
Emory University School of Medicine Consent to be a Research Subject

Title: Granulocyte-Macrophage Stimulating Factor (GM-CSF) for Mobilization of Progenitor Cells in Peripheral Arterial Disease: A Phase II Randomized Study

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Sponsor: Emory University School of Medicine

Investigator-Sponsor: Arshed Quyyumi, M.D.

Study-Supporter: National Institutes of Health

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 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.** 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.

- 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
- Feel free to take home an unsigned copy of this form and take your time to think about it and talk it over with family or friends

If you agree to join this research study, you will receive a copy of this consent form with your signature and the date, to keep. 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.

Purpose

The purpose of this study is to evaluate whether a drug called GM-CSF (granulocyte-macrophage colony stimulating factor or Sargramostim) improves symptoms and blood vessel function in people who have pain in their legs while walking because of blockages in the arteries of their legs from peripheral arterial disease (PAD). You should already have had an angiogram (X-ray dye test) of the leg arteries showing the blockage and have symptoms related to it such as pain, aching, cramps, or fatigue in the muscles of the leg when you walk, that gets better when you rest.

Background: People who have blockages in the arteries of their legs have reduced blood flow to the muscles of their legs – especially with exercise, which causes the pain, aching, cramping or tiredness in the muscles of the legs when they walk. Some individuals are able to naturally grow new blood vessels in an attempt to form bypasses around the blockages, so that ultimately they are getting blood to the muscles of the legs – even with exercise. Often, however, these new blood vessels are inadequate in their ability to supply sufficient blood.

We now believe that stem cells made in our bone marrow contribute to the making of these new blood vessels when blockages develop. Specific types of stem cells called progenitor cells are thought to be mainly responsible for the growth of new blood vessels and repair of damaged ones.

Substances like GM-CSF stimulate the bone marrow to release stem cells. We will use one of the most commonly used drugs called GM-CSF to study if it can safely be given by injections under the skin in patients with your condition to stimulate new blood vessel growth and relieve symptoms. You will receive GM-CSF or placebo (an injection of sterile salt water) three times a week for four weeks. In an earlier study in 30 patients with PAD, we found GM-CSF given for 2 weeks was well tolerated and not associated with serious side effects. There was some improvement in exercise capacity of the treated subjects. We are now doing a larger study to see if a longer duration of treatment over 4 weeks will help improve symptoms.

Currently, GM-CSF is approved for use in the following situations: 1. in cancer patients receiving chemotherapy; 2. in normal individuals to stimulate their bone marrow to release stem cells for donation, and 3. in patients who have had bone marrow transplants. It is not approved for use in patients with your condition and is therefore considered experimental.

In addition, we are studying whether tests of blood vessel function and stem cell levels help to predict which patients with PAD will develop complications from cardiovascular disease. Accordingly, if you agree to participate in this study, a member of our staff will contact you by telephone at 6 months, 1 year, 2 years, and 3 years after enrollment in the study to ask about your overall health.

Procedures: We will ask you to fill out questionnaires, do blood tests, walk on the treadmill, and if you meet the selection requirements, have measurements of blood flow in the arm and leg. We are seeking to enroll 188 patients. The study will take 24 weeks to complete. During this period, we request that you not change the medicines you are taking unless there is an emergency.

Schedule of Study Visits**Visit 1A**

Test	Time for Test
Discuss & Sign Consent Form	45 minutes
History and Physical	30 minutes
Treadmill Test #1	20 minutes
Blood Work	10 minutes
Treadmill Test #2	20 minutes
Arm Blood Flow	45 minutes
ABI before and after exercise	35 minutes
Questionnaires	20 minutes

Total visit time: 3 ½ - 5 hours

**Visit 1B
(pre-treatment)**

Test	Time for Test
Mini Physical Exam	10 minutes
Treadmill Test with VO2 max	20 minutes
MRI	60 minutes
Nerve conduction studies	20 minutes

Total visit time: 3 ½ hours – 4 hours

**Visits 2, 3, 4, 5, 6
(Weeks 1 through 4)**

Test	Time for Test
Mini Physical Exam (Visits 3 and 5 only)	10 minutes
Blood Work	10 minutes
Questionnaire (Side effects)	10 minutes

Total visit time: 20 – 30 minutes

**Visit 7
(Week 12)**

Test	Time for Test
Physical Exam	30 minutes
Blood Work	10 minutes
Treadmill Test with VO2 max	30 minutes
MRI	60 minutes
Nerve conduction studies	20 minutes
ABI before exercise	10 minutes
ABI after exercise	10 minutes
Arm Blood Flow	45 minutes
Questionnaires	30 minutes

Total visit time: 3 ½ -4 hours

**Visit 8
(Week 24)**

Test	Time for Test
Physical Exam	30 minutes
Blood Work	10 minutes
Treadmill Test with VO2 max	30 minutes
Nerve conduction studies	20 minutes
ABI before exercise	10 minutes
ABI after exercise	10 minutes
Arm Blood Flow	45 minutes
Questionnaires	30 minutes

Total visit time: 2 ½ -3 hours

The study will be performed in the Clinical Interaction Unit (CIN) on the first floor of Emory University Hospital. During the study, you will meet several people including physicians, research nurses, and the ultrasound technician. They are all familiar with the study and will be able to answer any questions that you might have.

You must not drink caffeine-containing beverages for at least 4 hours before each study visit and you must also follow the instructions you will be given regarding the medications that you are taking. We will do a physical exam initially and at 2, 3, 4, 5, 12, weeks. This will take about 30 minutes. A brief exam lasting 10 minutes will also be done at week 24. Blood tests will be done at each visit. During some visits approximately 3 tablespoonfuls of blood will be taken with a small needle placed into a vein in your arm. During visits 2, 4, and 6 smaller volumes (2 tablespoons will be taken. We will measure your blood count and other routine tests as well as research tests that measure progenitor cells, inflammatory markers, growth factors, markers of immunity, and DNA. The DNA (genetic material) in your blood sample will be isolated and stored for future studies. Permanent cells may be created. Once DNA is isolated, it can be duplicated indefinitely for future research. Blood will also be stored for future testing, even if you do not meet the selection requirements to participate in the full study. During the first 3 weeks we encourage you to walk three times a day until you get your usual symptoms in your leg(s).

Treadmill Test

If you have not been on a treadmill before, the first treadmill test will serve to familiarize you with the test. Following this, you will have another treadmill tests within two weeks before starting the study. If there is a large difference in your performance in the two tests, we will do a third test. If there continues to be a large difference, we will not include you in the study. You should have no food or drink other than water with your regular medications for 4 hours before you come for the treadmill test.

Your ability to exercise can be measured using equipment that records your heart rate, blood pressure, and respiration. ECG electrodes are attached to your chest (the area may be shaved if necessary), and a blood pressure cuff is placed on your arm, . A clip is placed on your nose to prevent air from leaking through the nostrils. You are given supporting headgear to keep the mouthpiece in place during the test. You insert the mouthpiece between your teeth and make sure your lips form a tight seal (loose-fitting dentures may have to be removed). After two or three minutes, the speed and incline on the treadmill is increased. You will be asked to inform us when discomfort first occurs in your leg and also when you want to stop. The ECG recording is performed continuously during the test, and your blood pressure and the amount of oxygen in your blood are monitored. Measurements taken during the test include heart rate, breathing rate, oxygen uptake by the lungs and the concentration of oxygen and carbon dioxide in the air you breathe out (only on visits 1B, 7 and 8). The test will take about thirty minutes.

Before and after each treadmill test, we will measure the pulses in your feet called the ABI test and oxygen in the bloodstream with an electrode attached to the leg. The ABI is done by taking blood pressure in each arm and in each leg. It is a routine and painless procedure. Each ABI measurement will take about ten minutes.

Leg Magnetic Resonance Imaging (MRI)

At the beginning and again at the end of the study, you may also have the blood flow to your lower legs measured with and MRI scan. For this test, you will enter a large room where the MRI scanner is located. This scanner uses a very strong magnet to take pictures of your legs and blood vessels. You will be asked to remove all jewelry and other metal-containing objects due to the magnet. You will then be placed on a narrow table that will slide into the MRI scanner. The tube is about 6 feet long and 25 inches wide. You will occasionally hear loud noises as the scanner takes pictures. You will be offered earplugs to wear while you are being scanned to decrease how loud the noise seems to you. You will be asked to lie still during the scan for about 60 minutes. An MRI causes no pain, and the magnet causes no known bad effects to your body. You will be able to talk to the people carrying out the scan at any time. After the resting pictures are taken you will be asked to exercise while lying down and the pictures will be repeated. We will not give you detailed results of the tests in the study as they are for research purposes only.

Nerve conduction studies

Nerve conduction studies (NCSs) will be performed to determine how well your nerves are working and whether you have neuropathy (sickness of the nerves). NCS involves the application of a small electric current to the nerve and recording the response from another point along the course of the nerve or from the muscle connected to the nerve that has been stimulated. The shocks are initially quite soft, but the intensity is gradually increased in order to elicit the best possible response from the nerve being stimulated.

1. You will be asked to bare your arm, leg, and foot (this may require that you put on a hospital gown) and lie down on your side on an examining table.
2. The skin temperature of your hand and foot will be measured. Depending on the temperature of your skin, a warm water bath or heating lamp may be used to warm your hand and foot.
3. Small surface electrodes (sticky pads with wire attached) will be attached to your ankle and then over your wrist to record the responses of your nerves.
4. The electrodes are attached to a computer that will send a small amount of electric current into your hand and leg. The nerves in the hand and leg will be stimulated with a very small amount of electric current. Each nerve will be tested separately, and each nerve may be stimulated several times (possibly as much as 15 to 20 times) to ensure an adequate measure of nerve response.
5. If you are having any difficulty or discomfort, the electrical stimulation can be slowed down or stopped immediately.
6. This entire procedure should take no more than 20 minutes and may take even less.

Arm blood flow

At the beginning and again at 12 and 24 weeks, we will measure the blood flow in your arm with ultrasound. The measurement requires a blood pressure cuff to be inflated so that it feels very tight for 5 minutes. It will then let down. You will be asked to lie still during the test. Immediately after doing this, you will receive one nitroglycerin tablet that will dissolve under your tongue, and have repeat measurements made of the blood vessel in your arm. This test will take about 45 minutes. Uncommonly, nitroglycerin can cause temporary low blood pressure. You will be monitored to make sure that your blood pressure is adequate during and after the study.

Leg Transcutaneous Oxygen Tension Measurements

At the beginning of the study, and at 12 and 24 weeks, we will measure the oxygen content in the tissues of your leg with an oxygen monitor. The measurement requires that a warm electrode be placed on the side of your leg. This electrode is connected to a machine that tells us the oxygen level in the tissues of your leg. This test will be done before, during and after the treadmill test.

Questionnaires

At the beginning of the study and visit 7 and 8 you will be asked to fill out two questionnaires regarding your health. They will take 15 to 30 minutes to complete. We will also ask you to complete a questionnaire regarding any side effects you may be experiencing from the treatment you are receiving. You will be asked to do this at each visit. This will take 5 to 10 minutes to complete.

Study Drugs

GM-CSF injections, as stated above, will be used in this study. We will study whether this drug will stimulate your bone marrow to produce more stem/progenitor cells and send them into your bloodstream that will help grow new blood vessels in your leg(s) and relieve your symptoms. The dose of this medication will be 500 micrograms per injection. We will randomly assign you to treatment with GM-CSF or placebo injections (salt water) rather than make a conscious decision about which treatment to give you. It is kind of like "drawing straws". This will help assure that both

known and unknown factors that may affect the results of the study are evenly distributed within each group. You will not be told which group you are in or if you are receiving GM-CSF or placebo.

The drug or placebo will be given by injection under the skin with a small needle in your upper arm, thigh or belly. At visit 1B you will be taught to give yourself the injections. If you do not want to give yourself the injections, a family member can be taught to give your injections. If you choose, you may come to Emory and the study nurse will give each of the injections. You will receive a one-week supply of study drug or placebo at Visits 1B, 2, 3, and 4.

We request that you walk every day at least three times so that you develop symptoms of pain or tightness in your legs during the first 4 weeks of the study while you receive treatment.

Risks and Discomforts

There may be side effects from the study drug that are not known at this time. Your condition may not get better, and it may even get worse, as a result of your being in this study. The most common risks and discomforts expected in this study are listed below.

Risks

Drug: GM-CSF (Sargramostim)

When given for two weeks, GM-CSF has been shown to be safe in patients being treated for a variety of cancers, receiving bone marrow transplants, for low blood counts, and in healthy people donating their blood for bone marrow transplant. It also appears to have been well tolerated in a small number of patients with blocked heart arteries.

The following is a list of side effects of GM-CSF:

Patients receiving GM-CSF have experienced fever; chills; nausea; vomiting; diarrhea; fatigue; weakness; headache; decreased appetite; blood clotting; rapid or irregular heartbeat or other heart problems; feeling of faintness; facial flushing; pain in the bones, muscles, chest, abdomen, or joints; local reaction at the site of injection; rashes; and kidney and liver dysfunction. Increases in certain white blood cells (eosinophilia) or other blood component abnormalities may occur.

There have been infrequent reports of fluid accumulation or worsening of pre-existing fluid accumulation in the extremities, in the lungs, and around the heart which may result in breathing problems or heart failure. Rarely, patients have developed acute allergic reactions. There have also been reports of low blood pressure, a low level of oxygen in the blood, transient loss of consciousness, and difficulty in breathing after the first injection of GM-CSF. These signs may or may not recur with additional injections of GM-CSF. Patients with prior heart, lung, kidney, or liver problems may have worsening of their symptoms following administration of GM-CSF. There may be other side effects that could occur.

Pregnant or nursing women and women of childbearing potential and fertile men not using an effective method of birth control are not permitted to participate in this study because the effects of the study drug on fertility or the risks of the study drug to an unborn or newborn child are unknown. If you are a woman who could become pregnant, you will agree to notify your physician immediately if

you suspect or know you are pregnant while on the study. If you are still receiving study drug, you will be withdrawn from the study.

Additionally, due to the investigational nature of this study, there may be risks associated with the study drug that are currently unknown.

Blood tests or administration of drug by injection under the skin may cause local pain, bleeding, bruising, and rarely, infection.

Exercise

The study is designed to minimize the risks to you. Patients who are exercised on a treadmill can get a musculoskeletal injury (like a sprained ankle) and rarely, can have a cardiovascular complication. The initial screening is done to make sure this risk is as small as possible. There is a 1 in 10,000 risk of heart attack, blackout, or death. The exercise tests will always be supervised by a physician.

Arm and leg blood flow

Inflating the blood pressure cuffs may cause numbness and tingling but this will last only a few minutes. Nitroglycerin is a short acting medication that can cause people to have a small drop in their blood pressure. However, the most frequent complaint from patients who are given nitroglycerin is a headache. The medication wears off within minutes and your blood pressure will be monitored throughout. The headache usually resolves on its own, but if it does not, will respond to Tylenol. There are no other risks with the procedure.

Nerve Conduction Studies

The only risk associated with NCS is a repeated, temporary, mild discomfort that occurs with electrical stimulation of nerves, similar to "hitting the funny bone".

Blood tests

There may be slight discomfort from the needle as it enters the skin and a small bruise may occur. This will resolve in a few days. There are no long term side effects. If during the routine tests we discover any abnormalities, we will inform you and your physician. The research tests are not hazardous and at present do not alter the way you are treated by your physicians. Due to the research nature of this study there may be other risks that are currently unknown. For instance, in the future it may be possible to link genetic factors to medical problems that could possibly influence insurability and employability, either for yourself or for your immediate family. To prevent this from being a problem for you in the future, your blood samples and research results will be labeled with a study ID number and not your name. Therefore, there will be no direct linkage between your blood sample and your name. However, this code will allow researchers to link your clinical information with your blood sample, without knowing your name.

As with any test or procedure, there may be risks or side effects that occur that are unexpected.

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 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 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. You and the study doctor should agree on a method of birth control to use throughout the study.

If you will be taking the study drug home, keep it out of the reach of children or anyone else who may not be able to read or understand the label. Do not let anyone else take the study drug besides you.

Follow up

We would like your permission to contact you regarding your condition in the future. We would like to contact all participants who sign a consent form, even if you do not qualify for participation in the study due to the selection requirements. This follow-up will likely consist of a questionnaire administered over the phone by a research staff member, or will be mailed to you with a stamped return envelope. If you would not like to be contacted in the future for follow-up questioning, please inform the research staff.

New Information

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.

Benefits

This study is not designed to benefit you directly. Your peripheral arterial disease (PAD) may improve while you are in this study but it may not, and it may even get worse. This study is designed to learn more about the usefulness of GM-CSF in PAD and its results may be used to help other patients in the future.

Payment for Participation

To cover your expenses, you will receive a total of \$250 for taking part in the study. You will receive \$50 at the Screening visit (visit 1A) and at Week 24. You will receive \$25 per visit for visit 1B, weeks 1, 2, 3, 4, and 8. If the study doctor recommends that you withdraw from the study for health reasons, you will be paid the full \$250. If you withdraw on your own, you will receive compensation only for the time you participated.

Other Treatment Outside this Study

If you decide not to enter this study, there is care available to you outside of research that is described below. The study doctor will discuss these with you. You do not have to be in this study to be treated for peripheral arterial disease.

Standard of Care/Alternatives to Study Participation

Patients with PAD (blockages in the arteries) can be treated in a variety of accepted ways. There are also several widely accepted ways to measure their response to treatment. In patients with PAD who do not have symptoms, i.e. who do not, especially with exercise, have pain, aching, cramping or fatigue in the muscles of the legs, their PAD is usually managed with observation and treatment of the risk factors that cause the blockages to get worse. This would include treatment of high cholesterol levels and smoking cessation. In patients who have symptoms, i.e. pain, aching, cramping or fatigue in the muscles of the legs with exercise, they can be treated with the following, usually in combination: aspirin or Plavix (a "super aspirin"), exercise, and smoking cessation. Cilostazol and pentoxifylline in some but not all studies have been shown to reduce symptoms. Angioplasty is a procedure that involves putting a balloon catheter into the artery, inflating the balloon that allows the blockage to be opened and more blood to flow to the legs. In the short term, angioplasty works. Finally, patients can undergo bypass surgery where the blood is routed around the blockage in the artery to restore blood flow to the leg, but not all patients are candidates for an operation. The above mentioned treatments for PAD are considered the standard of care. If you have not discussed these treatments with your physician, you should do so before agreeing to participate in this study, as one or more of these approved treatments may also be suitable for you.

The use of medications proposed in this study to promote the development of new blood vessels is not an accepted treatment for PAD. There are some early studies that lead us to believe that it will work, but we do not know that for sure. That is why we are doing this study.

The tests we are doing to evaluate the effects of the experimental medication on formation of new blood vessels are standard tests used by both doctors who are treating patients with PAD to see if their treatment is working and by doctors who are doing experiments in patients with PAD to try and find better treatments. These tests are not experimental; rather they are the standard of care. These tests include: exercise treadmill test, ABI, calf blood flow, arm blood flow, foot transcutaneous oxygen tension measurements, and questionnaires.

Confidentiality

Certain offices and people other than the researchers may look at your medical charts and study records. Government agencies, Emory employees overseeing proper study conduct may look at your study records. Study sponsors may also look at your study records. These offices include Food and Drug Administration, the Office for Human Research Protections, the sponsor(s), the Emory Institutional Review Board, the Emory Office of Research Compliance and the Office for Clinical Research. Emory will keep any research records we produce private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

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 **not** be created for you just because you are in this study.

To better protect the confidential nature of your research information, the results from these study tests and procedures should **not** be included in any medical record you have.

These research results will be kept by the researchers only in a research record. The researchers will take steps to make sure that these results are **not** placed in your Emory Healthcare medical record. The results will **not** be made available to any other healthcare providers who may be giving you treatment. It will be up to you to let your healthcare providers know that you are in a research study.

Other useful study results such as your blood count **will be placed your Emory Healthcare medical record**. Anyone who has access to your medical record will be able to have access to all results that are placed there. Emory Healthcare may use these results in caring for you. 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 done at other places. So these results would not be placed in your Emory Healthcare medical record. And 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. So if you decide to be in this study, it is up to you to let them know.

Some tests and procedures that may be done during this study will be reviewed **only for research purposes, not for your healthcare purposes**. These results will not be reviewed to make decisions about your personal health or treatment. The specific tests or procedures, if any, would be reviewed only for research purposes include: treadmill testing, exercise capacity testing, leg MRI, blood tests, forearm ultrasound, ABI.

To better protect the confidential nature of your information, a copy of your signed Informed Consent form and signed HIPAA Patient Authorization form should **not** be included in your medical record. If you have an Emory Healthcare medical record, copies of these forms will not be placed there.

For safety reasons, however, some basic information will be placed in your Emory medical record:

- The fact that you are enrolled in a research study and you gave informed consent to join it
- Contact information for the researcher who is in charge of the study
- A description of health care that would be called for in case of medical problems you may have arising from the study; and
- A description of when and how health care providers may get research information, upon request, that they may need to give you medical care.

We encourage you to let your health care provider know if you decide to take part in this study. That way they can have extra information that can help them to make decisions about your health care.

In Case of Injury

If you get ill or injured from being in this study, Emory and/or Grady Health System would give/arrange for you to have urgent health care. Here we explain who would pay for this health care:

Would Emory Pay? Emory and/or Grady Health System has not set aside any funds to pay for urgent health care. Also, Emory and/or Grady Health System has not set aside any funds to pay you if you become ill or injured from being in this study. The only exception to this policy is if it is proven that the negligence of an Emory and/or Grady employee directly caused your injury or illness. "Negligence" means the failure to follow a standard duty of care.

Would the Study Sponsor Pay? The Study Sponsor has not set aside any funds to pay for urgent health care. Also the Study Sponsor has not set aside any funds to pay you if you become ill or injured from being in this study.

If you believe you have been injured by this research, you should contact Dr. Quyyumi (Phone 404-727-3655.)

Costs

Extra Costs to You if You Take Part in this Study:

If you take part in this study, you will not have to pay extra costs for the study drug, procedures or follow-up. The study is funded by the National Institutes of Health.

Items that the Sponsor will Provide Free-of-Charge: The following items and services will be provided to you free of charge by the study Sponsor:

GM-CSF, exercise treadmill tests, forearm blood flow, blood testing, MRI, nerve conduction studies

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 drug. If you leave the study before the final planned study visit, the study doctor may ask you to have some of the final steps done.

The study doctor and sponsor also have the right to take stop your participation in this study without your consent if:

- they believe it is in your best interest;
- You were to object to any future changes that may be made in the study plan;
- or for any other reason.

Questions

Contact Dr. Arshed Quyyumi at 404-727-3655:

- 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

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797.

If you are a patient receiving care from the Grady Health System, and you have a question about your rights, you may contact Dr. Curtis Lewis, Senior Vice President for Medical Affairs at (404) 616-4261

Consent

I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

By signing this consent form, I have not given up any of my legal rights.

Name of Subject

Signature of Subject

Date

Signature of Legally Authorized Representative (when applicable)

Date

Authority of Legally Authorized Representative or Relationship to Subject
(when applicable)

Signature of Person Conducting Informed Consent Discussion

Date