Informed Consent Cover Page

Official Title: Analysis of Bone Marrow and Blood B cell Immune Responses to Influenza Vaccination

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You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 55 people who are being studied, at Emory.

Why is this study being done?

This study is being done to test and understand the immune response to vaccination with the influenza (the "flu") vaccine in the blood and bone marrow. You are being asked to participate in this study because you are a healthy volunteer. If you agree to be in this study we will be giving you one dose of an FDA-approved influenza vaccine.

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.

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

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 one year (365 days) (6 study visits). The researchers will ask you to do the following: attend all clinic visits involved with this study. In addition to the screening visit, there will be a baseline visit, and visits at 7 days, 14 days, 28 days, 90 days and 365 days after vaccination.

As part of the study visits, you will receive a limited physical exam, have blood drawn, and will also have a bone marrow aspiration/draw at specific study visits. All of these procedures will be paid for by the study.

How is this study going to help you?

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. All studies have some risks. Some risks are relatively small, like being bored or losing time. Other risks include risks associated with drawing blood such as pain and

bruising at the place where the blood is taken. There are some common, expected reactions to the killed flu vaccine. Some of the common reactions to the killed flu vaccine are: discomfort and bruising at the site of the shot, stiff or achy arm for a few hours, sore throat, headache, chills, and fatigue. A few people experience mild fever and body aches for 24 hours after getting the flu shot. Some are more serious – for this study, these include very rarely, people have a serious allergic reaction to the flu vaccine. Other potential risks include loss of privacy, and breach of confidentiality. The physical risks of undergoing a bone marrow removal are pain and bruising that may last 1 to 3 days. 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, in particular those that are not covered by your medical insurance. There is more information in the cost section below.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.), and please make sure that you understand what the study involves. Take time to consider this and talk about it with your family and friends.

EMORY UNIVERSITY | Institutional Review Board
Research Administration

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: Analysis of Bone Marrow and Blood B cell Immune Responses to Influenza Vaccination

IRB #: IRB00079280

Principal Investigators: Edmund Waller, MD, and Rafi Ahmed, PhD

Sponsor: National Institutes of Health

Study-Supporter: National Institutes of Health

Introduction

You are being asked to volunteer for a research study at Emory University and sponsored by NIH to test your immune response you a vaccination for influenza (the "flu"). You are being asked to participate in this study because you are a healthy volunteer. This consent form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in 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.**

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 about what is stated in this form and the study as a whole.

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 may search this Web site at any time. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You may search this Web site at any time. The results of this study may be published in a scientific journal. In the event of publication, the journal will not receive any information about you nor will any information that can identify you be published in the article.

What is the purpose of this study?

The purpose of this research study is to understand the immune response to vaccination with the flu vaccine in the blood and bone marrow. The number of immune cells that help protect your body against influenza will be measured in your blood and bone marrow. If you agree to be in this study, we will be giving you one dose of an FDA-approved influenza vaccine.

Influenza ("Flu") infection carries a risk of serious illness. The immune system is your body's defense against all sorts of infections and foreign invaders. When you get the flu vaccine, you are getting a dose of killed or weakened flu virus. Your immune system then builds protective responses against the flu virus. Later, if you get exposed to the flu, these

responses help attack and kill the virus. As a result, you may not get sick at all, or you may have a much shorter or milder illness.

The killed flu vaccine is a vaccine made from a killed influenza virus that has been split apart and modified in such a way as to not be able to grow at all in a human. The killed flu vaccine is given as an injection into your arm.

The study will measure the way your immune system responds to the seasonal flu vaccine by measuring the immune response in your blood and bone marrow over a period of time, in this study up to 1 year post (after) vaccination. Researchers expect to see a change in your immune system before and after receiving flu vaccine. It is possible that by measuring these differences, especially in the bone marrow, they can better understand how the body responds to flu vaccination and how long the immunity lasts. This is important because it could help make more effective flu vaccines in the future.

The flu vaccine used in this study is the same seasonal flu vaccine that is approved by the government for this year.

Up to 55 healthy volunteers will be enrolled into the study. You have been chosen for this study because you are a healthy volunteer and are eligible to get the flu vaccine. If you agree to participate in this study, your participation will last for up to 365 days, or 1 year. If you have enrolled in this study in a prior year, you may re-enroll into the study this year if you meet eligibility criteria. By enrolling in this study, you will be restricted to receive the FDA approved influenza vaccine provided by the study. You may not participate in other vaccine studies while you participate in this study.

What will I be asked to do?

You will be asked to attend all clinic visits involved in this study. There are six clinic visits altogether, including the screening and enrollment visits, and 4 follow-up visits. The total length of your participation in the study will be 365 days (one year).

To participate in this study, you must meet inclusion and exclusion criteria. You may participate in the study beyond 365 days, but you must meet inclusion and exclusion criteria again. You cannot receive another influenza vaccine until the Day 365 visit has been completed. If you choose to receive an additional dose of the influenza vaccine before you have completed the day 365 visit, you will not be eligible to participate in the day 365 study visit.

Procedures:

Pre-Vaccination /Screening Visit:
You will be seen for all of your visits in the Winship Cancer Institute Ambulatory Treatment Center. You will be asked to read and, if you are willing to participate, sign this consent form. We will ask you some questions about your health and what vaccines you may have had in the past to ensure that you are a healthy volunteer, including whether you have a history of Guillain-Barre syndrome. We will write down what medicines you are taking. You will have your height and weight taken. You will have a brief physical exam performed by a licensed healthcare provider. You will have your blood pressure, pulse rate, respiration rate and temperature recorded. You will have a brief physical exam by a licensed healthcare provider. You will have blood work drawn to see if you have normal blood counts and normal blood chemistries. For these tests you will have about 30 milliliters (1 ounce or 2 tablespoons) of blood drawn.

Women of child-bearing potential will have a urine pregnancy test and required to use a barrier method of birth control or an FDA approved form of birth control for the duration of study participation. We do not want you to be pregnant or have plans to become pregnant while on study. The influenza vaccine is safe for pregnant women, but bone marrow aspirations are not typically performed during pregnancy, and if you become pregnant, you will not be able to complete

the study. If you become pregnant while enrolled in the study, you will not be asked to come back for any study visits; however, the study team will contact you monthly for safety monitoring monthly via telephone for the duration of your pregnancy.

Enrollment/Day 0
You will receive a limited physical exam. Up to 64 milliliters (2 ounces or 4 tablespoons) of blood will be drawn to test for baseline antibody levels in your blood. Women of child-bearing potential will have a urine pregnancy test. You will have your blood pressure, pulse rate, respiration rate and temperature recorded. You will be asked about any health changes or change in your medications since your screening visit. The killed flu vaccine will be given by an injection (shot) into your upper arm.

Bone Marrow Aspiration (Removal)
On the day you are to get your vaccination you will have a sample of your bone marrow removed in the procedure area of Winship Cancer Institute Ambulatory Treatment Center. You are being sent there because that is where bone marrow samples are routinely performed. The visit for the bone marrow aspiration will take up to one hour. After the aspiration has been done, you may resume regular physical activity immediately but should avoid getting the aspiration site dressing wet for two days to avoid infection. You will have the skin and bone surface numbed to pain by injecting lidocaine, a medicine similar to what dentists use to numb the mouth. Sedation is not offered in this research study because the risks associated with sedation do outweigh its benefits for pain control. Bone marrow is the inside part of your bone, where new blood and immune cells are created.

After your vital signs have been taken you will be placed on a treatment table and an area on your back hip bone will be located where the bone marrow will be removed. The area on your hip bone is just below your waist near the spine. The area will be thoroughly cleaned with a substance that kills the bacteria on your skin. A Novocain-like medication called lidocaine will be injected into the area to make it numb so the procedure will be less uncomfortable. There will be a single needle stick into your hip bone to obtain about 30 milliliters (1 ounce or 2 tablespoons) of bone marrow.

Once the bone marrow has been removed the area will be cleaned again and a dressing will be applied. You will be instructed on how to care for this area from the nurse in the treatment center. Your hip bone will be sore for a few days, and you may feel tired for the next several days until your body can replace the bone marrow that was taken out.

Following bone marrow aspiration (see description above), the flu vaccine will be given by an injection (shot) into your upper arm. When you receive the shot, there may be slight pain and burning during the injection and your arm may feel sore for a few hours after the shot. There is a small chance that the vaccine may cause a slight fever or a sense of feeling mildly ill.

Follow-up visits
You will be asked to come back to have blood drawn 4 more times: day 7, day 14, day 28 and day 90 post vaccination. You will have your blood pressure, pulse rate, respiration rate and temperature recorded. About 64 ml (4 tablespoons) of blood will be drawn to test baseline antibody levels. You will be asked about any health changes or change in your medications since your last study visit.

Due to the COVID-19 pandemic, the window for the Day 28 and Day 90 visits have been expanded to allow for the collection of samples that were unable to be collected due to the temporary halting of this study. The window for the Day 28 visit will be expanded by a maximum of up to 180 days, and the window for the Day 90 visit will be expanded by a maximum of up to 180 days. The procedures at these respective visits will not change, only the timing of these two visits.

Due to the COVID-19 pandemic, the window for the Day 28 visit has been increased by a maximum of up to 180 days. The same procedure described above will be performed at your Day 28 visit to take the bone marrow. If you are a woman of childbearing potential, you will have a urine pregnancy test and you will only be included if the pregnancy test is negative. On all other follow-up visits, you will have about 64 milliliters (2 ounces or 4 tablespoons) drawn. You will also be asked about any changes in your health or changes in the medicines you are taking.

You will be invited to return for a visit 365 days post vaccination. You will have blood work drawn to see if you have normal basic blood work, a brief physical exam performed by a licensed professional health care provider, and an update to your medical history. For this blood work, you will about 1 teaspoon of blood drawn. Your temperature, pulse rate, blood pressure and respiration rate will be recorded. You will also be asked about any changes in your health or changes in the medicines that you are taking. If you are a woman of childbearing potential, you will have a urine pregnancy test, and you will only be allowed to have the bone marrow aspirate procedure if your pregnancy test is negative. You will have the same amount of blood drawn for the study, as well as your bone marrow will be sampled again using the same procedure as before. With this visit, you will have a total of about 402 ml (14 ounces or 28 tablespoons) of blood drawn during the course of this study

How will my medicine be provided?
The medicine/flu vaccine dose that you will receive will be dispensed by the pharmacy and delivered to the principal investigator or study team member. The principal investigator or health care providers on his/her research team will provide the medicine to you. If you have questions about the medicine, you should ask the study team member who is your point of contact for this study. You may also call the pharmacy at (404) 712-7485 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?
The risks associated with drawing blood include pain and bruising at the place where the blood is taken. Sometimes, blood drawing causes people to feel lightheaded or to faint and may cause infection at the site of the blood draw.

There are some common, expected reactions to the killed flu vaccine. Some of the common reactions to the killed flu vaccine are: discomfort and bruising at the site of the shot, stiff or achy arm for a few hours, sore throat, headache, chills, and fatigue. A few people experience mild fever and body aches for 24 hours after getting the flu shot. Very rarely, people have a serious allergic reaction to the flu vaccine. You should not receive the flu shot if you are allergic to chicken, or eggs.

Bone marrow aspiration:
Following a discussion of the procedure with Dr. Waller, you will be asked to review and sign a separate Emory healthcare consent for the bone marrow aspiration procedure. The physical risks of undergoing a bone marrow removal are pain and bruising that may last 1 to 3 days. Very rarely more serious side effects could occur including damage to normal blood vessels, veins or bone structures, or rarely a localized infection at the site where the bone marrow is removed. The removal of 30 milliliters (1 ounce or 2 tablespoons) of marrow produces a transient and mild anemia that may last one or two weeks. A small number of people experience a sense of feeling light-headed called "vaso-vagal syndrome" during the blood draw or bone marrow procedure. Vaso-vagal reactions may include sweating, nausea, lightheadedness, temporary low blood pressure, fainting, and very rarely loss of consciousness. Bone marrow aspiration

procedures will be performed by a board-certified hematologist/oncologist. Care will be taken to obtain these specimens in a safe and sterile manner.

Blood draws:
You may experience discomfort and bruising from the needle stick required to draw the blood sample. There is a small chance of infection and bleeding at site of the needle stick. You may have redness or skin irritation where the band-aid or tape is placed over the site.

Local anesthetic:
The risk for the local anesthetic is a possible allergic reaction. Very rarely more serious side effects which include allergic reactions to lidocaine or damage to normal blood vessels, veins or bone structures or localized infection at the area where the marrow is removed. Reactions to lidocaine include cutaneous lesions, urticarial, edema or anaphylactoid reactions. Pruritis, burning, edema, erythema, purpura and bleeding may occur at the local injection site Please tell the nurse who is caring for you if you have had any unusual reactions to anesthetics used at your dentist's office as these drugs are related.

Flu vaccine (Killed influenza vaccine):
There are some common, expected reactions to the killed flu vaccine. Some of the common reactions to the killed flu vaccine are: discomfort and bruising at the site of the shot, your arm may feel stiff or achy for a few hours. A few people experience mild fever and body aches for 1 – 3 days after getting the flu shot. Very rarely, people have a serious allergic reaction to the flu vaccine. You should not receive the flu shot if you are allergic to chicken or eggs. Associated with the 1976 flu vaccine, a few subjects experienced temporary paralysis, a condition known as Guillain-Barre syndrome. Several studies have linked a small but significant risk of Guillian-Barre Syndrome associated with the H1N1 (swine flu) vaccine in 2009; however, this syndrome has not been seen with the more modern version of the A/H7N9 vaccine which will be used in this study. Persons with a history of Guillain-Barre syndrome will be excluded from study participation.

Occasionally, recipients of the killed flu vaccine have experienced flu-like symptoms such as fever, feverishness (chills/shivering/sweating), fatigue (tiredness), malaise (general unwell feeling), myalgia (body aches/muscular pain), arthralgia (joint pain), headache, and/or nausea. Some people have reported reactions at the injection site, including pruritus (itching), ecchymosis (bruising), erythema (redness), induration (hardness)/swelling, pain, and/or tenderness. These reactions usually occur within the first 24 hours after vaccination and usually disappear without treatment within 1 or 2 days. Over the counter pain medications (e.g., acetaminophen, or ibuprofen or similar non-steroidal anti-inflammatory drugs [NSAIDs]) and rest may generally relieve or lessen these reactions. Bruising can sometimes occur due to the vaccination procedure.

Very rarely (occurring in about 1 in 4 million people given a vaccination) there can be a serious allergic reaction to a vaccine. These reactions can manifest as skin rash (hives), swelling around the mouth, throat or eyes (angioedema), difficulty breathing (bronchospasm), a fast pulse (tachycardia), or loss of blood pressure (hypotension). If these reactions occur, they can usually be stopped by the administration of emergency medications by the study personnel. As with any vaccine or medication, there is a very small chance of a fatal reaction (death), although researchers do not expect this to occur. You may not participate in this study if you have any history of allergies to the flu vaccine or any of its ingredients such as chicken or eggs as listed above.

Additional rare reactions to the seasonal flu vaccine include: neuritis, convulsions, severe allergic reactions, syncope, encephalitis, thrombocytopenia, and vasculitis. Reports of these reactions were rare; however, exact incidence rates cannot be precisely calculated. To ensure safety of all subjects, anyone who has previously had an adverse reaction to the seasonal flu vaccine will not be able to participate in this study.

Flu vaccine and pregnancy:
Assessment of the immune response to flu vaccines in pregnant women is not included in the scope of this study. Therefore, if you are pregnant or planning to become pregnant during the time this research is being conducted, we will not include you in this voluntary research.

Unknown Risks:
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 so 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.

New Information:
It is possible that the study investigators will learn something new during the study that may affect your health or your decision as to whether you want to stay in the study or not. If this happens, we will tell you about it. Then you can decide if you want to continue to be in this study or not. You will/may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

New Findings:
During your participation in this study, Dr. Waller will inform you of any significant new findings (good or bad) from this research study that may affect your willingness to continue in this study. If new information is provided to you regarding the risks of the study, you will be asked to sign a new consent if you wish to continue in this 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 a method of birth control to use throughout the study. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant women will be taken out of the study.

If you are a woman of childbearing potential, you will have a urine pregnancy test and you will only be included if the pregnancy test is negative.

If you are a woman of childbearing potential, you will have a urine pregnancy test, and you will only be allowed to have the bone marrow aspirate procedure if your pregnancy test is negative.

Will I benefit directly from the study?
By participating in this study, you may learn whether you have influenza. There is no benefit to subjects who undergo blood drawing or bone marrow aspiration. Seasonal flu vaccine is considered beneficial to most subjects, as it generally provides protection against circulating flu strains. If vaccine is given after flu season, there is no benefit to you. There will be no direct benefit to you from being in this study. However, in the future other people might benefit from the information we learn from this study.

Will I be compensated for my time and effort?
For your time, inconvenience, travel and parking, you will be paid $50 each time you have blood drawn for this study. For each of the three (3) bone marrow draws you will be compensated with $200 per appointment. You will receive

$900.00 total, if you complete all study visits. Payment will be via gift cards. If you do not finish the study, we will compensate you for the visits you have completed.

What are my other options?

You are free to choose whether or not to participate in this study. The alternative to choosing to be in this study is to not be in the study. Your participation is completely voluntary and you have the right to refuse to be in this study. Taking part in this study, however, will make you unable to participate in other research studies. 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.

Emory will keep any research records that it creates private to the extent that this is required to do so by law. Emory will keep any research records that it creates private to the extent that this is required to do so by law. 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.

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 are or have been an Emory Healthcare patient, you have an Emory Healthcare medical record. If you are not and have never been an Emory Healthcare patient, you do not have one. Please note that an Emory Healthcare medical record will be created if you have any services or procedures performed by an Emory provider or facility for this study.

If you agree to be in this study, a copy of the consent form and HIPAA subject form that you sign **will** be placed in your Emory Healthcare medical record. Emory Healthcare may create study information about you that can help Emory Healthcare take care of you. For example, the results of study tests or procedures. These useful study results **will be** placed in your Emory Healthcare medical record. Anyone who has access to your medical record 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. On the other hand, some state and federal laws and rules may not protect the research information from disclosure.

Emory does not control results from tests and procedures performed at other places, so these results would not be placed in your Emory Healthcare medical record. They will not likely be available to Emory Healthcare to help take care of you. Emory also does not have control over any other medical records that you may have with other healthcare providers. Emory will not send any test or procedure results from the study to these providers. If you decide to be in this study, it is up to you to let them know.

The researchers will review the results of certain study tests and procedures only for the research. The researchers will not be looking at these results to make decisions about your personal health or treatment.

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.

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

The sponsor may choose to pay for Subject Injury Costs for all subjects, no matter if the subject is insured, or how he/she is insured.

You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact the Principal Investigator, Dr. Edmund Waller, at telephone number 404-778-1900 or Dr. Rafi Ahmed at 404-727-4700. 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 to get medical treatment. Emory has not set aside any money to pay you if you are injured as a result of being in this study. 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. "Negligence" is the failure to follow a standard duty of care. If you get ill or injured as the direct result of the study drug or a study procedure, the sponsor will pay the costs for your medical treatment of the illness or injury. The sponsor will not pay for co-payments or co-insurance that your insurer says you must pay. Also, the sponsor will not pay for illness or injury:

(a) from medical conditions you had before you started the study;
(b) from the natural progression of your disease or condition;
(c) from your failure to follow the study plan; or
(d) that is directly caused by the negligence of an Emory employee. Negligence" is the failure to follow a standard duty of care.

If you have Medicare or Medicaid: the sponsor may need information about your identity and your study treatment to give to the government agencies that run these programs.

Your insurance will be billed for any costs of medical treatment that the sponsor does not pay. Your insurer may be told that you are in a research study.

You will have to pay for any treatment costs that are not paid for by your insurance or the sponsor.

In addition, you may be eligible for compensation through the National Vaccine Injury Compensation Program. You can get information about this program by calling 1-800-338-2382. Alternatively, you can use the internet to contact the program at: http://www.hrsa.gov/gethealthcare/conditions/compensation.html

By signing this form, you do not give up any legal rights. Emory will keep any research records that it creates private to the extent that this is required to do so by law. 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.

Costs

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

You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care. If you have insurance, Emory 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. You are free to choose whether or not to participate in this study. The alternative to choosing to be in this study is to not be in the study. Your participation is completely voluntary and you have the right to refuse to be in this study. You can stop at any time after giving your consent. This decision will not affect in any way your current or future medical care or any other benefits to which you are otherwise entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

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.

Reasons why you may be taken off study without your consent:
You may be removed from the study without your consent at any time. Reasons why you may be removed from the study include, but are not limited to, the following:

- Your doctor determines that it is in your best interest not to take part.
- You are unable to complete required study tests
- The study is stopped by the Institution, the Sponsor(s), or by the Food and Drug Administration (FDA) or other health authorities

If you are removed from the study Dr. Waller or his designee will contact you to discuss the study stopping procedures.

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. 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.

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 or receive research-related treatment.

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

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory may use and disclose your PHI to 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.
- 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 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 write to:

Edmund Waller, MD
Winship Cancer Institute
Emory University
1365 Clifton Road NE
Atlanta, GA 30322

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

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

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

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

Contact Information
Contact Dr. Waller at 404-778-1900 (email ewaller@emory.edu) with questions or concerns involving your clinical procedures, tests, results or visits or Dr. Ahmed (rahmed@emory.edu) at 404-727-4700 with questions or concerns that are non-clinical regarding the basic scope and purpose of the study:

- 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 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/ycewgkke.

One purpose of this research is to collect, store, and use your samples for future research. The lab will not give the results of future use studies to you or this clinic, and the results will not become part of your study record. Your specimens will be protected with the same level of confidentiality as your medical records, described in the Confidentiality section below.

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

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

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

Authority of Legally Authorized Representative or Relationship to Subject

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

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