muscle cramps and bone pain
- Diarrhea
- Hemorrhage (bleeding problems)
- Skin rash
- Fever

Less common side effects while taking imatinib are:

- Headache
- Tiredness
- Joint pain
- Indigestion (heartburn)
- Belly pain
- Cough
- Shortness of breath
- Poor appetite
- Constipation
- Night sweats
- Nose bleeds
- Weakness
- Blurred vision

Rare, but possible serious risks with taking imatinib include:

- Liver problems
- Kidney damage

Please note: In subjects who took imatinib for 2 weeks, followed by another 2 weeks taking imatinib plus the antibiotics isoniazid and rifabutin, many subjects had low white blood cell counts after starting the antibiotics. While these counts recovered quickly when study drugs were stopped, and no treatment was required, this was a safety concern. We now no longer give imatinib plus antibiotics – we give imatinib alone. We do not expect low blood cell counts to occur in subjects taking imatinib alone, but you will be closely monitored and we will alert you if you have low blood cell counts or any other lab readings that would warrant early drug discontinuation.

Blood tests and catheter placement: A small blood clot may form at the site of the intravenous needle or catheter tube used for blood sample collections, or there may be swelling in the area. This will resolve in a few days. There is a small risk of a minor infection at the place that the needle is inserted. Lightheadedness and fainting can also occur. There are no long-term side effects from blood draw procedures.

ECG (electrocardiogram): This test is done to see how well your heart is working and beating. The risks from an ECG can include skin irritation and a rash from the gel that is used or from wearing or removing the patches.

There may be side effects from the study drug or procedures that are not known at this time. Results from routine blood and urine tests performed at the GCRC and the Emory Medical Laboratory will be placed in your Emory medical record. Results from other research tests will not be recorded as part of your medical record. However, if we find out something in the routine clinical and laboratory tests that is important to your health, we will inform you or refer you to a doctor if you wish.

Keep all study drug out of the reach of children or anyone else who may not be able to read or understand the labels. 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.

If you are a woman: to protect against possible side effects of the study drug, women who are pregnant or nursing (breast feeding) 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 combination of birth control methods to use during the study and for 2 weeks after the last dose of study drug. A woman is considered to be of childbearing ability unless she is postmenopausal (over 45 years old with no menses for at least 1 year) or has undergone a hysterectomy. A female participant of childbearing ability (and her partner) must agree to use one of the following combinations of birth control during the study and for 2 weeks after the last dose of study drug (or tubal ligation as a single method):

1) Use of a double-barrier method of contraception: condoms (male or female) **and** a diaphragm or cervical cap with spermicide;

2) Use of an intrauterine device (IUD, hormonal or non-hormonal) **and** a barrier method: condoms (male or female, with or without spermicide) or a diaphragm or cervical cap with spermicide;

3) Use of hormone-based contraceptives (pill, patch, implant, ring, or injectable) **and** a barrier method: condoms (male or female, with or without spermicide) or a diaphragm or cervical cap with spermicide;

4) Tubal ligation.

You should not be in the study if you are undergoing any type of assisted reproduction treatment. 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 become pregnant during the study, you will be followed to assess any bad outcomes to your pregnancy that may have resulted from your participation in this study. Urine pregnancy tests will be conducted at screening, and at visits 1, 4, and 7 and 8. Results will be kept in study records, but not in your medical record.

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 2 weeks after the last dose. You and the study doctor should agree on a method of birth control to use during the study and for 2 weeks after the last dose of study drug. You should not be in the study if you are collecting/donating sperm for any assisted reproduction purpose.

Will I benefit directly from the study?

This study is not designed to benefit you directly, nor to treat any medical condition you may have. If you have a medical condition, it might improve while you are on the study, or it may not improve, and it may even get worse. This study is designed to learn more about the safety of taking imatinib, and the effects of imatinib on circulating white blood cell counts. This knowledge will be important as we try to use imatinib to help tuberculosis patients. Hence, the study results may be used to help others in the future.

Will I be compensated for my time and effort?

To compensate you for your time and effort, you will receive $50 for the screening visit, $125 for visit 1, $75 for each visit 2, 3, 5, 6, 7 and 8 (6 visits), and $300 for the PK study visit 4, for a total of $925 for the entire study. If you do not finish the study, we will compensate you for the visits you have completed.

You will be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options.

What are my other options?

This study is not designed to prevent or treat any disease or medical condition. The alternative to participating in this study is to not participate. You are free to choose not to take part in it.

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.

Are there any special instructions to follow while participating in this study?

During this study, it is important that:

You do not consume grapefruit, grapefruit juice, or grapefruit-related citrus fruits (e.g., pomelos) during this study (7 days before and while taking any study drug). These may interfere with drug metabolism.

You do not use Tylenol or other acetaminophen-containing medications during the 28-day drug dosing period since such medications may increase the risk of liver toxicity

You do not consume any alcoholic beverages while participating in this study.

You must follow instructions for timing of meals around the daily morning drug doses. On non-study visit days, the study drug(s) should be taken upon waking. Breakfast may be eaten 1 hour later. On study visit days, you may eat a small breakfast 2 hours before your scheduled study appointment. You will take the study drug at the visit (at least 2 hours after eating). A meal or snack will be provided 1 hour later at the study center for visits 4 and 8.

There may be certain medication and herbal supplements that you should not take while participating in this study. Your study doctor will review what medications you are currently taking. Please notify your study doctor if you begin taking anything new while you are participating in this study and also inform your doctor / specialist that you are participating in a drug trial for the study drug (you can ask your physician to contact the Principal Investigator for any further details)

Tell a study doctor immediately if you have any symptom, complaint, or injury. If you seek emergency care or if hospitalization is required at any time during the study, please tell the treating doctor that you are enrolled in this research study and that study personnel must be informed promptly.

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.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.

- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you), 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.

Medical Record

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

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

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

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

In Case of Injury

If you believe you have become ill or injured from this research, you should contact Dr. Waller 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 will help you get medical treatment. Neither Emory nor the sponsor will pay for your medical treatment. 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.

Emory and the sponsor have not 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, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory 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

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under "injury" as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. For your safety, however, if you leave the study before the final planned study visit, the researchers may ask you to have a final medical evaluation.

If you become sick due to infection such as COVID-19, influenza, cytomegalovirus, adenovirus, strep throat, etc., or test positive for any such active infection, you will be discontinued from the study.

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, if you are judged by the investigator to be at significant risk of failing to comply with the provisions of the protocol, or if you were to object to any future changes that may be made in the study plan. The study principal investigator, Dr. Waller, the study sponsor (National Institutes of Health NIH/NIAID/DAIDS), the Food and Drug Administration, and the Institutional Review Board of Emory University may stop the study or withdraw you from further participation if any one of these listed people or regulatory agencies feels that it is in your best interests to stop your participation. You could also be withdrawn from the study at the request of your primary care provider, or at the discretion of the Office for Human Research Protections (OHRP) or other government agencies.

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 in which you may choose to participate.

PHI that Will be Used/Disclosed:

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

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

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

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

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, then you may not participate in the research study.

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.
- Emory may use and disclose your PHI 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 National Institutes of Health 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.
- Other local, US, and international regulatory entities may review participant records.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Office for Human Research Protections; Food and Drug Administration.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.

- 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:

Edmund Waller, 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.

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. Waller 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 404-712-0720 or 877-503-9797 or irb@emory.edu:

- 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

_____ _____

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

Month-Date-Year AM / PM

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

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

Month-Date-Year AM / PM