Informed Consent Form

IRB00091740

Title: **Glargine U300 Hospital Trial:** A Randomized Controlled Trial Comparing Glargine U300 and Glargine U100 for the Inpatient and Post-Hospital Discharge Management of Medicine and Surgery Patients with Type 2 Diabetes

Principal Investigator: Guillermo Umpierrez, M.D. Professor of Medicine
Emory University School of Medicine
Director, Diabetes and Endocrinology Section
Grady Health System

01/28/2019

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: **Glargine U300 Hospital Trial:** A Randomized Controlled Trial Comparing Glargine U300 and Glargine U100 for the Inpatient and Post-Hospital Discharge Management of Medicine and Surgery Patients with Type 2 Diabetes

Principal Investigator: Guillermo Umpierrez, M.D. Professor of Medicine
Emory University School of Medicine
Director, Diabetes and Endocrinology Section
Grady Health System

Investigator-Sponsor: Guillermo Umpierrez, M.D.

Study-Supporter: Sanofi
This study receives support from Sanofi. Dr. Umpierrez serves as consultant to Sanofi and receives compensation for these services. The terms of this arrangement have been reviewed and approved by Emory University in accordance with its conflict of interest policies.

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 Food and Drug Administration and the European Commission recently approved Glargine U300 insulin for the treatment of patients with diabetes. Glargine U300 is long-acting insulin with duration of action longer than 24 hours. This pilot, randomized clinical trial will compare the efficacy and safety of a basal bolus regimen with glargine U300 and glargine U100 (standard of care) in general medicine and surgery patients with type 2 Diabetes (T2D).

The purpose of this study is to find out if treatment with glargine U300 when compared to glargine U100 will result in similar sugar control in patients with T2D, who are admitted to the hospital and then transition at home, after discharge from the hospital.

We will randomize (assign to treatment 1:1) 300 subjects from 3 medical centers in the United States. One hundred and fifty (150) patients will be consented at Grady Memorial Hospital, Emory University Hospital Midtown, and Emory University Hospital. This study has two parts: Inpatient (hospital stay) and Discharge (outpatient) part. For the inpatient part, we will follow you for the total length of your hospital (inpatient) stay. The discharge or outpatient part of the study will last three (3) months after your discharge from the hospital.

For the optional sub-study:
The purpose of this study is to determine differences in glycemic (sugar) control, frequency of low blood sugar determined by continuous glucose monitoring (CGM) in patients with type 2 diabetes (T2D) treated with basal bolus insulin regimen with glargine U300 or U100 plus glulisine (rapid acting insulin) before meals.
About 100 subjects from 2 medical centers in the United States will wear the continuous glucose monitoring sensor. About fifty (50) patients will be consented at Grady Memorial Hospital, Emory University Hospital Midtown, and Emory University Hospital**.**

What will I be asked to do?
In-Patient (Hospital) Part:
During your hospital stay, you will be assigned by random (like a flip of a coin) to one of the two treatment groups:

1. Group 1: Basal bolus with glargine U300 once daily and glulisine insulin before meals.
2. Group 2: Basal bolus with glargine U100 once daily and glulisine insulin before meals.

The following procedures will happen:

- We will discontinue any oral diabetes medications that you were taking prior to your admission to the hospital.
- Basal (glargine U100 or glargine U300) insulin will be injected under the skin (in the abdomen, thigh or upper arm) once daily, at the same time of the day.
- Glulisine (rapid acting) insulin will be given three (3) times (with each meal) a day under the skin.
- You will also receive additional (supplemental or correction) insulin [rapid acting insulin analogs (glulisine)] if your blood sugar is greater than 140 mg/dL
- Blood sugar monitoring: We will measure your blood sugar levels before each meal and at bedtime (or every 6 hours if you are not eating) using a glucose meter. This is done at bedside by pricking your finger with a small needle and placing a drop of blood on a special strip to measure your blood sugar.

For the optional study - benefits of continuous glucose monitoring (CGM):
If you choose to participate in this optional study, we will ask you to wear a FreeStyle Libre Professional (continuous glucose monitoring) CGM sensor which is FDA-approved as an adjunctive tool in the outpatient settings to complement information obtained from standard self-monitored blood glucose (SMBG) and to aid in detecting hyper- (high blood sugar) and hypoglycemic (low blood sugar) episodes. You will wear this sensor during your hospital stay and/or discharge up to 14 days. This sensor will measure your sugars every 15 minutes and will allow us to review information on numbers of high or low blood sugars compared to the fingersticks done while you admitted to the hospital. You and the research team will not see in 'real time' blood sugar information in the hospital. This information will be analyzed after your discharge from the hospital.

Inpatient Diabetes Education. Prior to discharge, you will receive training:

- Diabetes education if not received within 1 year of admission. All patients will be instructed on insulin administration.
- Blood sugar targets for fasting and premeal BG between 80 to 140 mg/dL.

- Use of glucose meters for home glucose self-monitoring (meters may vary at different institutions).
- Keeping sugar (BG) records and you will get a logbook to record sugar tests results.
- Hypoglycemia (low blood glucose) recognition and management.

Outpatient-Discharge Part

- We will follow your diabetes control once you have been discharged from the hospital if your HbA1C level (a test that tells the average blood sugar during the previous 3 months) is 7.5% or higher.
- Your treatment at discharge will depend on your HbA1C level.
- Your participation in the Discharge Protocol will last about 3 months.
- Once you complete all study visits at 3months, we will ask you to continue your diabetes care with your primary care physician.

The Discharge Part will be carried out as follows:

We will ask you to monitor your blood sugar. Blood sugar levels will be measured at home by finger stick before meals two or three times per day. This is the standard care for patients after leaving the hospital. Blood glucose levels will be used to tell how you respond to treatment.

We will ask that if you have any blood sugar less than 70 mg/dL, to write it down in a diary along with how you treated it. Please call the site or your health care provider if you have very low blood sugar, and you asked for the assistance of another person.

Follow-up Care-Discharge Part:

- After discharge, a member of the diabetes research team will contact you via telephone every 2 weeks to assess response to therapy. In addition, we will ask you to attend an outpatient clinic visit at 1 and 3 months after hospital discharge. An optional telephone call or clinic visit may be done at one week following discharge to ensure that you are taking the medication(s) and have sufficient supplies.
- We will provide the insulin (glargine U300 or glargine U100) to you. Any oral anti-diabetic medications are standard of care; therefore, we will not provide these medications after discharge.
- At discharge, you will receive a one-month supply of insulin (glargine U300 or glargine U100). We will not provide testing supplies or insulin syringes (this is standard of care for patients with diabetes).
- We will ask you to attend an outpatient clinic visit within one month after hospital discharge. During this visit, you will receive a 2-month supply of insulin (glargine U300 or glargine U100). We will not provide testing supplies or insulin syringes (this is standard of care for patients with diabetes. We will ask you to return to the research center 2 months later (3 months after discharge visit).
- A licensed physician (fellow or study physician) will provide recommendations on how to adjust insulin after each telephone contact and clinic visit.
- We will adjust insulin dose as per your blood sugar test results. You may need to receive less or more insulin if your blood sugar is low or high. This is the standard or usual care for patients with diabetes.
- You should continue your diabetes care with your primary care provider once you complete the study (3 months after your hospital discharge).

During each one of your outpatient (discharge part) visits, we will collect and measure the following:
Vital Signs:

- Blood pressure
- Heart rate
- Temperature
- Respiratory rate

Body measurements:

- Body weight
- Height

Laboratories:

- Measurement of your fating blood sugar by finger stick (fasting for at least 8 hours, nothing to eat or to drink, except water),
- Urine pregnancy test if you are a woman of childbearing age,
- Draw about 1 tablespoon of blood from a vein from one of your arms to check your A1C that tells the average blood sugar during the previous 3 months and chemistry (kidney function, electrolytes) test.

How will my medicine be provided?

The medicine that you will take will be dispensed by the pharmacy and delivered to your nurse while you are at the hospital, once you are discharged from the hospital, the pharmacy will deliver the study medication 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.

For the optional study:

We will place the FreeStyle Libre Professional CGM sensor in the back of one of your upper arms. We will clean the area with an alcohol wipe and allow the site to dry. We will place the Sensor Applicator over the prepared area and push down firmly to apply the Sensor to your body. Applying the Sensor may cause some mild bruising or bleeding. If there is bleeding that does not stop, we will remove the Sensor, and apply a new one at a different site.

Who owns my study information and samples?

If you join this study, you will be donating your study information. You will not receive any compensation if your information are used to make a new product. If you withdraw from the study, data that were already collected may be still be used for this study. If you desire, you can request that your study information be destroyed.

What are the possible risks and discomforts?

There may be side effects from the study drug that are not known at this time.

The most common risks and discomforts expected in this study are:

Risks from Blood Draw

The risks of taking blood include pain, a bruise at the point where the blood is taken, redness and swelling of the vein and infection, and a rare risk of dizziness and fainting.

For all medications: Glargine U300, Glargine U100 and glulisine (all are insulin medications):

Low blood sugar (hypoglycemia)

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. 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.

Low blood sugar can be treated by taking some form of sugar, such as juice, honey, or hard candies/jellybeans. If hypoglycemia (low blood sugar) becomes severe, accidents, injuries, coma, or death may occur. To raise blood glucose

(sugar) levels in persons having a severe hypoglycemic episode, glucose (sugar) may need to be given IV. In rare cases, glucagon (a protein that stimulates the liver to increase blood glucose [sugar] levels) may be given.

To know if you have low blood sugar, the site staff will check your blood sugar frequently during the time you are staying at the study site. At home, you will check your own blood sugar. We will review your blood sugar levels at each clinic visit. We will also ask you to write down any blood sugar that is less than 70 mg/dL, any symptoms you had and what did you do to treat the low blood sugar.

Shot (Injection) Site and Allergic Reactions: Shot site reactions with insulin includes 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 allergy is rare and may cause skin rash, shortness of breath, fast heartbeat, sweating and a drop in blood pressure.

The less common risks and discomforts expected in this study are:

Heart failure. Taking certain diabetes pills called thiazolidinediones or "TZDs" with Glargine or Glulisine may cause heart failure in some people. This can happen even if you have never had heart failure or heart problems before. If you already have heart failure, it may get worse while you take TZDs with glargine. Your healthcare provider should monitor you closely while you are taking TZDs with glargine Tell your healthcare provider if you have any new or worse symptoms of heart failure including shortness of breath, tiredness, swelling of your ankles or feet and sudden weight gain. Treatment with TZDs and glargine may need to be adjusted or stopped by your healthcare provider if you have new or worse heart failure.

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. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant women will be taken out of the study.

If you 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.

Will I benefit directly from the study?

This study is not designed to benefit you directly. Your diabetes 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 management of diabetes type 2. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

For participation in the main study, you will receive one hundred dollars ($100.00) prior to discharge (leaving the hospital). If you stop the study before it is over, you will receive $10.00 per day to a maximum of $100.00 during the hospital stay. In addition, for the outpatient portion of the study, you will get seventy-five dollars ($75.00) for each outpatient completed in-person visit. If you do not finish the study, we will compensate you for the visits you have completed. Total compensation for participation in the main study (hospital and discharge studies) is two hundred and fifty dollars ($250.00).

For participation in the ancillary optional sub study you will receive fifty dollars ($50.00) after removal of the sensor. If a participant should stop participation before completion, the payment will be prorated at $10.00 per day to a maximum of $50.00. Total compensation for participation in this ancillary trial will be fifty dollars ($50.00)

What are my other options?

Since this study is not intended to provide any therapeutic or other health-related benefit, your alternative is not to take part in this study. If you choose not to join this study, there is care available to you outside of this research.

There are many medications to treat high blood sugar levels in persons with diabetes. If you have any questions about treatments, please ask your study doctor. You and your doctor can choose what is best for you. You do not have to be in this study get treatment for diabetes.

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?

Emory and Grady Health System will keep any research records that it creates private to the extent that this is required to do so by law. Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

Your health information will be stored and shared with other researchers. The information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may have come from.

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. For example, the results of study tests or procedures. These study results will 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.

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. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Guillermo Umpierrez at telephone number 404-778-1665. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured as the direct result of being in this study, the sponsor will pay the costs for your medical treatment of the illness or injury if it:

(a) is not a medical condition that you had before you started the study;
(b) is not the result of the natural progress of your disease or condition;
(c) is not caused by your failure to follow the study plan; and
(d) is not proven to be directly caused by the negligence of an Emory or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you have Medicare or Medicaid: the sponsor may need information about your identity and your study treatment to give to the government agencies that run these programs.

Your insurance will be billed for any costs of medical treatment for your injury or illness that the sponsor does not pay. Your insurer may be told that you are in a research study. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory and Grady Health System have not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. The only exception to this policy is if it is proved that your injury or illness is directly caused by the negligence of an Emory or sponsor employee.

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 and Grady Health System will submit claims to your insurance for items and services that the sponsor does not cover. Emory and Grady Health System 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 Grady Health System and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory and Grady Health System 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 (inpatient and discharge parts of the hospital) and for the optional benefits of CGM study 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. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is required to Participate:

By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form 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. Umpierrez is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- 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 IRBs, the Grady Research Oversight Committee, the Emory Research and Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: 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.

Optional Sub-Study

There is an optional research Sub-Study related to the main study. It is your choice to join or not to join this sub-study. If you choose to join, you can change your mind later on and leave the study. If you choose not to join the Sub-Study, you may still join in the main study. The FreeStyle Libre Pro CGM will be inserted shortly after giving consent. You will use the sensor during the first 14 days of treatment. No major risks are expected with the use of the CGM sensor. Pain and bleeding with insertion is minimal. Skin irritation may occur in those sensitive to adhesives

Optional Study/Storage of Data:

PHI That Will be Used/Disclosed for Optional Study:

The PHI that we will use and/or disclose (share) for the optional 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 for Optional Study:

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

Authorization for This Use of PHI is Required to Participate in Optional Study, 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 study, then you may not participate in the optional research study. You can still be in the main research study even if you don't participate in the optional study.

People Who Will Use/Disclose Your PHI for Optional Study:

- 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 research study of PHI for future research.

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. Guillermo Umpierrez at:
69 Jesse Hill Jr. Dr. SE, Atlanta, GA 30303

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The Sponsor, and people and companies working with the Sponsor on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

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. Guillermo Umpierrez at 404-778-1665:

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

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

Benefits of CGM:

_____ ***I agree to participate in the benefits of continuous glucose monitoring (CGM).***
Initials

OR

_____ ***I do not agree to participate in in the benefits of continuous glucose monitoring (CGM).***
Initials

TO BE FILLED OUT BY SUBJECT ONLY

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

_____
Name of Subject

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

_____ _____
Signature of Legally Authorized Representative with authority for Research decisions **Date** **Time**

_____
Authority of Legally Authorized Representative or Relationship to Subject

TO BE FILLED OUT BY STUDY TEAM ONLY

_____
Name of Person Conducting Informed Consent Discussion

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