Informed Consent Form

WINSHIP4933-19: Improved Staging of Lobular Breast Cancer with Novel Amino Acid Metabolic and Tumor Neovasculature Receptor Imaging

NCT Number: NCT04750473

Document IRB Approval Date: 9/21/2020

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 20 people who are being studied, at any Emory facility including Saint Joseph's and Johns Creek's Hospitals.

Why is this study being done?

This study is being done to better detect metastasis in a type of breast cancer (called Invasive Lobular breast cancer or ILC). You are being asked to be in this research study because you have been diagnosed with this type of breast cancer (ILC).

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for the duration of treatment (two study visits) and a follow-up period. The researchers will ask you to do the following: undergo two imaging tests called PET-CT scans performed on individual days. Additionally, during one of the two study visits, approximately 20 mL of blood will be taken for research purposes. All of these procedures will be paid for by the study. Based on the results of your scans, you might undergo one-two tissue biopsies or additional imaging tests after discussion with your oncologist. These biopsies or additional imaging tests will not be paid by the study but will be billed to your insurance.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. The information we get from this study may help us to better detect metastasis in real-life practice and may help us to better treat patients with ILC in the future.

What are the risks or discomforts I should know about before making a decision?

The study will take time. The procedure that is being tested may not work any better than regular care, and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include common risks associated with radiation exposure, allergic or other reactions to radiotracers

(used for the imaging tests), biopsy associated risk (ex. bleeding or infection, 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. You do not have to be in this study to be treated for your cancer.

Costs

You WILL NOT have to pay for the study procedures, such as the two experimental PET-CT scans and the special blood test. All other tests such as possible biopsies will be billed to your insurance.

What Should I Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts are research and which are standard care that you would have even if you did not join the study. Take time to consider this and talk about it with your family and friends.

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

Title: Phase 1 Feasibility Trial: Improved staging of lobular breast cancer with novel amino acid metabolic and tumor neovasculature receptor imaging.

IRB #: STUDY00000675

Principal Investigator: David Schuster, MD

Sponsor: National Institutes of Health (NIH)

Investigator-Sponsor: David Schuster, MD

Study-Supporter: Blue Earth Diagnostics Ltd. Telix Pharmaceuticals Ltd.

Introduction
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:
- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You can search this Web site at any time.

What is the purpose of this study?
The purpose of this study is to see if studying body images from PET scans (PET scan with either fluciclovine or GaPSMA) will be useful in helping your doctor better understand and classify your breast cancer. Doctors expect also to better identify any possible distant spread of the tumor (metastasis) which could impact your care.
PET (Positron emission tomography) imaging or PET scan, is a type of nuclear medicine imaging. Nuclear medicine imaging uses small amounts of radioactive material (called radiotracers) to diagnose, evaluate variety of diseases.
In this study two different radiotracers will be used: fluciclovine and GaPSMA. Radiotracers are injected into the vein. After the substance is injected, PET scans are done. The images show color where the radiotracer emits radiation, the PET scanner can pick up the radiation being released to create a picture from within the body.

Fluciclovine was developed here at Emory and has been approved by the FDA (Food and Drug Administration) for routine use in people with recurrent prostate cancer. Fluciclovine is not yet FDA approved for breast cancer. This study may help in getting fluciclovine approved to be used in people diagnosed with breast cancer.

68Ga-PSMA is also a PET radiotracer and is still under investigation. It is currently not approved by the FDA (Food and Drug Administration). We expect it will become FDA approved in the next 1-2 years. PSMA is currently produced at Emory Center for Systems Imaging for an ongoing prostate cancer trial.

We plan to enroll a total of 20 patients in this study.

What will I be asked to do?

You will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor. After you **sign this informed consent form** and before starting the study procedures

- The study team will review your health history
- The study team will review your diagnosis of breast cancer (ILC)
- The study team will review prior conventional imaging (mammography, breast US, breast MRI, FDG PET-CT).
- You will undergo two PET-CT scans (using the radiotracers: Fluciclovine and Ga-68 PSMA) on two separate days.
- A 20 ml (4 teaspoons) of blood will be drawn for research tests, typically on day of the first PET scan.

VISIT PROCEDURES

On the day of the Fluciclovine PET scan,

- You will be required to fast (except for water) for 4 hours before the scan.
- You will be given oral contrast to drink; this allows the abdominal organs to be better visible.
- Images will be acquired approximately 4 min post intravenous injection of fluciclovine.

On the day of the PSMA PET scan,

- Fasting is not required for this exam.
- You will be given oral contrast to drink; this allows the abdominal organs to be better visible
- Imaging will be performed approximately 60 minutes post intravenous injection of PSMA.

- **PET scan (Fluciclovine or GaPSMA PET scan)**:
  The scans will be performed at the Emory Center for PET located in the Nuclear Medicine Department on the first floor of the Emory University Hospital or in the Winship Cancer Institute or Emory-affiliated site. The entire procedure will last about 2 hours, including set up and preparation time.
  Before the **fluciclovine PET scan**, you will be asked to not eat or drink for four hours. This will allow the fluciclovine radiotracer to get in your blood system easier. You will meet with a technologist and doctor who are approved to work on this study, and who will be performing the procedures on you. An intravenous tube called a catheter (IV) will be inserted in a vein in your arm to be used later for injection of the radiotracer (fluciclovine or GaPSMA). One hour prior to scanning, you will drink 1 bottle (500 ml) of oral contrast over 1 hour to allow for better pictures of your abdomen and pelvic structures.

- After placement of the IV **for fluciclovine**, you will lay down on a mobile couch that will slide into the scanner. The scanner has the appearance of a large box containing a large round opening into which your body is placed. An initial "transmission" scans lasting about 1 minute in which the couch will move. This transmission scan is similar to a CAT scan and is used to correct for the effect of your body on the PET scan in order to produce better images. This transmission scan is done on the PET scanner and will look no different to you. You will then receive an injection through the IV tube of the radiotracer fluciclovine. A set of PET scans (pictures) will be done over thirty minutes. The couch will move. When finished, the IV will be removed. You will be able to leave the PET Center after this time.

- After placement of the IV **for GaPSMA**, you will be brought into a quiet room and you will then receive an injection through the IV tube of the radiotracer GaPSMA. You will wait in the quiet room for approximately an hour. After this, you will then lay down on a mobile couch that will slide into the scanner. The scanner has the appearance of a large box containing a large round opening into which your body is placed. An initial "transmission" scans lasting about 1 minute in which the couch will move. This transmission scan is similar to a CAT scan and is used to correct for the effect of your body on the PET scan in order to produce better images. This transmission scan is done on the PET scanner and will look no different to you. A set of PET scans (pictures) will be done over thirty minutes. The couch will move. When finished, the IV will be removed. You will be able to leave the PET Center after this time.

After the two PET exams, abnormal findings on the PET scan will be carefully correlated with already obtained CT or MRI to determine if a previously unsuspected abnormality can be identified which may need to be biopsied. Before biopsy a discussion between you and your provider (who will also be the co-investigator of this study) will take place on the benefits versus risks to definitively determine if a metastasis is present which could affect therapy. Biopsy will be undertaken in the least invasive manner as a standard of care. Biopsy will be performed for the distant, most accessible lesion. A second biopsy may be needed in some cases to best determine if the cancer has spread elsewhere.

All subsequent therapy for breast cancer will be standard of care.

- About a week after each scan our nurse will call you to make sure you are doing well.
- We will continue to follow your case up to 5 years by looking at your medical record and talking with your oncologist to best determine if the experimental PET scans were correct about your particular situation. No additional study specific visits are required.

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 still be used for this study.

What are the possible risks and discomforts?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, researchers don't know all the side effects that may happen. Side effects may be mild or very serious. In some cases, side effects can be serious, long lasting, or may never go away. In addition, some of the side effects may be life threatening and, in rare instances, may cause death. You will receive radiation from diagnostic procedures to evaluate your condition. The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. However, the additional risk of radiation-induced cancer from these diagnostic procedures is low compared to other risks from the medical therapy.

The procedures described in this study may cause all, some, or none of the side effects listed here. These are common procedures that are considered relatively safe. Previously unknown side effects can also occur. If new side effects are reported, you will be told. It is also important that you give us accurate and complete information about your past medical history.

You may also find it uncomfortable to lie motionless during the approximately 30 minutes necessary to complete the scan. If you believe you cannot lie still for 30 minutes, you should not participate in this study.

Although the risk is small, it is possible to develop an allergic reaction to the fluciclovine or GaPSMA. This can result in hives, rash, itching and difficulty breathing which may require emergency medical treatment. There have been no previous instances of allergic reaction. In prior studies with both radiotracers, the risk of adverse events which can be attributed to the radiotracer is extremely low, and of minimal medical impact such as burning at IV site or a strange taste in the mouth.

Fluciclovine: In previous studies with many hundreds of patients, there were no problems reported. However, it is important to report any unusual side effects that you are having such as itching, skin rashes, fever, chills, nausea, dizziness, and vomiting. Please also see the risks of radiation exposure below.

GaPSMA: In previous studies, there were no problems reported. However, it is important to report any unusual side effects that you are having such as itching, skin rashes, fever, chills, nausea, dizziness, and vomiting. Please also see the risks of radiation exposure below.

Contrast Agents: Your CT, PET-CT or MRI procedure may require the use of a contrast agent, which is a substance that helps the radiologist interpret the images. The contrast agent will be injected by either a hand-held needle or a machine that does the injection. Most contrast agents stay in your body for only a few minutes, but some of them can remain for a few hours or days without any harm to you or anyone near you. Contrast agents are generally quite safe, but any injection involves some risks. The injection could harm a nerve, artery or vein, or cause infection. The contrast agent could affect kidney function or cause an allergic reaction, though these outcomes are rare. The contrast agent could also leak from your veins a little, causing swelling and discomfort, which is typically treated with ice packs.

Reproductive Risks: To protect against possible side effects of the study radiotracer, 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 will be given a pregnancy test within 24 hours of each PET scan. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately.

Intravenous Catheter: One tube will be placed in your vein (arm or hand.) It is called an intravenous catheter or IV. It is placed under sterile conditions by piercing the skin and underlying vein with a needle, over which is threaded the IV catheter and then the needle is withdrawn. When the catheter is placed or removed, the site of insertion may become sore or bruised. Rarely, bleeding or infection can occur at this site; however, this is highly unlikely. A small gauze pad or bandage is placed over the site after the IV catheter is removed. This is similar to what happens when one donates blood.

Vein Puncture
You could experience bruising, pain, and rarely infection at the vein puncture site for the blood draw. Care will be taken to minimize these risks.

Risks of Biopsies: Common side effects of a biopsy are a small amount of bleeding at the time of the procedure, pain at the biopsy site, bruising, swelling and scarring. Rarely, an infection can occur.

Radiation Risks:
You will be exposed to radiation from nuclear medicine. These procedures are not necessary for your medical care and will occur because you participate in this study. The estimated radiation dose that you will receive is equal to or less than the annual radiation exposure limit allowed for persons who are occupationally exposed to radiation (for example, x-ray technologist, radiologist). The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. The risk for radiation-induced cancer from this study is minimal.

New Findings
It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?
Taking part in this research study may not benefit you personally. We do know that the information from this study will help researchers learn more how to better identify metastatic disease in ILC which will impact appropriate staging. The study results may be used to help others in the future.

Will I be compensated for my time and effort?
You will get $ 50 for each completed study visit, to compensate you for your time and effort. If you do not finish the study, we will compensate you for the visits you have completed. You will get $ 100 total, if you complete all study visits.

You may 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?
If you decide not to enter this study, there is care available to you outside of this research study. You will receive standard of care imaging which includes CT, MRI or FDG PET-CT. Your doctor will decide about these different imaging tests as which ones to order, depending upon the stage and treatment planning for your cancer. The study doctor will discuss these with you. You do not have to be in this study to be treated for your breast cancer.

How will you protect my private information that you collect in this study?
Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order.

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), including your de-identified genetic information, may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data [and specimens] from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your de-identified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

We will use your sample and data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial cell line, a medical or genetic test, a drug, or other commercial product) that could be sold by a company. You will not receive money from the sale of any such product.

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Medical Record

If you have been an Emory and Saint Joseph's Hospital patient before, then you already have an Emory and Saint Joseph's Hospital medical record. If you have never been an Emory and Saint Joseph's Hospital patient, you do not have one. An Emory and Saint Joseph's Hospital medical record will be made for you if an Emory and Saint Joseph's Hospital provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory and Saint Joseph's Hospital medical record you have now or any time during the study.

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

The results of some study tests and procedures will be used only for research purposes and will not be placed in your medical record. For this study, those items include:

- Fluciclovine PET scan or GaPSMA PET scan results (besides basic documentation of scan completion).
- Research blood samples

Copies of the consent form/HIPAA authorization that you sign will be put in your Emory and Saint Joseph's Hospital medical record you have now or any time during the study.

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

In Case of Injury

OPTION 1: If you believe you have become ill or injured from this research, you should contact Dr. Schuster's research nurse (study coordinator) Bridget Fielder at [redacted]. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory and Saint Joseph's will help you to get medical treatment. Neither Emory, Saint Joseph's nor the sponsor have set aside money to pay for this medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

For Emory and Saint Joseph's, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory or Saint Joseph's employee. "Negligence" is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

Costs

OPTION 2: The sponsor will pay for certain items or services associated with the study.
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 and Saint Joseph's Hospital will submit claims to your insurance for items and services that the sponsor does not cover. Emory and Saint Joseph's Hospital will send in only those claims for items and services that it reasonably believes your insurance will pay and that the 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 Saint Joseph's Hospital 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 and Saint Joseph's Hospital will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps and procedures done.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI that Will be Used/Disclosed:

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

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

Purposes for Which Your PHI Will be Used/Disclosed:

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

Use and Disclosure of Your Information That is Required by Law:

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:

By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form. If you do not sign this form, you may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:

The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory and Saint Joseph's Hospital may use and disclose your PHI to get payment for study related treatment and to run normal business operations.

- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- Dr. Schuster 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.
- Your PHI may be used by Blue Earth Diagnostics Ltd. or Telix Pharmaceuticals Ltd. for regulatory filings with the Food and Drug Administration.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory and Saint Joseph's Hospital offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Compliance Offices, and the Emory Office for Clinical Research.
    - Other researchers and centers that are a part of this study.
    - Government agencies that regulate the research including: [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: Bridget Fielder, RN, MSN, BSEd
1365 Clifton Road, Clinic A, AT 600
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. Schuster's research nurse (study coordinator) Bridget Fielder at [redacted]

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at [redacted]

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

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**