Informed Consent Form

TITLE: Perioperative Stress Hyperglycemia in General and Vascular Surgery Patients

NCT NUMBER: NCT04862234

IRB APPROVAL DATE: April 17, 2024

You Are Being Asked to Be in a Research Study

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 245 people who are being studied at Emory and Grady Health System.

Why is this study being done?
This study is being done to understand the blood sugar control of individuals before surgery and to learn about factors that may cause poor blood sugar control in individuals who do not have known diabetes. We also want to compare dulaglutide (diabetes injection medication) and placebo (saline injection) for the prevention of high blood sugar during surgery. You are being asked to be in this research study because the knowledge gained from this study may be used to help others. Research studies are not intended to benefit you directly, though some might.

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 may be in only in the observational part of the study (study visit before surgery and blood tests/glucose monitoring during hospital stay) or also in the medication part of the study if you qualify and consent to it (study visit before surgery, administration of study medication and blood tests/glucose monitoring during hospital stay). The researchers will ask you to do blood tests and a glucose tolerance test at the study visit before surgery. If you join in the study and you qualify for the medication part of the study, you will receive an injection of study medication (dulaglutide) or placebo within 3 days before surgery at your study visit. ALL of these procedures will be paid for by the study.

How is this study going to help you?
If you are in the study, you will be helping the researchers to understand more about the high blood sugars that can happen around the time of surgery. You will also help the researchers to determine if dulaglutide can prevent the development of high blood sugars after surgery.

What are the risks or discomforts I should know about before making a decision?
The study will take time. The drug/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 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
If you decide to not enter this study, there is care available to you outside of this research study. You should know that there are other types of diabetes drugs and insulins available to treat elevated blood sugar in the hospital. The study doctor will discuss these options with you. You do not have to be in this study to be treated for high blood sugars after surgery.

Costs
There are no research costs to you for participating in the study. However, you will still be responsible for your usual ongoing care, including any procedures and/or medications that your regular doctor requires as part of your usual medical care. You will not be charged for any of the research activities. You will be billed for the standard care you receive for the treatment of your condition. You may also have to pay for basic transportation costs. There is more information in the cost section below.

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

Emory University and Grady Health System
Consent to be a Research Subject / HIPAA Authorization

Title: Perioperative Stress Hyperglycemia in General and Vascular Surgery Patients: An Observational and Randomized Controlled Pilot Trial.

IRB #: STUDY00097659

Principal Investigator: Georgia M. Davis, M.D.

Study Supporter: National Institutes of Health/National Institute of Diabetes and Digestive and Kidney Diseases

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 characterize the blood sugar control of individuals before surgery and learn about factors that may lead to poor blood sugar control in individuals who do not have known diabetes. We also want to compare dulaglutide (diabetes injection medication) and placebo (saline injection) for the prevention of high blood glucose (sugar) during surgery. About 30% of patients (3 out of 10) develop high glucose after general surgery. High glucose is linked to a higher risk of hospital complications. High glucose increases the risk of wound infection, kidney failure and death. Patients with high glucose are treated with insulin given through an arm vein or by frequent injections. This study will help us to understand more about high blood sugars that happen around the time of surgery. The study will also determine if dulaglutide can prevent the development of high sugars after surgery. Dulaglutide is a diabetes medication approved by the Food and Drug Administration (FDA) to treat clinic patients with diabetes. Dulaglutide has been shown to improve blood sugar control in patients with diabetes. It is not known if dulaglutide can prevent the development of high blood sugars in the hospital.

We will also measure levels of certain blood tests related to blood sugar metabolism before and after surgery. We will use a Continuous Glucose Monitoring (CGM) medical device that provides constant readings of blood sugars to determine when high blood sugars may happen after surgery. This medical device is approved by the Food and Drug Administration (FDA). You will have the option of authorizing these blood samples to be stored for use in future research that may help understand more about blood sugar control in the hospital.

A total of 245 patients from Grady Memorial Hospital and Emory University Hospitals will participate in this study. A total of 80 of these patients who qualify will be invited to be in the medication part of the study. You will have the option of authorizing your participation in each part of this study.

What will I be asked to do?

Patients with no history of diabetes and with normal blood glucose who are undergoing surgery will be considered for this study. If you are a woman of child bearing age, you will take a pregnancy test one time prior to enrollment in the trial. If you join in the study and you qualify for the medication part of the study, the medication you receive will be decided randomly (by chance or like flipping a coin). You will either be given 1) dulaglutide injection, or 2) placebo (saline) injection within three days before your surgery at your study visit.

The study will be carried out in two parts as follows:

A. Prior to hospital admission (Within 72 hours before surgery) at the clinical research center:

- You will have the Oral glucose tolerance testing (OGTT) blood test to assess how your body controls blood sugar. For this test, we will ask you to fast the night before your visit. You will have your blood drawn in the morning at your study visit in the clinical research center. You will then drink a small amount of high sugar solution and blood samples will be taken several times over a 2-hour period to check how your body handles the high sugar solution.
- You will have the Continuous Glucose Monitoring (CGM) medical device placed on your body to monitor blood sugar values for up to 14 days, even when you are in the hospital for surgery. These glucose values will not be seen or used for clinical care.
- We will collect blood samples to test for certain blood markers. A total of about 60 mL (or 4 tablespoons) of blood will be drawn.
- If the results from your OGTT show your body has difficulty processing the high sugar solution, or if your blood sugar goes high enough to diagnose diabetes, you will be asked if you want to participate in the medication part of this study.
- In the medication part of this study, you will be given an injection of a diabetes medicine called dulaglutide, or placebo saline. The injection you receive is decided randomly. If you agree to be in the medication part of the study, you will be given either dulaglutide or placebo at your study visit in the clinical research center.

B. During hospital stay:

- During and following surgery, blood sugars will be checked by fingerstick testing by the usual hospital protocol. Blood glucose levels will be used to see if insulin is needed to control your blood sugar.
- You will continue to wear your CGM during your surgery and hospital stay, up to a total of 14 days or until you go home. The study team will remove the sensor before you leave the hospital.
- If your fingerstick blood sugar is greater than 180 mg/dl, you will be treated with subcutaneous insulin (under the skin) shots. This is the standard or usual care for patients with diabetes and high blood sugars in the hospital.
- A blood draw will also be done once after surgery to test certain blood markers. You may have additional blood draws if requested by your primary hospital team.

How the CGM (Abbott Freestyle Libre) System Works:

The Abbott Freestyle Libre Pro CGM System includes a sensor and receiver. The sensor is circular and about 1.5 inches in diameter. The sensor probe is a little thicker than a strand of a

human hair and is about a ½ inch long. The needle is slightly thicker and the same length as most insulin syringe needles. The sensor probe is inside the needle. Once the sensor is inserted, the needle is pulled out and the sensor probe stays under your skin for up to 14 days. The sensor continuously measures your blood sugar levels. The sensor collects and stores blood sugar information.

If your sensor is displaced or removed before a medical procedure or at any point in time before the end of 14 days, please ask the research staff or nurse to remove and replace the sensor if you have:

- Discomfort or
- Are going for magnetic resonance imaging (MRI), computed tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. The FreeStyle Libre sensor hasn't been tested in those situations. The magnetic fields and heat could damage the components of the sensor, which may cause it to not function properly.

How will my medicine be provided?

The medicine that you will take will be dispensed by the pharmacy and delivered to the principal investigator or study team member. The principal investigator or health care providers on his/her research team will provide the medicine to you. If you have questions about the medicine, you should ask the principal investigator or study nurse. You may also call the pharmacy if you have questions about the medicine. The number for the pharmacy is included on your medicine package.

Who owns my study information and samples?

If you join this study, you will be donating your samples and study information. You will not be given any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study.

What are the possible risks and discomforts?

There may be side effects from the study drug or procedures that are not known at this time. The most common risks and discomforts expected in this study are:

Oral Glucose Tolerance Test: The risks for this test are similar to that of drawing blood. This includes pain and discomfort from placing the tubes in your arm. You may experience bruising, lightheadedness, fainting and on rare occasions, an infection. Occasionally, after drinking the Glucola (the high sugar solution), some people may experience nausea or stomach discomfort. This usually lasts for a short time and goes away.

Hypoglycemia (low blood sugar): Low blood sugar (less than 70 mg/dl) can occur in about 20% (20 patients out of one hundred) of insulin treated patients in the hospital. Dulaglutide and placebo are unlikely to cause low blood sugars. However, the combination of dulaglutide and insulin may cause more low blood sugars than insulin alone. Symptoms of low blood glucose include sweating, nervousness, confusion, agitation, sleepiness and even coma (loss of awareness). If it occurs, low sugar will be managed by a standard protocol, including decreasing the amount of insulin and by the use of dextrose (sugar) solution.

Hyperglycemia (high blood sugar): High blood glucose levels (greater than 300 mg/dl) can occur in 10-20% of patients (10 to 20 patients out of one hundred) in the hospital. It is possible that the combination of dulaglutide may cause more high blood sugars than insulin. Symptoms of high blood sugar include increased thirst, dry mouth, urinating more, blurred vision, dry skin, weakness, sleepiness and confusion. If not treated, high blood sugars can even lead to serious illness, blacking out or death. During the study, if your blood sugar becomes too high, you will receive extra doses of insulin.

Dulaglutide side effects: Dulaglutide may cause certain side effects in some people. These possible side effects include: diarrhea or loose stools (8.9%), nausea (12.4%), vomiting (6%), abdominal pain (6.5%), decreased appetite (4.9%), indigestion (4.1%), and fatigue (4.2%). In people who have kidney problems, diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration) which may cause kidney problems to get worse.

Risks of Wearing the CGM System

When the sensor is inserted you should expect to feel a feeling like an insulin injection. After insertion, you may feel some tenderness, but you should not feel any large amount of pain.

Pain, redness, swelling, minor infection, and minor bleeding at the sensor insertion site are possible risks with use of the device. In very rare cases an infection might spread to other parts of the body. Significant or serious health risks with the study device are not expected.

Redness may occur where the adhesive pads are placed. This will occur in most research participants and will clear up no more than a week after removal. You may develop an allergic reaction to one or more parts of the sensor and transmitter. This is like allergies that occur due to hospital tape or jewelry. Allergic reactions will usually be mild and require only a skin cream to make them better. Major allergic reactions are rare. If you have an allergic reaction you should notify the study researcher or study staff.

On rare occasion, the sensor may cause skin to blister or peel. If this happens you should notify the study staff as soon as possible.

There is a chance that the sensor or needle may break. This is not expected to occur; but, if it does, you should talk with your Study Clinician about what to do. Usually, if there is no sign of infection or irritation and you cannot see the sensor above the skin, it is not recommended to remove it.

The radio waves that the study device puts out will not hurt you and you will not be aware of them.

Shot (Injection) Site and Allergic Reactions: Shot site reactions with insulin include redness, pain, itching, hives and swelling. Regularly changing of the place where insulin is given may help to reduce or prevent these reactions. Most minor reactions resolve in a few days to a few weeks. Generalized insulin allergy is rare and may cause skin rash, shortness of breath, fast heart beat, sweating and a drop in blood pressure. Skin irritation, pain or a small amount of bleeding may occur in relation to the CGM device or adhesives.

Blood Draws: Phlebotomy. Risks associated with blood draws are low and include small amounts of pain, possible bruising, swelling, redness, and rarely an infection at the site or fainting.

The less common risks and discomforts expected in this study are:
Dulaglutide has also been reported to cause allergic reactions (itching, swelling of the skin and difficulty breathing).

Pancreatitis or inflammation (irritation) of the pancreas is a possible complication of the study drug, dulaglutide. Symptoms of pancreatitis include vomiting and persistent, bad abdominal pain.

Rare but possible risks include:

Possible thyroid tumors, including cancer. It is not known if dulaglutide causes thyroid tumors or a type of thyroid cancer called medullary thyroid carcinoma in people. Possible symptoms of thyroid cancer include a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath.

If you are a woman: to protect against possible side effects of the study drug, women who are pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not yet known. If you are a woman of childbearing ability, you and the study doctor must agree on a method of birth control to use throughout the study. Insulin glargine and dulaglutide are not approved for use during pregnancy. Their effects on an unborn child are unknown.

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.

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?

This study is not designed to benefit you directly. This study will determine if dulaglutide (a diabetes injection) can prevent the development of high blood glucose in the hospital. The study results may be used to help other patients having general surgery in the future.

Will I be compensated for my time and effort?

You will get $50.00 for completion of the study visit at the clinical research center. You will receive an additional $25.00 when you leave the hospital if you completed the observational part of the study only, or an additional $50.00 if you completed the medication part of study.

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 should know that there are other types of diabetes drugs and insulins available at Emory and Grady Hospitals to treat elevated blood sugar in the hospital. The study doctor will discuss these with you. You do not have to be in this study to be treated for high blood sugars after surgery.

Taking part in this study, however, may make you unable to participate in some other research studies, if they exclude people who have taken certain treatments. You should discuss this with the researchers if you have concerns. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

How will you protect my private information that you collect in this study?

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

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study

information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

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

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

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

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

Storing and Sharing your Information

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

If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used. These samples may be kept indefinitely and used for future studies involving to test for

other abnormalities such as how your body controls glucose. We may also use the samples collected in this study for future studies without another consent. If you want us to destroy your samples, you will need to send this request in a letter to:

Dr. Georgia Davis
Address: [redacted]

Medical Record

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

Emory and Grady Health System may create study information about you that can help with your care. This may include the results of study tests or procedures. These study results may be put in your Emory and Grady Health System 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:

Tests and procedures done at non-Emory and Grady Health System places may not become part of your Emory and Grady Health System medical record. 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 being in the study, Emory and Grady Health System will help you to get medical treatment. Emory and Grady Health System and Principal Investigator have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an

Emory and Grady Health System or sponsor employee. “Negligence” is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Georgia Davis at telephone number [redacted] You should also let any health care provider who treats you know that you are in a research study.

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.

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 main study.

Main Study

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:

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

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

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

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study

or receive research-related treatment. 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 Grady Health System 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.
- The National Institutes of Health is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory and Grady Health System 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 Grady Research Oversight Committee, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Food and Drug Administration, Office for Human Research Protections (OHRP).
    - National Institutes of Health (NIH).
    - 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 Dr. Georgia Davis at: [redacted]

At that point, the researchers would not collect any more of your PHI. But they may use specimens 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 main 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. Georgia Davis 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, or concerns about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.

- if you have complaints about the research or an issue you rather discuss with someone outside the research team.

You may also let the IRB know about your experience as a research participant through our Research Participant Survey at **https://tinyurl.com/ycewgkke.**

If you are a patient receiving care from the Grady Health System and have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.

Consent and Authorization

Consent and HIPAA Authorization for optional medication part of Main Study:

If I qualify, I agree to participate in the medication part of the Main Study:

☐ **Yes** ☐ **No** **(check one box only)**

_____Initials

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study, and any optional studies you initialed above. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

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

_____ _____

Signature of Legally Authorized Representative **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**