Early Substitution of Subcutaneous Abatacept for Belatacept as Costimulation Blockade to Minimize Calcineurin Inhibitors (CNI) Exposure After Kidney Transplantation

NCT05975450

Date: July 11, 2024

STUDY00005929

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. This document contains information that will help you decide whether to take part 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 18 people who are being studied, at Emory.

Before making your decision:

- Please read this form carefully or have it read to you.
- The study physician or a member of the study staff will explain this research study to you.
- Please ask questions about any of the information you do not understand before you decide whether to participate.

You can take a copy of this consent form, to keep. 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.

Why is this study being done?

You are being asked to be in this research study because you have received a kidney transplant from a living or deceased donor and are currently receiving monthly infusions of belatacept.

After a kidney transplant, patients take drugs called anti-rejection drugs (immunosuppressives) to prevent their body from rejecting the new kidney. At present it is not possible to have a successful transplant without these drugs. These drugs make it possible for a person who receives the transplant to accept the “foreign” kidney. Most patients who get a transplant need to take anti-rejection medications for the rest of their lives, or for as long as the kidney continues to work.

You’re currently being treated with monthly belatacept infusions. Researchers are looking to learn whether abatacept is as good as belatacept in preventing rejection, whether there are other benefits or harms associated with abatacept treatment, and possibly allow greater flexibility on your travel and time since abatacept is self-administered at home.

This study is being done to answer the question:

- Are weekly abatacept injections under the skin a safe and effective substitute for monthly belatacept intravenous (IV) infusions.
- How well the kidney functions after switching from belatacept to abatacept.

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 you have to do if you choose to join this study?
If you qualify and choose to join the study, you will participate for up to 12 study visits until you reach your 12th month post-transplant anniversary. The researchers will ask you to do the following: blood tests, questionnaires at certain study visits, weekly abatacept injections under the skin up through your 12th month post kidney transplant, and a kidney biopsy at your 12th month post kidney transplant. The abatacept injections will be paid for by the study.

Many of these visits will align with your standard post-transplant clinical care visits.

How is this study going to help you?
It is unknown whether participation in this research study will result in worse, better, or unchanged outcome as compared with routine medical care.

What are the risks or discomforts you should know about before deciding?
Treatment and procedures in this research study may involve risks that are not possible to predict. As with any experimental procedure, there may be adverse events or side effects that are currently unknown and certain of these unknown risks could be permanent, severe, or life-threatening. You will be informed of any new risks that may be identified during the study. Please ask your study doctor or the research staff to explain any procedures or risks that you do not understand. Risks for this study include:

- Injection site reactions, infections
- Allergic reactions, headache, sore throat, nausea
- Possible allograft rejection
- Loss of privacy

- Breach of confidentiality

You can find a full list of expected risks, their frequency and severity in the section titled "What are the possible risks and discomforts?"

Alternatives to Joining This Study

The alternative to joining this study is to continue receiving your monthly belatacept IV infusions.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

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.

There is more information in the "Costs" section further below.

What Should You 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 such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to think about this and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: Early substitution of subcutaneous abatacept for belatacept as costimulation blockade to minimize CNI exposure after kidney transplantation. RTB-016

IRB #: STUDY0005929

Principal Investigator: [redacted], MD

Investigator-Sponsor: [redacted], MD

Study-Supporter: National Institute of Allergy and Infectious Diseases (NIAID)

Introduction

You are being asked to be in a medical research study. This form tells you what you need to think about before you choose if you want to join the study. **It is your choice. If you choose to join, you can change your mind later and leave the study.** Your choice will not cause you to lose any medical benefits. If you choose not to join this study, your doctor will still treat you.

Before you decide:

- Read this form or have it read to you
- Listen to the study doctor or study staff explain the study to you
- Ask questions about anything that is not clear

You will get a copy of this form. Take your time to think about joining the study. You may wish to discuss it with family or friends. Do not sign this form if you still have questions or something does not 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 website will not include information that can identify you. At most the website will include a summary of the results. You can search this website at any time.

What is the purpose of this study?

The purpose of this study is to learn whether abatacept is as good as belatacept in preventing rejection, and whether there are other benefits or harms associated with abatacept treatment.

Abatacept is an immunosuppressant which is not yet approved by the FDA for use in kidney transplant recipients. This drug works in a very similar way to belatacept. Abatacept is approved for use in rheumatoid arthritis. This drug is administered by an injection under the skin (subcutaneous or SC) each week. When you enroll in this study, your monthly belatacept infusions will be stopped and you will begin taking abatacept. The research team will teach you how to give yourself the weekly abatacept injections.

Study Components

This study is sponsored by the principal investigator, Dr. [redacted]. It is funded by the National Institutes of Allergy and Infectious Diseases (NIAID) and National Institutes of Health (NIH). The research team will purchase the abatacept for the duration of the study period. Up to 18 recipients will be enrolled at Emory University Hospital.

What will you be asked to do?

Screening

Screening is when the study team collects information about your medical history, laboratory test results and medications to see if you qualify and that it is safe for you to participate in the study. The research team will discuss the study with you and answer all your questions. If you agree to participate, you will sign this consent form. Additional details about study procedures are listed below.

Study Procedures

The research team will obtain some blood samples for this study. You will be asked to complete some questionnaires. A urine pregnancy test will be done on all female patients of childbearing potential. The results of screening tests may determine that you are not eligible to participate in the study. If it is decided that you are not eligible, the study doctor will discuss this with you.

At the first study visit after you have completed the screening visit, your monthly belatacept IV infusions will be discontinued. The day you are scheduled to receive your first dose of abatacept, you will be taught how to give yourself the weekly injections under your skin. You will continue to take your other immunosuppressants as ordered: MMF, tacrolimus, prednisone.

Medical Record Review

We will review your medical records and record the following information in the study database:

- Lab test results;
- age, race and gender,
- medical history before entering this study and during the study,
- medications you are taking,
- transplant rejection history,
- types of infections you may have had or currently have.

Blood Draws

Since blood draws are necessary after kidney transplantation, additional research blood sample collection has been scheduled to coincide with standard of care testing whenever possible. You may also have non-standard of care blood draws for research purposes.

We will record the results of some of your routine laboratory tests. These tests will be performed during your routine clinic visit. The laboratory tests may include, but not limited to the following which are included in the standard of care for all kidney transplants at Emory:

- Blood chemistry tests (i.e., creatinine, BUN, glucose, sodium, AST, ALT, bilirubin, albumin, calcium, and phosphate);
- CBC with differential tests (i.e., hemoglobin, hematocrit, white blood cell, red blood cell, platelet, neutrophils, lymphocyte, monocyte, eosinophil, basophil, and granulocyte)
- Hemoglobin A1c (measures your average blood sugar over past 2 – 3 months)
- Viral monitoring lab tests cytomegalovirus (CMV) and polyomavirus (BKV)

- Human Leukocyte Antigen Panel Reactive Antibodies (HLA PRA) – It is possible that antibodies may form when your immune system identifies something foreign in your body. We measure this by a test called HLA PRA.
- Donor Specific Antibodies (DSA) – When antibodies form in the immune system as a response to your organ transplant, we call that a donor-specific reaction. We will be looking for antibodies against your kidney donor by performing the lab test called DSA.

In addition to routine blood draws, you will have blood drawn for research tests at the same time as clinical labs, when possible. During your study visits, you will not have more than 37 tablespoons (550mL) of blood drawn for clinical and research tests in an 8-week period. Additionally, up to 75mL (about 5 tablespoons) of urine will be collected for women of childbearing potential at screening visit.

This is a list of some of the research tests that will be performed on the blood that is collected from you:

- Pharmacokinetics (PK) refers to the movement of drugs through the body. We will measure how efficiently your body breaks down abatacept in your body.
- Immunophenotyping – Different types of T cells will be identified and compared in the blood.
- HLA DR/DQ Eplet Score – Antibodies form when the immune system identifies something foreign, such as an organ transplant. We will be looking for antibodies against your kidney donor.
- Gene Expression – Researchers will look at when certain genes are turned on or off when the kidney is working normally, and when there is inflammation or rejection.

How will your study drug be provided?
The study drug that you will take will be dispensed by the pharmacy and delivered to the principal investigator or study coordinator. The principal investigator or health care providers on his/her research team will provide the study drug to you. If you have questions about the study drug, you should ask the principal investigator or study nurse. You may also call the pharmacy at ([redacted] if you have questions about the study drug. The number for the pharmacy is included on your study drug package. Abatacept is provided free of charge by the research study.

Note: The research team for this study includes non-licensed team members who may obtain your consent or help guide you through the study. There are some kinds of questions only licensed clinicians can answer. For example, detailed questions about drug interactions. If you have questions like these, the non-licensed coordinator will ask a licensed study team member to answer your questions.

Abatacept
Abatacept is an anti-rejection medicine. It is currently FDA approved for patients who have rheumatoid arthritis. This study will use it to prevent transplant rejection in people who have received a kidney transplant in the past 2 – 5 months. Transplant rejection happens when the body's immune system senses that the new transplanted kidney is different or foreign and attacks it. This drug is not approved by the FDA for use in kidney transplant recipients.

Abatacept is given as a subcutaneous (through the skin into the fat cells) injection once a week. It is important for you to keep all of your appointments. Take all medicines prescribed by your doctor to prevent infection or transplant rejection. Talk to your doctor if you have any questions about how to take your medicines.
Anti-Rejection Medications
You will continue to take your standard of care immunosuppressive medications mycophenolic acid (MMF), tacrolimus (Prograf) and prednisone as ordered. However, you will no longer need to receive your monthly belatacept infusions.

Kidney Biopsy
If the health of your kidney becomes a concern, your doctor may recommend a "for-cause" unplanned biopsy. At the time of a "for-cause" biopsy, a blood sample of up to 45cc (about 3 tablespoons) will be taken for research as well.

Follow Up
If you choose to take part in this study, your participation will last up to your 12-month post kidney transplant anniversary. You will have up to 12 study visits, depending on the date of your kidney transplant. You may also have extra visits if rejection is suspected.

Pregnancy Testing for Women of Childbearing Potential (WOCP)
It is not known whether abatacept can cause harmful effects to an unborn baby or nursing child. If you are thinking about becoming pregnant, you should not take part in this study. If you are female and can become pregnant, a pregnancy test will be done prior to getting the study drug. You cannot take part in this study if you are currently pregnant or are breastfeeding an infant.

If you participate in this study, you must agree to use FDA approved methods of birth control during the study. You and your study doctor will discuss acceptable methods of birth control. If you should become pregnant while participating in this study, or if you suspect that you have become pregnant, you must contact your study doctor immediately. If you become pregnant during the study you will continue to take part in the study, but you will no longer get any investigational medications. Your doctor will determine the best anti-rejection regimen for you.

Who owns your study data and samples?
If you join this study, you will be donating your samples and data. You will not be paid if your samples or data are used to make a new product. If you leave the study, the data and samples that were already collected may still be used for this study.

What are the possible risks and discomforts?
Treatment and procedures in this research study may involve risks that are not possible to predict. As with any experimental procedure, there may be adverse events or side effects that are currently unknown and certain of these unknown risks could be permanent, severe or life-threatening. You will be informed of any new risks that may be identified during the study. Please ask your study doctor or the research staff to explain any procedures or risks that you do not understand.

Abatacept
More Common (happen in more than 50% of subjects):

- infections (upper respiratory tract infection, nasopharyngitis (an infection that affects your nasal passages and may appear as common cold symptoms: stuffy nose, runny nose and sore throat), sinusitis (an infection in your sinuses and may appear with common cold symptoms and feeling of pressure over sinuses) , urinary tract infection)

- Frequent: (happen in 10 - 20% of studysubjects):
    - nausea
    - headache
    - sore throat

- Occasional: (happen in 1-10% of subjects):
  - -cough
  - - back pain
  - - pain, irritation at site of injection

- Rare (less than 1%)
  - -Hepatitis B reactivation for patient who has had Hepatitis B in the past
  - - Allergic reaction (hives, swollen face, trouble breathing)
  - - New or worsening psoriasis
  - - Certain kinds of cancer

Blood Draws
The risks of drawing blood are pain, bruising, bleeding, infection, redness, swelling at the site of the needle entry, and a small chance of fainting. There is also a very small chance of infection at the needle puncture site.

Biopsy
The risks of a kidney biopsy include bleeding, infection, pain and, very rarely, loss of the transplanted kidney due to hemorrhage (uncontrolled bleeding of the kidney) and bleeding in or around the kidney that may cause a fall in blood pressure and rise in heart rate. In very rare cases, a hole between blood vessels can form, called a fistula. Complications of the biopsy procedure may require a blood transfusion; or very rarely this may require surgery or cause loss of the kidney. Other risks include pain and bleeding at the site of biopsy, infection, discomfort, and bloodstained urine. To lessen these risks, the biopsy procedure will be done using ultrasound guidance. There is a very small chance that a small scar may form.

Infection
It is possible that some part(s) of the immune system might be temporarily weakened and not work normally. This may put you at a higher risk for getting infections.

All anti-rejection drugs used for transplantation suppress the immune system. Patients who take these drugs are more likely to get infections, including serious and life-threatening infections. Your care team and the research team will monitor you closely during the study to detect infections as early as possible. If an infection occurs, it will be treated as needed. If you get an infection while you are in the study, it might not be possible to know if it is the result of the study or of your standard care.

If you are a woman: to protect against possible side effects of the study drug, women who are pregnant, plan to get pregnant in the next 12 months 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.

Study drugs and procedures involved in this research project may involve unexpected risks to your unborn or nursing child. If you are female of childbearing potential, a pregnancy test will be done before you receive study drugs.

If you are female and take part in this study, you must agree to use birth control during the study. You and the study team will discuss acceptable methods of birth control. Female subjects in this study must agree to practice birth control as outlined above.

If you or your partner become pregnant while participating in this study, or if you think that you may be pregnant, you must contact the study team immediately. The study doctor will talk to you about your care or the care of your pregnant partner.

If you are a man: the effect of the study drug on sperm is not known. To protect against possible side effect if you are a man; you should not get a sexual partner pregnant while taking the study drug for 30 days after the last dose. 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.
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.

Researchers may learn something new during the study that may affect your choice to be in the study. If this happens, they will tell you about it. Then you can choose if you want to stay in this study. You may be asked to sign a new form if you choose to stay in the study.

Will you benefit from the study?
If you agree to take part in this study, there may be no direct medical benefit to you. The information learned from this study may someday benefit future kidney transplant recipients. You may benefit by being closely followed for your health status.

Will you be paid for your time and effort?
You will receive no payment for taking part in this study, however you will receive an outpatient parking voucher to cover the cost of parking for each completed outpatient study visit which is only for research purposes.

What are your other options?
If you choose not to join this study, you can get care outside of this study. The study doctor will discuss these with you. You do not have to be in this study to be treated for your condition.

If you choose to join this study, you may not be able to join other research studies. Discuss this with the researchers if you have concerns. You may wish to look on websites such as clinicaltrials.gov and ResearchMatch.org for other research studies you may want to join.

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

Certificate of Confidentiality

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

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

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

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

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

Storing and Sharing your Information

We will store information about you, including your biospecimens, that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Information about you, including your biospecimens may be useful for other research being done by investigators at Emory or elsewhere. We may share information about you, including your biospecimens, linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.

We may also place data in public databases accessible to researchers who agree to maintain data confidentiality, if we remove the study code and make sure the data are anonymized to a level that we believe that it is highly unlikely that anyone could identify you. Despite these measures, we cannot guarantee anonymity of your personal data.

Returning Results to Participants/Incidental Findings

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

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

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.

How is my Genetic Information Protected? What are the Risks?

The Genetic Information Nondiscrimination Act (GINA) is a federal law that generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that GINA does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, and does not apply to employers with less than 15 employees. In addition to GINA, the State of Georgia has laws that prohibit insurers from using genetic testing information for any non-treatment purpose. However, like GINA, this state law protection has exclusions: life insurance policies, disability income policies, accidental death or dismemberment policies, Medicare supplement policies, long-term care insurance policies, credit insurance policies, specified disease policies, hospital indemnity policies, blanket accident and sickness policies, franchise policies issued on an insurance policy written as a part of workers' compensation equivalent coverage, or other similar limited accident and sickness policies.

Storage of Samples and/or Information for Future Use

We are asking your permission to store and share samples and information resulting from the analysis of samples of biological specimens (e.g., blood and tissue) collected during the course of this study to be used in the future for tests that aren't yet planned. These tests may or may not be related to the study of transplantation.

Genetic Testing on Stored Samples

Your stored samples will be used to obtain knowledge about genetic information in relation to kidney transplantation (for example, the rejection process). Genetic tests study an individual's inherited characteristics, found in DNA, which is present in each of the cells of your body. DNA contains information needed to construct and operate the human body. However, your samples could also be used in studies that are not related to transplantation (for example, the immune system as a whole)

Some information about a research specimen will always be linked to it (also see section Genetic Information).

For example, researchers will know the sample is from a kidney transplant recipient. Because of this, allowing for specimens to be stored for future use also means allowing for the linked information to be stored and used when the specimens are needed.

The results of tests performed on stored samples or reports resulting from the analysis of your samples will not be given to you or your doctor and they will not be put in your medical record. They will not identify you and will not affect your routine medical care.

Benefits of Stored Material and Genetic Testing

There is no benefit to you from the storage of samples and information. However, the use of your samples and information may help researchers learn more about your disease or the genetics related to a specific condition. The purpose of storage and sharing data is to make information available for use in health research. Collecting, storing, sharing information and making it available for other studies may help people in the future. Samples will be stored at the Emory University Hospital If you decide to allow storage, your samples and information may be stored for an unknown length of time.

Risks of Stored Material and Genetic Testing

Although your stored research samples will not be sold, the information obtained from the research performed on your samples may in the future lead to the development of commercial products. You will not receive any money from research using your stored samples and information

There may be unknown risks associated with the storage of samples and linked information. For example, if the future research involves genetic testing it is possible that it could be traced back to you because your genes are specific to you. We will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known.

You can change your mind at any time and ask to have your samples destroyed. This request should be made in writing to the study doctor. If you make this request, all remaining stored samples will be destroyed. However, the results of any previous tests using your stored samples will be used. Your decision regarding the storage of samples or the information resulting from the analysis of your samples will not affect your ability to participate in this study. The future use of your samples and information may contribute to learning more about disease or help to study the genetics related to a specific condition.

Medical Record

If you have been an Emory patient before, then you already have an Emory medical record. If you have never been an Emory patient, you do not have one. An Emory medical record will be made for you if an Emory Atlanta 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 medical record you have now or any time during the study.

Emory 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 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 all lab work processed by Emory Transplant Center Biorepository: Immunophenotyping, HLA DR/DQ Epilet Score and Gene Expression.

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

In Case of Injury

If you get ill or injured from this research, contact the person listed in the contact section of this form. Emory will help you get immediate medical care. However, Emory and the Federal Government (including but not limited to the National Institutes of Health), do not have programs to pay for this medical care or compensate you if you are hurt from being in this study.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

You do not give up any legal rights you may have by being in this study, including any right to pursue a claim through the legal system.

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.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the last planned study visit, the researchers may ask you to complete some of the final steps such as lab work or imaging as applicable.

The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study.

These are some reasons why the researchers may take you out of the study:

- The study doctor feels it is not in your best interest to continue in this study.
- You are unable to complete required study treatments and examinations.
- The study is stopped by Emory University Hospital, the Sponsor ([redacted]), or by the Food and Drug Administration (FDA) or other health authorities.

If you are removed from the study, your study doctor will contact you to discuss your future care. The study coordinator or doctor will request that you complete the remaining study follow-up visits and procedures and will explain why those visits and procedures are important.

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 this study.

PHI that Will be Used/Disclosed:

The PHI that we will use or disclose for this 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 disclose your PHI for the conduct and oversight of the research study. We will use and disclose your PHI to provide you with study related treatment and for payment for such treatment. We will also use and disclose your PHI to conduct normal business operations. We may disclose your PHI to 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 disclose 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. For this study, the principal investigator is also the study Sponsor. 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.
- Emory 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 disclose your PHI to other people and groups to help conduct the study or to provide oversight for the study.
- NIAID is the Supporter of the study. The Supporter 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 research team 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 disclosed with that new institution and their oversight offices. PHI will be disclosed 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 HIPAA authorization will expire when this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

[redacted]

At that point, we will not collect any more of your PHI. We may use or disclose the PHI already collected so we 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 PHI to people who are not covered by the Privacy Rules, then your PHI won't be protected by the Privacy Rules. People who do not have to follow the Privacy Rules can use or disclose your PHI to 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 to other people or organizations for purposes besides this study.

Contact Information
If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact Dr. [redacted] or [redacted] pager [redacted] (24 hours).

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at [redacted] or [redacted]

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at https://tinyurl.com/ycewgkke.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. 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**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

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

Making a Decision for Stored Human Subject Material and Genetic Testing

Your decision regarding the storage of samples or the information resulting from the analysis of your samples will not affect your ability to participate in this study.

Please indicate your response below:

I agree to the storage and sharing of samples (blood and/or tissue) for genetic tests not currently planned.

☐ **Yes** ☐ **No**

_____

Initials of Research Subject

I agree to the storage and sharing of samples (blood and/or tissue) and information resulting from the analysis of my samples for other tests not currently planned.

☐ **Yes** ☐ **No**

_____

Initials of Research Subject