Informed Consent Form

TITLE: Metabolic Phenotyping During Stress Hyperglycemia in Cardiac Surgery Patients

NCT NUMBER: NCT03743025

IRB APPROVAL DATE: June 21, 2023

You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

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

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

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., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
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: Metabolic Phenotyping During Stress Hyperglycemia in Cardiac Surgery Patients
Ancillary protocol: Use Of Continuous Glucose Monitoring Technology to Characterize Stress Hyperglycemia in Cardiac Surgery Patients

Principal Investigator: Francisco Pasquel, MD, MPH
Assistant Professor of Medicine
Department of Medicine/Endocrinology
Emory University School of Medicine

Co- Investigator: **Georgia M. Davis, MD**
Assistant Professor of Medicine
Department of Medicine/Endocrinology
Emory University School of Medicine

Co- Investigator: **Michael Halkos, MD, MSc**
Associate Professor of Surgery,
Division of Cardiothoracic Surgery, Department of Surgery,
Emory University School of Medicine

Co- Investigator: **Guillermo Umpierrez, MD, CDE**
Professor of Medicine
Department of Medicine/Endocrinology
Emory University School of Medicine

Study Supporter: *NIH National Institute of General Medical Sciences*

Study Supporter to Ancillary Protocol: *DexCom, INC.*

Introduction

We are asking you to be in a medical research study. This form will 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 compare dulaglutide (diabetes injection medication) and placebo (saline injection) for the prevention of high blood glucose (sugar) during surgery and to find out what are the causes of high blood sugars after cardiac (heart) surgery. About 60% of patients (6 out of 10) develop high sugar levels after heart surgery. High sugar is related to an increased risk of hospital complications. High sugar increases the risk of wound infection, kidney failure and death. Patients with high sugar are treated with insulin given through an arm vein or by frequent insulin injections under the skin. This study will determine if dulaglutide can prevent the development of high sugars after heart surgery. Dulaglutide is a diabetes injection approved by the Food and Drug Administration (FDA) to treat patients with diabetes. Dulaglutide has been shown effective in improving glucose control in patients with diabetes in the hospital. It is not known; however, if dulaglutide can prevent the development of high blood sugars in the hospital in patients at high risk.

We will also measure levels of certain blood tests related to blood sugar metabolism and use a continuous glucose (sugar) monitoring (CGM) device to look at the characteristics of high blood sugar in a high-risk population (patients undergoing CABG surgery), including its timing, duration, severity.

A total of 150 subjects from Grady Memorial Hospital, Emory University Hospital at Midtown, and Emory University Hospital will participate in this study. We will analyze the samples collected from patients participating in the intervention trial (Placebo group) in an observational study. We will follow you for the total length of your hospital (inpatient) stay and up to thirty (30) days after you leave the hospital.

A) Clinical trial: If you are older than 40 years and have a body mass index (BMI) of 25 or higher we would like to invite you to participate in an intervention study aiming at improving sugar levels during surgery (the intervention includes a single dose of dulaglutide or placebo).*

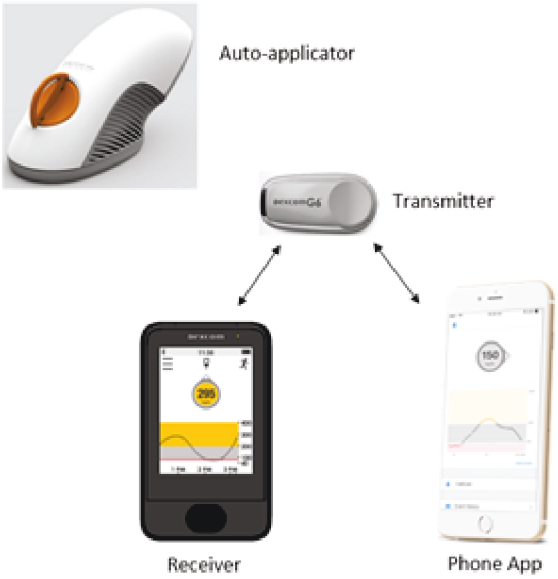
B) Observational study: If you are younger than 40 years and have a BMI less than 25 we would like to invite you to participate in an observational study (we will only monitor glucose levels continuously (CGM) and will collect blood samples)

**Note*: You may also choose to participate in the observational study only.

For both options:

Blood samples in either option will be taken as described below:
Baseline samples before your heart surgery and at two (2), twenty-four (24), seventy-two (72) to ninety six (96) hours after your surgery, and about thirty (30) days after your heart surgery. This will help understand what can cause high blood sugars after heart surgery.
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.

Continuous Glucose Monitoring (CGM):
The Dexcom G6 Pro System (Figure 1) includes a transmitter, sensor, receiver and mobile app. The transmitter is about the size of a thumbprint. The sensor probe is 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 10 days. The sensor continuously measures your blood sugar levels. The transmitter snaps onto the sensor pod and collects and stores blood sugar information. A receiver will not be used in this study.



What will I be asked to do?

Patients with no history of diabetes and with normal blood glucose (sugar) who are scheduled to have heart surgery will be considered as candidates in this study.

1) You can choose to participate in the intervention part (we will give you study medication as described below), we will place one (1) CGM in your belly before surgery and one on your arrival to the intensive care unit (ICU) after heart surgery) and blood samples will be taken.

   If you are a woman who is able to get pregnant, you will receive a pregnancy test one time prior to enrollment in the trial.
   The type of treatment you receive while in the hospital will be decided randomly (by chance or like flipping a coin).

   You will receive a single dose of either 1) dulaglutide injection, or 2) placebo (saline) injection up to three days before your surgery. This is a blinded study (you will not know if you received dulaglutide or placebo).

2) You can choose to be in the observation part only, in this option we will place one (1) CGM in your belly before surgery and one once you arrive to ICU after heart surgery and collect blood samples only.

Study (both options):

The study will be carried out as follows:

- We will place a Dexcom G6 device in your abdomen (belly) before your heart surgery and another Dexcom G6 on the opposite side of your belly (after you arrive to ICU after your heart surgery) with the display-off for up to 10 days or leaving the hospital (whichever comes first), you will continue to have to blood sugar checked by fingersticks by the nursing staff (1-2 hours in the intensive care unit or before each meal and at bedtime once you start eating). Display-off means you and/or nursing staff will not see sugar values on the mobile application. We will continue to manage your high sugars and adjust insulin based on your fingerstick sugar readings. Prior to leaving the hospital, study staff will remove the hospital CGM.

- Before surgery, we will collect 12 ml (about 3 teaspoons) of blood to measure markers of blood sugar control. We will also collect blood samples four (4) times after surgery at 2, 24, and 72-96 hours after your heart surgery and at about 1 month (30 days) after your heart surgery when you return for follow up with your heart surgeon. The cost of all research visits and samples will be covered by the study funds. You may have additional blood draws for your regular care if requested by your primary care team.
- After surgery, if your blood sugar is greater than 140 mg/dl in the intensive care unit (ICU), you will receive insulin to treat this. This is the standard or usual care for patients who develop high sugars after heart surgery in the hospital.
- You will receive intravenous insulin (in one of your arm veins) while you are in the ICU or until you are stable and able to eat. Then, you may receive subcutaneous insulin (under the skin) shots if your blood sugar levels are still high.
- In the ICU, nursing staff will measure your blood sugar levels at the bedside using a glucose meter every one or two hours. Once you are able to eat, we will measure your blood sugar before meals and at bedtime.
- The nurse will prick your finger with a small needle and place a drop of blood on a special strip. This strip measures how much sugar is in your blood.
- We will use your blood sugar levels to determine if you need insulin to control your blood sugar.
- We will call you on day 2 after discharge if you developed nausea during hospitalization.
- We will also conduct a short visit at the time of your post-operative visit with your heart surgeon to draw blood and collect information on any visits to the emergency room or admissions to the hospital since your discharge after your heart surgery.

If you choose to participate in the **OBSERVATIONAL PART ONLY**:
You will not receive any study medication and you will wear CGM devices and blood samples will be collected as described above to study the potential causes of high sugars.

How will my medicine be provided?
If you choose to participate in the intervention part, 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. We will administer the study medication up to three (3) days before your heart surgery. 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. If you are admitted to the hospital: your treating nurse will give the study medication to you.

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

What are the possible risks and discomforts?
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:
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 low blood sugars. 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 those receiving placebo develop higher sugars than those receiving dulaglutide, however, all patients with high blood sugars will receive insulin to control it. 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.

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 heartbeat, sweating and a drop in blood pressure.

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 rare complication associated with 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 an adequate method of birth control or abstinence for the duration of 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.

Risks of Wearing the CGM System
When the sensor is inserted you should expect to feel a feeling like a needle-stick. After insertion, you may feel some tenderness, but you should not feel any large amount 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.

Pregnancy (While Wearing a CGM System)
If you think that you have become pregnant while being in the study, you must contact the study staff immediately. It is unknown whether the use of the study device and the intensive testing performed during the study pose a risk during pregnancy. As a precaution, if you are female and of child-bearing age, you will have to take a pregnancy testing before entering the study. You will not be allowed to be in the study if you are pregnant.

This study may include risks or side effects that are unknown at this moment.

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. Your stress hyperglycemia (high sugars) may improve while you are in this study but it may not, and it may even get worse. This study is designed to learn more about preventing high sugars in patients without diabetes that undergo cardiac surgery. We will use the study results to help others in the future.

Will I be compensated for my time and effort?
You will receive fifty dollars ($50.00) in compensation for your time, trouble, and inconvenience, for your visit before your heart surgery, fifty dollars ($50.00) for wearing the Dexcom G6 CGM; fifty dollars ($50.00) prior to discharge (leaving the hospital) and fifty dollars ($50.00) at the time of your last visit at approximately 1 month after leaving the hospital . If you decide to stop study procedures before it is over, you will receive $10.00 per day to a maximum of $50.00 during the hospital stay. Total compensation if you complete all the visits will be two hundred dollars ($200.00)

What are my other options?
If you decide not to enter this study, there is care available to treat your stress hyperglycemia (high sugars) outside of this research. You should know that there are other types of insulins available at Grady and Emory Hospitals to treat high blood sugars.
The study doctor will discuss these with you. You do not have to be in this study to receive treatment for high blood sugars after cardiac 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 may be shared with the research community at large to advance science and health. Data from this study 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.

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. The results of all 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: metabolomics (blood sugar metabolism samples).

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. 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 being in the study, Emory and Grady Health System will help you get medical treatment. Emory and Grady Health System and the sponsor 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. Francisco Pasquel at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

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. If the study procedures result in any medical complications that would not fall under "injury" as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

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 study in which you may choose to participate.

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. c
- 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. Francisco Pasquel is the Sponsor of the study. DexCom, Inc. is providing funding for the study. The Sponsor and DexCom, Inc. 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 and DexCom, Inc. may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The research team and the Sponsor may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory 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: 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.

Storage of Data/Specimens for Future Research:

PHI That Will be Used/Disclosed for Storage of Data/Specimens:

The PHI that we will use and/or disclose (share) for the optional storage and future research use of your PHI includes: blood samples from before and after surgery.

Purposes for which your PHI will be Used/Disclosed for Optional Study:

We will use and disclose your PHI for the conduct and oversight of the optional storage and future research use of your PHI.

Authorization for This Use of PHI is Required to Participate in Optional Storage of Data/Specimens, but Not in Main Study:
You do not have to authorize the use and disclosure of your PHI. If you do not authorize the use and disclosure of your PHI for the optional storage and future research use, then you may not participate in the option for storage and future research use of your PHI. You can still be in the main research study even if you don't participate in the option for storage and future research use of your PHI.

People Who Will Use/Disclose Your PHI for Optional Storage of Data/Specimens:
The same people and groups who will use and disclose your PHI for the main study will also do so in connection with the optional storage and future research use of your PHI.

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. Francisco Pasquel at:
[redacted]

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.

As long as it is possible to find your samples, the Sponsor will remove your consent to use them for future biomedical research. One way it might not be possible to find your samples is if the code linking them to the Sponsor's records has been destroyed at the study site. Any data that has been created from your samples before your request to leave this sub-study will not be deleted. If you leave, you will not lose any benefits, medical treatment or legal rights.
Leaving the main study does not mean you have also stopped being a part of this sub-study. To stop being a part of this sub-study, you will have to make a separate request.

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 [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 University 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 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.

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 Study/Studies:

Please initial below if you opt to participate in and authorize use and disclosure of your PHI in the optional study/studies previously described:

_____**I agree** to participate in the Intervention, CGM, and Collection & Storage of Blood Samples Study _____**Initials**

_____**I agree** to participate in the observational CGM and **Sample Collection & Storage Only** _____**Initials**

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in the main 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**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

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