Informed Consent Form

Title: Use of Continuous Glucose Monitoring (CGM) in End-Stage Renal Disease (ESRD) Patients with Type 2 Diabetes

NCT Number: NCT04473430

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You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 100 people who are being studied, at Emory University Hospitals and Grady Hospital, and Davita Dialysis Centers.

Why is this study being done?

This study is being done to answer the question:
What are the benefits of using Continuous Glucose Monitoring (CGM) system versus blood glucose monitoring (BGM) for people with diabetes on hemodialysis and are receiving insulin? We will collect additional information regarding the accuracy and safety of using the CGM system in patients on hemodialysis.

You are being asked to be in this research study because the current system for glucose (blood sugar) monitoring in patients with dialysis is not optimal. This CGM system allows patients to monitor and make treatment decisions to treat diabetes, without the need for performing finger sticks. Hence, the use of CGM will decrease the painful and burdensome task of performing finger sticks several times per day and may prevent low blood glucoses in patients on dialysis.

Do you have to be in the study?

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

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

If you are eligible and want to be part of the study, you will participate for 10 days for the "Observational CGM phase" and for 12-14 weeks for the "Randomized Controlled Trial" (5 study visits). The researchers will ask you to do the following:
Observational CGM Phase: Complete food and medication questionnaire, wear a Dexcom G6 CGM sensor for 10 days, and perform self-monitored blood glucose (sugar) several times per day (as you should be doing for your diabetes treatment), collect blood samples (up to 10 samples) for glucose measurement during one dialysis session (as usually performed by your dialysis team).
Randomized Controlled Trial: After completing the above described phase, we will ask you to wear a real-time Dexcom G6 CGM that provides you with glucose (sugar) measurement during

24-hours for 4 weeks, then continue checking glucoses by fingersticks for 2 weeks (as usual), and then wear a blinded Dexcom G6 CGM that will not provide you with real-time data but will record the glucose measurements for 4 weeks. These devices are currently approved by the FDA for patients with diabetes, but there is no FDA approval or studies on patients on dialysis.

Some of these procedures will be paid by the study. Since performing fingersticks is considered your standard or usual care, this will not be paid by the study.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. Participation in the study may increase your awareness to low blood glucose levels and improve the management of diabetes. The study may help in the management of patients with diabetes on dialysis.

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

The study will take time. The device that is being used may not work any better than regular care and may rarely cause harm by not providing accurate glucose values. 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 risks of the Dexcom G6 CGM **(already FDA-approved for patients with Diabetes, but not approved for patients with diabetes on dialysis**) insertion, some of which include: pain or bleeding with insertion (<10%), infections (<1%), skin irritation from the adhesive (<10%), loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate.

Costs
You WILL NOT have to pay for any of the study procedures, in particular those that are not covered by your medical insurance. Since performing fingersticks is considered your standard or usual care, this will not be part of or paid by the study.

The study team can help you work out how much you might have to pay. There is more information in the cost section below.

What Should I Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to 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: Use of Continuous Glucose Monitoring (CGM) in End-Stage Renal Disease (ESRD) Patients with Type 2 Diabetes

Principal Investigator: Guillermo Umpierrez, MD, FACE

Study Sponsor: National Institute of Health – National Institute of Diabetes and Digestive and Kidney Diseases

Study-Supporter: Dexcom, INC

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 look at the benefits of using Continuous Glucose Monitoring (CGM) system versus blood glucose monitoring (BGM) for people with diabetes on hemodialysis and are receiving insulin. We will collect additional information regarding the accuracy and safety of using the CGM system in patients on hemodialysis. This system allows people to use CGM to monitor and treat diabetes, without performing fingersticks. This study will enroll participants receiving hemodialysis and treated with insulin.

What will I be asked to do?
We are asking you to be in a research study of a medical device that has been cleared by the U.S. Food and Drug Administration (FDA) for diabetes management, but it has not been approved for specific use in patients on dialysis. The study device is Dexcom's G6 Continuous Glucose Monitoring (CGM) system. We will ask you to measure your blood sugar levels with your meter at home, and also to perform several blood (8) sugar measurements one day before dialysis

(at the start of each large meal, 2 hours after each large meal, at bedtime and the last one at the middle of the night). For this specific task, we will provide you a Glucose meter (Nova Stat Strip Xpress 2).
We will also draw blood samples (up to 10 samples) during one dialysis session for glucose measurement. This will be performed by your dialysis team.

How the Dexcom G6 CGM System Works:

The Dexcom System includes a transmitter, sensor, receiver and mobile app. The transmitter is about 1.5 inch x 0.9 inch. The sensor probe is flexible, 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 probe 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.

How the Stat Strip Xpress 2 Glucose meter Works:

As usual, the system includes a glucose meter and glucose test strips. The glucose meter is about 3.9 in x 2.4 in x 0.9 in. The test strips are inserted into the glucose meter to turn on the device. After six (6) seconds, the glucose result will show up on the screen.

Study Procedures:

Study 1. Observational

All patients will wear a CGM for up to 10 days. This sensor will be blinded, meaning the display will show no glucose data. You will need to monitor your diabetes and make treatment adjustments based on your glucose fingersticks as usual. If you qualify, you will be invited to participate in Study 2 after completing this observational study.

Study 2. Randomized Controlled Trial

All patients will wear a CGM for up to 10 days before the randomization visit (initial intervention visit) to obtain baseline glucose (sugars) data, as described above. All patients will participate in both study phases: 1) standard of care or 2) CGM intervention. Patient completing one phase (4 weeks) will continue to a "wash-out" period of no intervention (2 weeks), and then continue/cross to the other phase.

During your nephrology clinic visits or during your visit to the dialysis center, we will randomly (like a flip of coin) assign you to one of the intervention groups:

1. **Standard of Care Group:** Using fingersticks glucose (sugar) measurements up to 4 times per day.
2. We will ask you to wear 1 CGM's sensor (in the current approved insertion site, the abdomen) during the intervention for 4 weeks. This sensor will have the display off. *Display-off* means you and/or nursing staff will not see sugar values on the mobile application.
3. You will make insulin adjustments using your sugar readings from fingersticks and based on guidance provided by the study team.
4. You will continue to have to blood sugar checked by fingersticks for 4 weeks.

   Or

5. **CGM Intervention group:** For 4 weeks, we will ask you to wear a CGM's sensors (in the current approved insertion site, the abdomen). The sensor will display glucose values continuously for 24 hours, with arrows indicating if glucoses are increasing, decreasing or remaining stable.

6. In this group, you will have "real time" notifications and will get alarms if your sugars are getting low (less than 55 mg/dL) within 20 minutes in advance.
7. The study team will provide with training on how to prevent low sugars from happening.
8. The study team will also provide you with guidance on insulin adjustment if glucoses are running high or low.
9. You will adjust your insulin based on the sensor readings, since the sensors does not require fingersticks for calibration.

The research staff will show you how to replace the sensors (each sensor lasts for 10 days).

Please ask the research staff or nurse to remove sensor if you have:

- Discomfort, pain, bleeding or irritation

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 samples or 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.

What are the possible risks and discomforts?

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

Risk from venipuncture: This will be very unlikely, since there will be no need for venipuncture for any study related procedures. We will collect venous blood samples for glucose testing from the dialysis access system, as usually performed. In the rare case, venipuncture is needed, there is some minor discomfort and risk of mild bruising during venipuncture. Standard sterile techniques will be used during phlebotomy; thus, infection is unlikely. Disposable pre-sterilized needles and syringes will be used for all blood drawing in this study; needles and syringes will not be reused. Discomforts associated with venipuncture are rapidly reversible. Approximately 10 mL of blood will be obtained for all the blood measurements proposed.

Risks of Wearing the CGM System

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

Pain, redness, swelling, and minor bleeding at the sensor insertion site (<10%) and minor 1%) are possible risks with use of the device. In very rare cases an infection (rare) might spread to other parts of the body. Significant or serious health risks with the study device are not expected. The device is FDA-approved for use in patients with diabetes since March 2018.

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 (<10%). 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.

Risks of Fingerstick Testing

When taking a fingerstick, your fingers may feel sore and tender. Rotate which finger you take your fingersticks to make it more comfortable for you. This part of your standard or usual care for diabetes.

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 during study visits. 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.

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.

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. We will continue to treat your diabetes based on the fingerstick blood sugar results. This study is designed to learn more about the CGM use during dialysis sessions. The study results may be used to help others in the future. Your glucose control and low glucose events may improve while you are in this study; but it may not, and it may even get worse.

Will I be compensated for my time and effort?
You will receive $50 for each study visit, to compensate you for your time and effort. If you do not want to finish the study, we will compensate you for the study visits you completed ($50 per visit).

You will receive a total of $150 for completing 3 visits in Study 1 (Observational Aim). If you choose to participate in both studies 1 and 2 (observation and intervention trials), you may receive a total of $300 for completing 6 visits in Study 2 (Randomized Controlled Trial Aim- which includes compensation of visits in study 1). If you choose to participate in study 2 only, you will receive up $250 for completing five (5) visits.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. The study doctor will discuss these with you. You do not have to be in this study to be treated for diabetes and/or renal failure.

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, Grady Health System and Davita Dialysis Centers will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory, Davita or Grady Health System 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, Davita or Grady Health System 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), 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.

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

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

Medical Record

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

Tests and procedures done at non-Emory or non- Davita Dialysis centers or non-Grady Health System places may not become part of your Emory or Davita Dialysis centers or 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 , Davita Dialysis centers and Grady Health System will help you get medical treatment. Emory , Davita Dialysis centers 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 , Davita Dialysis centers 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 **DrGuillermo Umpierrez** at telephone number [redacted] You should also let any health care provider who treats you know that you are in a research study.

Costs

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, Davita Dialysis centers and Grady Health System will submit claims to your insurance for items and services that the sponsor does not cover. Emory, Davita Dialysis centers 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, Davita Dialysis centers 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 , Davita Dialysis centers 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 and for any optional studies 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. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study

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

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

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

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory, Davita Dialysis centers 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 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 , Davita Dialysis centers 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 Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Food and Drug Administration and Office for Human Research Protections.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.

- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

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

Dr. **Guillermo Umpierrez**
[redacted]
Atlanta, GA 30303
PH: [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.

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 **Guillermo Umpierrez**, MD, FACE at [redacted]:

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

Contact the Emory Institutional Review Board at [redacted]

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

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 [redacted]

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

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

_____

Name of Subject

_____ _____

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

_____ _____

Signature of Legally Authorized Representative **Date** **Time**

_____

Authority of Legally Authorized Representative or Relationship to Subject

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

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