Cover Page

Official Title: Continuous Glucose Monitoring (CGM) in Kidney-Transplanted Adults

NCT Number: 05352230

Date of document: 09/30/2024

Inclusion of Individuals Across the Lifespan

Individuals 18 years of age and older are eligible to participate in this study. We anticipate the majority of patients will be 45-65 years of age, as this is the average age of end-stage renal disease patients eligible for kidney transplant.

Individuals less than 18 years of age are not approved by the FDA to use the Freestyle Libre continuous glucose monitoring system.

Dr. Zelada is an Endocrinologist that sees patients at the Kidney-Transplant Clinic at the UAB Comprehensive Transplant Institute. He and his study team are well equipped to work with individuals 18 years and older in the inpatient and outpatient clinics associated with the UAB Comprehensive Transplant Institute that are designed to accommodate the adult kidney transplant patient population from pre-op through outpatient recovery.

Inclusion of Women and Minorities

We plan to enroll a total of 30 participants.

Based on UAB Comprehensive Transplant Institute's reporting to the Scientific Registry of Transplant Recipients, 60% of kidney transplant recipients are male. Therefore, we anticipate participants will be 60% male (n=18) and 40% female (n=12). No sex/gender group will be excluded or targeted for enrollment in this study.

Based on UAB Comprehensive Transplant Institute's reporting to the Scientific Registry of Transplant Recipients, we anticipant participants will self-identify their race/ethnicity according to the following percentages: 63% African American (n=19), 32% Caucasian (n=10) and 4% Hispanic/Latino (n=1). However, no racial or ethnic group will be excluded or targeted for enrollment in this study.

Recruitment and Retention Plan

Recruitment:

The proposed pilot study plans to enroll 30 end-stage renal disease patients awaiting kidney transplant at the Kidney-Transplant Clinic that is part of the UAB Comprehensive Transplant Institute.

To facilitate recruitment, our team plans to leverage UAB's electronic medical record system/reporting, as well as routine care plans and coordinators. Specifically, the study team will identify potential participants by querying UAB's electronic medical record. Using that information, the study team will supply patients on the kidney transplant waiting list letters with information about the study. Patients admitted to the hospital to receive a kidney transplant will also be directly contacted about the study.

Retention:

To minimize the burden of study participation, we integrated study activities with routine care plans and coordinators. Planned study activities coincide with standard post-kidney transplant care plans. Kidney transplant coordinators facilitate post-kidney transplant standard of care.

	May					June				July				August					September				October				November					December				January					February				March				April			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52
Administrative																																																					
Clinical Integration of Reseach Project	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x																																						
Staff Hire / Training				x	x	x	x	x	x	x	x																																									
CGM Purchase										x	x	x	x	x	x																																							
Recruitment										x	x	x	x	x	x	x	x	x	x	x																																			
Scientific Aims																																																					
First Arm														x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x																							
Washout																									x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x													
Second Arm																																		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
Data Analysis																																										x	x	x	x	x	x	x	x	x	x	x	x
Goals																																																				
Abstracts/Meetings																																																		x	x	x	x
Manuscripts																																																		x	x	x	x
Grant Applications																																																		x	x	x	x

STUDY TIMELINE

Miscellaneous

Summary | HSCT Post Submission

Inclusion Enrollment Report 1 v1.0

OMB Number: 0925-0770
Expiration Date: 09/30/2024

* 1. Inclusion Enrollment Report Title	Continuous Glucose Monitoring (CGM) in Kidney-Transplanted Adults
* 2. Using an Existing Dataset or Resource	○ Yes ● No
* 3. Enrollment Location Type	● Domestic ○ Foreign
4. Enrollment Country(ies)	UNITED STATES OF AMERICA
5. Enrollment Location(s)	Hospital
6. Comments	

Planned

	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
Racial Categories	Female	Male	Female	Male	
American Indian/Alaska Native	0	0	0	0	0
Asian	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	7	12	0	0	19
White	3	7	0	1	11
More than One Race	0	0	0	0	0
Total	10	19	0	1	30

Cumulative (Actual)

	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
Racial Categories	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	
American Indian/Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0

	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
Racial Categories	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Instructions for Participant Level Data Upload

Participant level data file (CSV):

Download Participant Level Data Template

Protection of Human Subjects

1. Risks to Human Subjects

a. Human Subjects Involvement, Characteristics, and Design

The primary outcome of this study is assessment of the feasibility and acceptance of CGM usage in the post-operative kidney transplant population (e.g. quality-of-life). Secondary outcomes will estimate if CGM usage improves post-operative diabetes management (e.g. time in range). The study is a randomized, open-label, cross-over clinical trial consisting of two study arms where participation will last eight months. A permutated block randomization list, block sizes varying from 2 to 6, will be developed to randomly assign subjects to treatment sequence (CGM followed by glucometers, or glucometers followed by CGM). We plan to enroll 30 post-operative kidney-transplant diabetics.

Inclusion Criteria:

- Age ≥ 18 years
- History of diabetes diagnosis (Type 1, Type 2, or atypical) prior to kidney transplant
- Current treatment for diabetes includes at least one daily injection of long-lasting insulin
- Able to read and understand English
- Able to consent for themselves

Exclusion Criteria:

- Age < 18 years
- History of kidney and/or pancreas transplant
- Has used CGM in the past
- Mental of psychiatric conditions that would preclude continuation in the study
- Unable to read or understand English
- Unable to consent for themselves

b. Study Procedures, Materials and Potential Risks

Study Procedures and Materials:

Eligible participants will engage study staff during regularly scheduled, standard of care, visits. The first (i.e. baseline) visit is one day post-operative surgery. Participants will be randomized to one of two groups. Group 1 participants (n=15) will receive a Freestyle Libre continuous glucose monitor (CGM) that reports glucose levels to participants every 15 minutes for twelve weeks. Group 2 participants (n=15) will receive a glucometer for self-management of their diabetes as per the standard of care for twelve weeks. Halfway through the study (week 12 post-operative surgery), all participants will use a glucometer to manage their diabetes eight weeks, which serves as a washout period. At week 20 post-operative surgery, Group 2 participants will receive a CGM to use for twelve weeks, and Group 1 will continue using a glucometer for twelve weeks. The study will conclude at week 32 post-operative surgery visit.

Participants managing their diabetes with glucometers during the first and last twelve weeks of the study (Groups 2 and 1 respectively) as well as Group 2 during weeks 18-20 of the study will use a Freestyle Libre "Pro" CGM, which collects glucose information in the same manner as the CGM described above but reporting not provided to participants and is accessible to the study team via remote monitoring.

At regularly scheduled post-operative visits on weeks 2, 12, 20 and 32, the study team will request participants to complete two quality-of-life surveys (Diabetes Treatment Satisfaction Questionnaire (DSTQ) and Hypoglycemic Confidence Scale (HCS)) and record glucose readings from the CGM and/or glucometers. Participants' medical records will be leveraged to assess surgical outcomes, diabetes management and related clinical information (e.g. clinical labs, kidney biopsies).

Potential Risks:

Glucose monitoring related pain, discomfort and Infection: Sensor insertion and finger-prick based glucose readings may cause temporary pain, bleeding and/or bruising at the site of insertion. Moderate to severe itching, reddening and/or scaling of the skin, rash and/or bleeding are infrequent risks associated with wearing the sensor. A infrequent risk is sensor breakage, which can require sensor tip extraction via tweezer.

Group Assignment: Participants are assigned to a group by chance, which may prove to be less effective or have more side effects than the other study group or alternatives.

Confidentiality: A breach of confidentiality may impact participants psychologically and could influence insurance and/or employers decisions based on study purpose, participant enrollment or health status. This risk is minimal.

2. Adequacy of Protection Against Risks

a. Informed Consent:

As approved by the UAB IRB, a HIPAA waiver will be utilized for all participants strictly for recruitment and screening purposes. A trained study team member will provide an IRB approved consent form to interested individuals likely meeting the inclusion/exclusion criteria. Such individuals will have access to it for more than 24 hours before the study team member reviews the consent form with the individual and answers any questions. The study personnel will explain the potential risks and benefits. Study team members will clarify that participants may refuse to answer any study questions without jeopardizing their continued enrollment in the study and that election to enroll or not enroll will not influence their care or future interactions with the institution. The signed informed consent form will be retained by the study team and a copy will be made available to the participant.

b. Protections Against Risk:

Glucose monitoring related pain, discomfort and Infection: Study team members and participants will take precautions to avoid infections at the site of finger pricking and sensor insertion (e.g. wearing gloves, washing hands and/or cleaning the skin with alcohol prior to pricks/insertion). Participants will be directed to contact study team staff if they notice any adverse reactions to wearing the sensor. If the sensor breaks, participants will be instructed to remove the sensor with tweezers and notify the staff.

Group Assignment: Participants are assigned to a group by chance, which may prove to be less effective or have more side effects than the other study group or alternatives. However, this risk is not greater than the standard of care.

Confidentiality: The University of Alabama at Birmingham regularly reviews its policies and procedures regarding the confidentiality of its study subjects. All staff receives training on the importance of maintaining confidentiality. Strict confidentiality will be maintained to the fullest extent by the research team. Hardcopy information will be kept in a secure, locked cabinet with limited access. Digital information will be stored in a HIPAA compliant, password protected database with limited access to authorized study personnel. Data are stored and analyzed according to subject identification numbers, and in no instances are subjects' names or other identifying information available in publically accessible files or in published material. The study consent form will inform participants that not sharing information about their participation in this study with others will minimize breach of confidentiality risks.

c. Vulnerable Subjects

The proposed study does not involve vulnerable subjects.

3. Potential Benefits of the Proposed Research to Research Participants and Others

Participants may benefit from this study by obtaining additional health information made available by continuous glucose monitors. The results of this study are expected to inform the acceptability and feasibility of continuous glucose monitoring among diabetics after kidney transplantation and estimate if continuous glucose monitoring improves glucose control among diabetic kidney transplant recipients.

4. Importance of Knowledge to be Gained

Diabetes is the largest risk factor for end-stage renal disease and kidney transplant rejection. The less glucose levels are controlled the more likely transplanted organs are to fail. Therefore, if continuous glucose monitoring improves glucose control in diabetic kidney transplant recipients, we anticipate to see a reduction in kidney transplant failure rates. This finding may benefit outcomes among other solid-organ transplant populations, as well as policies related to insurance coverage of continuous glucose monitoring in solid-organ transplant populations.

Data and Safety Monitoring Plan

Monitoring Responsibility:
Data and Safety Monitoring is the responsibility of the study director, Dr. Henry Zelada.

Adverse Event (AE) Management:
Expected Events: Adverse events include expected side effects of a serious nature or unexpected side effects/events, regardless of severity. All potential risks, as well as protections against those risks, are detailed in the "Protection of Human Subjects" document, the human subjects protocol and the informed consent document.

Frequency: Adverse event information will be collected during each standard of care clinic visit. In addition, participants will be instructed to report adverse events as they occur to the study director, whose contact information is provided in the informed consent. Throughout the study, the study director will be available to address subject related medical questions and to ensure subject safety.

Actions: As needed, the study director will refer participants to the appropriate medical care (e.g. urgent care or non-urgent care). In cases of emergency, participants will be instructed to call 911. Should a participant require urgent or emergency care, the study director will follow up with the participants' healthcare providers to determine whether it is safe for the participant to continue in the trial. Should an adverse event occur while the participant is being seen at UAB, study related injuries will be promptly addressed and treated using resources available at UAB.

Documentation: Adverse events will be documented on specialized case report forms and graded on their attribution (unrelated to the protocol, or possibly, probably or definitely related to the protocol), severity (mild, moderate, severe), expectedness (unexpected versus expected) and frequency. We will also document any actions taken related to the adverse event and the outcome or resolution of the event.

Reporting: All adverse events will be reported to the UAB IRB with a description of the event, when and how it was reported, and appropriate documentation to corroborate the event on case report forms. A summary of all adverse events are reported as part of the IRB protocol Continuing Review. Serious Adverse Events (SAE) will be reported by the study director to the IRB no later than five business days after the event. Non-serious, unexpected adverse events that are related or possibly related to the study will be reported to the IRB within 10 business days of the event. The IRB will have the responsibility to confirm the severity of the adverse event, determine if it is likely that the adverse event was related to the study and make recommendations for continuation, modification or cessation of the study.

Data Monitoring Management:
Dr. Zelada will review the quality and accuracy of all data collected during the study. Protection of data from a breach of confidentiality is described in the Protection of Human Subjects document.

Statistical Design and Power

A permutated block randomization list, block sizes varying from 2 to 6, will be developed to randomly assign subjects to treatment sequence (CGM followed by glucometers, or glucometers followed by CGM). 66 individuals would be required to achieve 80% statistical power in this crossover design for a medium effect size of 0.5 using a two-tailed Type I error of 0.05. Given we have only one year to conduct the pilot, we believe a sample size of 30 is the highest number of individuals that can be recruited and studied within that period. We will include 15 patents in each group. One group will receive CGM and the other will use glucometers for glucose monitoring. The only way this sample size could achieve adequate statistical power is that the difference in interventions generates a very large effect size (>0.8). We do not anticipate effect sizes that large and believe the smallest clinically relevant effect sizes would be in the range 0.2 to 0.5. Therefore, this study is unlikely to generate adequate statistical power. However, achieving statistical power is not the objective of a pilot study. The objective is to demonstrate the feasibility of recruiting individuals to the study, demonstrating that individuals will complete the study, demonstrating that clean and usable data can be collected, and examination of that data provides preliminary evidence of an effect in the direction anticipated. Therefore, the criteria for evaluating this pilot are that a) 80% of all individuals recruited will agree to randomization and complete the study with usable data and b) adequate evidence is observed in the direction anticipated. If we observe a test statistic for treatment effect difference greater than or equal to 1.055 with 28 degrees of freedom, which equates to effect size an effect size of 0.275, we will consider this as adequate statistical evidence to proceed. Such an approach equates to conducting the analysis with a one-tailed Type I error rate of 0.15. If both criteria are met (rate of completion and preliminary data provides evidence in direction anticipated), we will utilize the data collected to design a larger randomized controlled trial. If the criteria are not met, we will refine protocol and data collection procedures.

Dissemination Plan

As Principal Investigator for this study, I will comply with the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information in NIH Guide Notice NOT-OD-16-149. The proposed study title is Continuous Glucose Monitoring (CGM) in Kidney-Transplanted Adults" and is currently registered on ClinicalTrials.gov (NCT05352230). As PI, I will be responsible for ensuring that the information in the clinical trial record is updated at least once every 12 months and I will ensure that results are reported no later than one year after the clinical trial primary completion date.

The consent form for this clinical trial will contain language specifying that the study is registered at clinicaltrials.gov. The required wording on all consent forms by the University of Alabama at Birmingham (UAB) Institutional Review Board for Human Use is:

> "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

The Center for Clinical and Translational Science (CCTS) works with investigators to provide education and assistance to meet the requirements of ClinicalTrials.gov for registration and reporting as specified in the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NOT-OD-16-149). The CCTS maintains a web site (https://www.uab.edu/ccts/clinical-translation/clinical-services/crsp/study-start-up/regulatory-issues/clinicaltrials-gov) specifically for the purpose of updating investigators regarding changes to ClinicalTrials.gov. The CCTS provides consultations and one-on-one training to assist investigators in initiating and maintaining their ClinicalTrials.gov entry.

Description of the availability of Investigational Product (IP) and Investigational New Drug (IND) or Investigational Device Exemption (IDE) status:

The Freestyle Libre 2 and Freestyle Libre Pro are FDA-regulated test articles, legally marketed in the United States (FDA Letters K193371 and P150021, respectively) when used in accordance with their labeling for continuous glucose monitoring (CGM). Therefore, these devices are no longer investigation as they have been approved for marketing and commercial distribution in the United States. This study will use devices in accordance with their labels.

All components of the device will be stored securely (behind a locked door) in the principal investigator's office in Faculty Office Tower (FOT) 754. All floors above 6 in FOT are badge-protected. Only qualified research staff will have access to the office where the devices are stored. The devices will be inserted for two weeks at the beginning and end of Phase I or Phase II, dependent on group assignment. The participation will only wear the sensor for the Pro version of the device and data will be collected remotely from the device. Participants will be instructed to discard the sensor after each two week period of monitoring is complete.

1. GENERAL QUESTIONS

Protocol Number IRB-300009227

Principal Investigator Name Zelada Castro, Henry

Title of proposed project:

Continuous Glucose Monitoring (CGM) in Kidney-Transplanted Adults

* Select the type of application you are submitting to the IRB for review. Initial Application

NOTE: The ePortfolio should NOT be used for submitting Reliance Agreements, Expanded Access (including emergency use), or Humanitarian Use Device applications.

For Reliance Agreements, submit a copy of the Institution Review Form.

For Expanded Access and HUD submissions, submit a copy of the Human Subjects Protocol.

Initial IRB Protocol Application

* **PURPOSE:** In non-technical, lay language, provide the purpose of the project. The contents of this section are copied to other areas of IRAP. As such, provide **only** the purpose of the project here.

The purpose of this study is to determine the feasibility and acceptance of continuous glucose monitoring (CGM) in adults with diabetes who underwent kidney transplantation compared to those who use glucometers, and to determine whether CGM improves Post-Transplant Hyperglycemia, microalbuminuria and subclinical rejection rates in kidney transplant patients, as compared with those who use glucometers.

BACKGROUND: In 2-3 paragraphs, summarize the past experimental/clinical findings leading to the design of this project. Include any past or current research that informed the study design and any previous results that are relevant to understanding the project. Lastly, list the study outcomes that will be measured to evaluate the purpose of the project . It is not necessary to include methodology in this section. NOTE: Technical terms must be defined in simple language. Abbreviations must be spelled out. Provide references for any specific citations.

The proposed study will address a current diabetes disparity in adults with low socio-economic status who underwent kidney transplant (KT) at UAB. During the last three years, over 1000 kidney transplants have been performed at the UAB Comprehensive Transplant Institute; however, according to our internal statistics, around 70% of our patients do not have access to advanced diabetes technology due to limited insurance coverage, making post-transplantation glucose monitoring challenging, and contributing to disparate outcomes for low-income patients, including possibly kidney allograft rejection rates.

Recent data has suggested that social determinants of health defined as the conditions in which individuals live and work such as poverty, unemployment, inability to pay for medications, public health insurance and lower education level can adversely impact kidney graft survival (15,16,17,18). However, despite increased awareness of kidney-related health disparities in low-income and minority populations, outcomes data specific to post-kidney transplantation remain sparse.

UAB Hospital is the major transplantation referral center in the southeast area. According to our last three years statistics, nearly 70% of patients who underwent KT at the UAB Kidney Diabetes Clinic are low-income and African Americans who are publicly insured.

The gold standard for glucose monitoring is the use of a glucometer (glucose meter). To use most blood glucose meters, a test strip is placed into the device. Then with a special needle, one pokes a clean fingertip to get a drop of blood. One then carefully touch the test strip to the blood and waits for a blood glucose reading to appear on the screen of the meter.

Continuous glucose monitors have been developed to take the pain of fingertip sticks out of the process of glucose monitoring, as this is a reason for noncompliance among those who are recommended to use a glucometer. A continuous glucose monitor uses a sensor placed under the skin to measure blood sugar level, transmits each reading to a smartphone, smartwatch or small recording device worn on the patient's body, and gives an alert when blood sugar levels are too low or too high.

Because continuous glucose monitoring (CGM) is either not covered by public insurance or incurs high out-of-pocket costs (19), the majority of these patients have no access to advanced diabetes technology, making Post-Transplant Hyperglycemia (PTRH) monitoring a challenge. The glucose management in post-transplant patients is unique due to the need for high doses of steroids and immunosuppressants, variations in kidney function, frequent gastric symptoms, and the presence of cardiovascular comorbidities. Lack of public health insurance coverage for CGM in this setting is largely driven by a dearth of rigorous data demonstrating improved health outcomes for low-income post-transplant patients when using CGM. The objective of this pilot study is to test for feasibility and acceptability of CGM in low income patients with diabetes who have undergone kidney transplantation. If successful, we will use the pilot data as the foundation for a larger well-powered trial to examine whether CGM improves PTRH and kidney graft survival. At this moment, access to CGM is largely relegated to patients with private insurance. We have designed this study in order to address the disparities in access to advanced diabetes technology, thereby promoting health equity in post-kidney transplant outcomes

The use of continuous glucose monitoring (CGM) compared with blood glucose meter monitoring in non-transplant patients with diabetes resulted in lower HbA1C by 0.4 to 0.5% within the first three months of use without major changes in patients' antidiabetic regimen, possibly due to patients become more conscious about their diabetes status and diet (10,11). CGM free style libre-2 measures the interstitial fluid every minute with glucose sensors being replaced every two weeks (12). To our knowledge there are no studies that assess the role of CGM in improving glycemic and transplant outcomes in solid organ transplant patients, mainly because access to CGM is often limited by inadequate health insurance coverage or high out-of-pocket costs.

METHODS: Describe the procedures for all aspects of your protocol. Tell us what you are doing.

A cross-over design will allow estimation of feasibility and acceptability of patients using CGM vs patients using blood glucose meter monitoring (conventional therapy). The study will consist on two phases. Phase I will last 3 months, followed by a 2 month washout period, before the beginning Phase II, which will also last 3 months (for a total of 8 months).

Note: Standard of Care for post-kidney transplant patients

Patients who receive kidney transplants at UAB return to the Kidney Transplant Clinic every two weeks for the first year after transplant to have routine exams and bloodwork drawn, to insure that their body will not reject the donor organ. We intend to schedule any study-related procedures during these routine clinic visits so that participants will not have to return to the clinic on a more frequent basis than they would for their routine post-op care.

We will not draw research only bloodwork during these visits. We will collect data from standard of care procedures that would happen for the patient, whether they were in the research study or not - this includes data from their glucometer readings, their kidney biopsy at Month 5/6, and data from the visits that are recorded in their medical record.

Note: CGMs

The Freestyle Libre 2 CGM system consists of a sensor and a reader. The sensor will be inserted into the participant's shoulder during their respective treatment phase by the study coordinator. The sensor is designed to be removed and replaced every two weeks while it is being used. The reader is a device that reads the information from the sensor. Please see Instructions for Use (IFU) directions that are included in the Device section for more details about the placement and removal of the sensor. Participants will be given the IFU for the CGM system at the time of sensor placement.

Participants will be able to utilize the provided reader or a smartphone app that is part of the Freestyle Libre 2 CGM system to follow their glucose readings in real time, to assist with their diabetes management.

As a control measure, we will have participants in the control phase wear the Freestyle Libre Pro for a two-week period at the beginning and end of their control phase of the study. The sensor is similar to the Freestyle Libre 2. When the sensors are removed, they will be discarded. The Freestyle Pro does not have an end user reader or smartphone app; only a healthcare professional can receive the data collected/recorded by the CGM sensor. This can (and will) be collected remotely, so that participants need not return the sensors to the study site, but can discard them as they would per the IFU.

Participants will be approached about enrollment following their kidney transplant while they are still in the hospital. If they agree to enroll, their medical record will be reviewed for history, diagnosis, and demographic information.

At baseline, participants will then be randomized into one of two arms: **Group 1**, which will receive the Freestyle Libre 2 CGM in Phase I or **Group 2**, which will be provided with glucometers, the standard of care method of glucose monitoring, in Phase I.

Each group will have 15 total participants.

Please find attached in Section 31 a Schedule of Events to assist with clarity of study flow.

Baseline Visit (Week 0)

- **For participants in Group 1 only**: participants will be fitted with a Freestyle Libre 2 continuous glucose monitor. A sensor will be inserted in their shoulder for this device. They will be given instructions on how to use the reader that is provided with the sensor to obtain your blood sugar readings. They will also be given instructions on how to change the sensors. They will be given the instructions for using the device that are provided by the device manufacturer.
- **For participants in Group 2 only**: Participants will receive a glucometer (glucose monitor) to check and record daily blood sugar readings, which they will be asked to do this three times a day, before meals. Participants will be fitted with a Freestyle Libre Pro continuous glucose monitor, which they will be asked to wear for two weeks. At the end of the two weeks, the participant will remove the Freestyle Libre Pro sensor and discard it at home. Data will be collected remotely from the Libre Pro system.
  For participants in both Group 1 and Group 2: medical record will be reviewed for information about diabetes, including lab work that was collected as part of standard of care. We will not collect lab work for research purposes only. Con meds and adverse events will be collected. Participants will be asked to complete 2 questionnaires, the Diabetes Treatment Satisfaction Questionnaire (DTSQ) and the Hypoglycemic Confidence Scale (HCS)

Phase I: Week 2 (Visit 2)

- **For participants in both Group 1 and Group 2:** medical record will be reviewed for information about diabetes, including lab work that was collected as part of standard of care. We will not collect lab work for research purposes only. Con meds and adverse events will be collected. Participants will be asked to complete the DTSQ and the HCS
- **For participants in Group 1 only:** obtain readings from the CGM from the time that it was initially inserted
- **For participants in Group 2 only:** participants will be fitted with a Freestyle Libre Pro continuous glucose monitor, which they will be asked to wear for two weeks. At the end of the two weeks, the participant will remove the Freestyle Libre Pro sensor and discard it at home. Data will be collected remotely from the Libre Pro system.

Phase I: Week 12 (Visit 3)

- **For participants in both Group 1 and Group 2:** medical record will be reviewed for information about diabetes, including lab work that was collected as part of standard of care. We will not collect lab work for research purposes only. Con meds and adverse events will be collected. Participants will be asked to complete the DTSQ and the HCS
- **For participants in Group 1 only:** participants will remove the Freestyle Libre 2 sensor and discard it. Participants will be given a glucometer to continue to monitor glucose levels.
- **For participants in Group 2 only:** participants will be fitted with a Freestyle Libre Pro continuous glucose monitor, which they will be asked to wear for two weeks. At the end of the two weeks, the participant will the Freestyle Libre Pro sensor and discard it at home. Data will be collected remotely from the Libre Pro system.

Washout period (Weeks 13-19)

A two month washout period will start at the end of Phase I, during which all participants, regardless of Group assignment, will use glucometers to monitor blood glucose levels.

After the washout period, participants will cross into the other arm of the study - those in Group 1 will continue using the glucometers, while those in Group 2 will receive the Freestyle Libre 2 CGM.

Phase II: Week 20 (Visit 4)

- **For participants in both Group 1 and Group 2:** medical record will be reviewed for information about diabetes, including lab work that was collected as part of standard of care, as well as data from the kidney biopsy generally performed at post-operative month 5 or 6. We will not collect lab work or complete biopsies for research purposes only. Con meds and adverse events will be collected. Participants will be asked to complete 2 questionnaires, the DTSQ and the HCS
- **For participants in Group 1 only:** participants will be fitted with a Freestyle Libre Pro continuous glucose monitor, which they will be asked to wear for two weeks. At the end of the two weeks, the participant will the Freestyle Libre Pro sensor and discard it at home. Data will be collected remotely from the Libre Pro system.
- **For participants in Group 2 only:** the Freestyle Libre-2 CGM will be inserted at this clinic visit by the study coordinator. Participants will be given the Instructions for Use (IFU) for the CGM at this time.

Phase II: Week 32 (Visit 5) - End of Study

- **For participants in both Group 1 and Group 2:** medical record will be reviewed for information about diabetes, including lab work that was collected as part of standard of care. We will not collect lab work for research purposes only. Con meds and adverse events will be collected. Participants will be asked to complete 2 questionnaires, the DTSQ and the HCS
- **For participants in Group 1 only:** participants will be fitted with a Freestyle Libre Pro continuous glucose monitor, which they will be asked to wear for two weeks. At the end of the two weeks, the participant will the Freestyle Libre Pro sensor and discard it at home. Data will be collected remotely from the Libre Pro system.
- **For participants in Group 2 only:** participants will remove the Freestyle Libre 2 sensor and discard it. Participants will be given a glucometer to continue to

monitor glucose levels.

REQUIRED - SELECT ONE OR BOTH: Will this be a retrospective study and/or a prospective study?

☐ Yes ☑ No * Retrospective

☑ Yes ☐ No * Prospective

☑ Yes ☐ No * Will the study involve the prospective collection or analysis of data, documents, or records?

☐ Yes ☑ No * Will the study involve the prospective collection or analysis of biospecimens?

What is the expected end date of the study (including data analysis)? 30-Jun-2024

* Provide the total number of subjects to be included at all sites, both retrospectively (including records) and prospectively. 30

* Provide the total number of subjects to be included at UAB, both retrospectively (including records) and prospectively. 30

Select the type of research.

☑ Biomedical (non-oncology)

☐ Behavioral (non-oncology)

☐ Oncology

Select the status of the Principal Investigator.

☑ Faculty/Staff

☐ Student/Trainee

☐ Yes ☑ No Are any of the investigators listed on the IRB Personnel Form students using this research for their capstone project, thesis, or dissertation?

☐ Yes ☑ No Is the project to be conducted internationally?

Methodology

Select all study procedures and indicate whether the procedures are research only or routine.

Procedure	Select whether the procedure is research or routine.
Record review (which may include PHI)	Protocol Driven
Devices	Protocol Driven
Surveys, questionnaires, or interviews (one-on-one)	Protocol Driven

☐ Yes ☑ No Does the protocol involve any procedures not described in the above table?

5. RESEARCH DETERMINATION

Research Determination Form

☑ Yes ☐ No * Is the activity a systematic investigation?

☑ Yes ☐ No * Is the activity designed to develop or contribute to generalizable knowledge?

☑ Yes ☐ No * Does the project involve obtaining information about living individuals?

☑ Yes ☐ No * Does the project involve an intervention or an interaction with participants?

☑ Yes ☐ No * Does the project involve an FDA regulated test article?

Briefly describe the proposed project, including what materials are being obtained and their sources. **If you provided this information on Page 1 (General Questions), enter "See above."**

See above

Risk Level - FDA Regulated

* **REQUIRED: Select whether the project involves minimal risk or greater than minimal risk to participants.**

Minimal Risk

Expedited Categories

Select the categor(ies) that apply to the project. If none of these categories apply, select none of the above apply to this project.

1 ☐ 2 ☐ 3 ☐
4 ☐ 5 ☐ 6 ☐
7 ☐

Expedited Category 1: Clinical studies of drugs and medical devices when either of these conditions are met.

Expedited Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture under these conditions.

Expedited Category 3: Prospective collection of biological specimens by noninvasive means (examples here).

Expedited Category 4: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x rays or microwaves (more information here).

Expedited Category 5: Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch

purposes (such as medical treatment or diagnosis).

Expedited Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes.

Expedited Category 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

☐ None of the above apply to this project.

Sources of Private Information

Indicate the information that may be obtained, accessed, used, disclosed, or shared from an individual (living or deceased). Select all that apply.

☐ An individual's genetic tests

☐ Genetic tests of family members of a particular individual (including an embryo or fetus)

☐ Genetic manifestation of a disease or disorder in family members of a particular individual

☐ Any request for, or receipt of, genetic services, or participation in a clinical study which includes genetic service, by the individual or any family member of the individual

☐ Education records of an individual

☐ Alcohol or substance abuse information, including diagnosis, treatment, or referral of treatment for alcohol abuse, substance abuse, or chemical dependency

☑ Yes ☐ No Will the PI or others obtain, review, or make other use of participants' "protected health information" (i.e., information, whether oral or recorded in any form or medium that (a) is created or received by a health care provider and (b) relates to past, present, or future physical or mental health or condition of an individual; or provision of health care; or payment for provision of heath care)?

☐ Identifiable, but not private, information

☐ Other identifying information

☐ Yes ☑ No * Will information be received from outside of UAB?

☐ Yes ☑ No * Will you share the information with an institution other than UAB?

☐ Yes ☑ No * Will you need to obtain information from a department other than your own?

Provide any additional information for the IRB to consider. Upload any relevant files in the Attachments section.

Please find attached the grant submission (with references) in Section 31.

6. NON-AFFILIATED PERSONNEL

Non-UAB/CoA Personnel

☐ Yes ☑ No * Are there any NON UAB, Children's of Alabama (CoA), Lakeshore Foundation, or Birmingham Veteran's Affairs Medical Center (BVAMC) key personnel on this study? NOTE: UAB, CoA, Lakeshore Foundation, and BVAMC investigators must be listed on the IRB Personnel Form. Additionally, this page does not apply to adding sites for Single IRB or multi-site research.

7. SPONSORS AND ENTITIES

Funding, University Contracts, Subcontracts, MTAs, or DUAs

☑ Yes ☐ No * Is this project funded in any way?

☑ Yes ☐ No * Is the funding internal?

☐ Yes ☑ No Does the project involve any University Contracts, MTAs, DUAs, or subcontracts/subawards? NOTE: Subawards are identified by the OSP Assigned Number with a three digit suffix (e.g., 000500000-001).

☐ Yes ☑ No Will the project receive non-monetary support (i.e., drugs, devices, services, etc.) from another entity?

9. PROSPECTIVE

In

☐ Yes ☑ No * Drugs/Dietary Supplements

☐ Yes ☑ No * Biologics

☐ Yes ☑ No * Radiopharmaceuticals

☑ Yes ☐ No * Medical Devices

☐ Yes ☑ No * In-vivo imaging, image guided interventions (e.g., CT, PET/CT, MRI, PET/MRI, x-ray, DEXA, fluoroscopy, nuclear imaging, ultrasound) or radiation therapy

☐ Yes ☑ No Is this a multi-site study?

☑ Yes ☐ No Does the study involve access, review, or disclosure of Protected Health Information (PHI) ?

☑ Yes ☐ No Does the study involve randomization?

Include the risks and benefits of randomization in the consent form.

☐ Yes ☑ No Does the study require clinical services at any of these sites?

☐ Yes ☑ No Will this study involve direct interaction with participants who have an infectious disease?

Target Accrual Information

35 Approximately how many subjects will need to undergo screening procedures to determine whether they qualify to be enrolled? Enter 0 if not applicable.
NOTE: This number is an approximation based on previously completed projects.

30 How many subjects do you intend to enroll at UAB? Enter 0 if not applicable.

Describe how the screening and enrollment numbers above are determined (e.g., provide a power analysis, explain the pilot data, or reference prior studies.

In collaboration with the CCTS BERD Unit, a permutated block randomization list, block sizes varying from 2 to 6 will be developed, to randomly assign subjects to treatment sequence (CGM followed by glucometers, glucometers followed by CGM). 66 individuals would be required to achieve 80% statistical power in this crossover design for a medium effect size of 0.5 using a two-tailed Type I error of 0.05. Given we have only one year to conduct the pilot, we believe a sample size of 30 is the highest number of individuals that can be recruited and studied within that period. We will include 15 patients in each group. One group will receive CGM and the other will use glucometers for glucose monitoring. The only way this sample size could achieve adequate statistical power is that the difference in interventions generates a very large effect size (>0.8). We do not anticipate effect sizes that large and believe the smallest clinically relevant effect sizes would be in the range 0.2 to 0.5. Therefore, this study is unlikely to generate adequate statistical power. However, achieving statistical power is not the objective of a pilot study. The objective is to demonstrate the feasibility of recruiting individuals to the study, demonstrating that individuals will complete the study, demonstrating that clean and usable data can be collected, and examination of that data provides preliminary evidence of an effect in the direction anticipated. Therefore, the criteria for evaluating this pilot are that a) 80% of all individuals recruited will agree to randomization and complete the study with usable data and b) adequate evidence is observed in the direction anticipated. If we observe a test statistic for treatment effect difference greater than or equal to 1.055 with 28 degrees of freedom, which equates to effect size an effect size of 0.275, we will consider this as adequate statistical evidence to proceed. Such an approach equates to conducting the analysis with a one-tailed Type I error rate of 0.15. If both criteria are met (rate of completion and preliminary data provides evidence in direction anticipated), we will utilize the data collected to design a larger randomized controlled trial. If the criteria are not met, we will refine protocol and data collection procedures.

What are the target age range(s) of the potential subjects with which you will interact?
1. <18 ☐
2. 18-89 ☑
3. >=90 ☐

Indicate which of the following populations you will be **targeting** (enrolling, interacting, or intervening with) for your study. Select all that apply.

☐ Cognitively impaired adults

☐ Economically or educationally disadvantaged

☐ UAB employees

☐ Fellows

☐ Individuals with Limited English Proficiency (LEP) or non-English speakers. Recruitment of study with LEP or non-English speakers is generally required, if the study holds the prospect of a direct therapeutic benefit to the participant.

☐ Individuals of specific racial, religious, or ethnic groups

☐ Individuals living outside the 50 US states

☐ Pediatric and neonates

☑ Patients (This includes existing patients)

☐ Persons who are institutionalized

☐ Pregnant women or fetuses

☐ Prisoners

☐ Medical Residents

☐ Study Staff or investigators named on this application

☐ Students

☐ Others

☐ None of the above, not targeting specific populations

How will the study team identify potential subjects? Select all that apply.

☐ Non-UAB physicians ☑ Non targeted/unknown (e.g., chart review) ☐ Other

If chart reviews will be used to identify potential subjects that are not your own patients, request a partial waiver of HIPAA Authorization for the purpose of identifying individuals for recruitment.

*Describe participant inclusion/exclusion criteria, including sex, race/ethnicity, age, and health status.

Inclusion criteria:

- Age > 18 years
- History of diabetes diagnosis (Type 1, Type 2, or atypical) prior to kidney transplant
- Current treatment for diabetes includes at least one daily injection of long-acting insulin shot
- Able to read and understand English
- Able to consent for themselves

Exclusion criteria:

- Age < 18 years
- History of kidney-pancreas transplant
- Has used CGM in the past
- Mental or psychiatric conditions that would preclude continuation in the study

- Unable to read or understand English
- Unable to consent for themselves

Describe the estimated time commitment of each subject. Examples: 1) One hour once a week for 52 consecutive weeks; 2) Twenty minutes to complete a one-time survey; 3) One interview lasting 60 minutes. Enter "N/A" if participants are not directly involved.

Participants will complete 5 study visits over the course of 8 months. These visits will coincide with their standard of care clinic visits. We anticipate that research procedures will take approximately 15 minutes.

☑ Yes ☐ No * Will a Certificate of Confidentiality be obtained from the NIH?

NOTE: Specific language must be added to the informed consent document and approved by the NIH. In addition, the consent documents must not be filed in the medical record.

What recruitment materials/methods will be used to recruit subjects. Select all that apply.

☐ Flyer

☐ Internet posting/website

☐ ResearchMatch

☐ Subject pool/repository

☐ Printed brochure

☐ Letter to healthcare providers

☑ Letter to potential subjects

☐ Printed ad

☐ Radio/TV ad

☐ Email solicitations

☑ Direct subject contact

Describe the methods used to recruit the subject (i.e., how, when).

Once the study has IRB approval, we will send letters to patients who are currently awaiting kidney transplants to tell them about the study, including the inclusion and exclusion criteria.

☑ Electronic Medical Record query using i2b2, Electronic Data Warehouse, or IMPACT

Describe.

We will query the EMR for the records of participants on the kidney transplant list.

☐ Other

*Describe all activities to identify and recruit prospective participants.

We will send letters of invitation to patients on kidney transplant waiting list through their kidney transplant coordinators, with information about the study including inclusion and exclusion criteria. We will approach every eligible patient as soon as they are admitted to the hospital to receive their kidney transplant about enrollment into the study. The Kidney Transplant Division is aware of the study and will support us.

Select the types of data collection tools that will be used in this study. Select all that apply.

☑ Survey/questionnaire(s) (UAB recommends using Qualtrics or RedCap for electronic surveys)

☐ Audio or video recordings

☐ Interview guides/scripts

☐ Subject diaries

☑ Mobile or web application

Provide a comprehensive description of the application.

All participants will be given a reader that is part of the Freestyle Libre 2 CGM system for use during the study; however, the Freestyle Libre 2 also has an optional smartphone app that participants can use for the same purpose as the provided readers. The study team will be able to obtain remote access to the data from both the Freestyle Libre 2 and the Freestyle Libre Pro using a web application. Participants will not have the ability to use the web application; they will only have the ability to check the readings from the Freestyle Libre 2 with the provided reader or the optional smartphone app.

☐ Electronic Medical Record query using i2b2, Electronic Data Warehouse, or IMPACT

☐ Other

Clinical Trials

* Select whether this protocol meet the definition of a clinical trial. ◉ Clinical Trial ○ Non-clinical trial

This protocol must be registered on clinicaltrials.gov. Provide the National Clinical Trial (NCT) identifier. 05352230

All key personnel must complete Good Clinical Practices (GCP) training.

Institutional Biosafety Committee (IBC)

☐ Yes ☑ No * Does this project involve gene transfer, recombinant DNA, or CAR T cells?

11. LOCATIONS

- [x] UAB Hospital
- [x] The Kirklin Clinic of UAB Hospital
- [ ] UAB Callahan Eye Hospital
- [ ] Children's of Alabama (CoA)
- [ ] Jefferson County Department of Health (JCDH)
- [ ] UAB Hospital - Highlands
- [ ] The Kirklin Clinic at Acton Road
- [ ] UAB Clinical Research Unit
- [ ] Jefferson County Department of Health (JCDH)
- [x] Other (i.e., any performance site not listed above, including those covered by subawards related to this protocol)

Provide a description of the location that will provide space, services, or facilities for the conduct of this protocol.

Faculty Office Tower (FOT) 754 (PI's administrative office)

- [ ] Yes [x] No * Is this a field study?

12. DEVICES

- [ ] Comparison
- [x] Randomized
- [x] Open Label
- [x] Control
- [ ] Other

- [ ] Yes [x] No * Is the trial blinded?

13. DEVICE SELECTION

Add a Device Review Sheet for each device the study involves.

Device Name	Device Review Sheet
Freestyle Libre-2	DEVICE REVIEW SHEET Complete
Freestyle Libre Pro	DEVICE REVIEW SHEET Complete

18. PATIENTS

- [x] Yes [ ] No * Will the investigators (any investigator listed as key personnel) be recruiting their own patients?

Provide the rationale for including patients of investigators.

Participants will be derived from the pool of patients who present to the UAB Transplant Institute for evaluation and treatment of renal disease with a comorbidity of diabetes. The University of Alabama at Birmingham is a referral center for diagnosis and treatment of both disorders. The Principal Investigator has a practice specifically designated in the treatment of diabetes in transplant patients, and has the means for receiving and treating referrals for this population.

What safeguards are in place to ensure that investigators are not unduly coercing their patients into participation?

Potential participants will be allowed the opportunity to ask questions regarding the protocol and alternative therapies. The patient will be given sufficient time to review the consent form and discuss it with research staff. As a part of the consent process, the patient will be instructed of alternative choices and that they will be provided standard of care therapy/monitoring regardless of their decision to participate in the study.

25. COST AND PAYMENT

Cost, Reimbursement, or Compensation

- [ ] Yes [x] No * Will subjects (or their insurance providers) experience costs associated with any of the procedures, drugs, biologics, devices, tests, or any aspect of their participation in the study?
- [ ] Yes [x] No * Will subjects receive any reimbursement or compensation for their participation (compensation should not be an amount that could be considered coercive or create undue influence)?

26. RISKS

Risks and Risk Minimization

Determine any anticipated risks or potential discomforts experienced by subjects for this study. Select all that apply.

☑ Physical risks (e.g., pain, bruising, and infection associated with venipuncture, adverse reactions to drugs, muscle soreness and pain as a consequence of exercise testing, heart attack induced by maximal exercise test, radiation risk (e.g., x-ray, CT scan, radiation therapy, radioisotopes, fluoroscopy))

Provide details of the risks, including expected frequency and severity.

Inserting the CGM sensor can cause slight temporary pain, bleeding and/or bruising at the site of insertion. There is a small risk of infection while puncturing the skin for sensor insertion.

Issues that have been experienced from wearing the sensor include moderate to severe itching and reddening of the skin; these have occurred infrequently. Moderate problems such as rash, bleeding, itching and scaling of the skin occurred rarely.

Some people may be sensitive to the adhesive that keeps the sensor attached to the skin. The sensor could break in the participant's lower back or stomach.

Describe any steps taken to mitigate the expected risks.

Precautions will be taken to avoid infections at the insertion point (for example, wearing gloves, cleaning the skin with alcohol prior to CGM placement). We will ask participants to contact study staff if they notice any adverse reactions to wearing the sensor. If the sensor breaks, participants will be instructed to remove the sensor with tweezers and notify site staff.

☐ Psychological risks (e.g., depression and confusion as a result of administration of drugs, feelings of guilt precipitated by a sensitive survey)

☑ Social risks (e.g., invasion of privacy, breach of confidentiality, loss of community standing)

Provide details of the risks, including expected frequency and severity.

There is a risk of breach of confidentiality with all research studies, but we do not believe there is a greater than minimal risk with this study.

Describe any steps taken to mitigate the expected risks.

All personal and medical information will be stores in a locked area the PI's locked office in FOT 754. Only qualified research staff will have access to this information. Once research data has been collected, all information that could link personal identity to medical information will be deleted. There will be no personally identifying information used to report any findings from this study.

☐ Economic risks (e.g., loss of employment, loss of potential monetary gain)

☐ Other risks

Indicate how safety is being monitored in this study.

☐ Data Safety Monitoring Board (DSMB)

☐ Independent medical monitor

☑ Data will be monitored by PI.

Describe how safety will be monitored locally and, if this is a multi-center study, how data and safety will be monitored across sites. Additionally, describe how often data will be monitored. If the only risk is breach of confidentiality, descrbe the method of monitoring for breaches.

All personal and medical information will be stores in a locked area the PI's locked office in FOT 754. Only qualified research staff will have access to this information. Once research data has been collected, all information that could link personal identity to medical information will be deleted. There will be no personally identifying information used to report any findings from this study.

☐ Data will not be monitored.

27. BENEFITS

Describe.

All participants will have access to the Freestyle Libre 2 CGM for approximately 3 months during the study period (either Phase I or Phase II). They will be encouraged to utilize this device and its app to record their glucose readings in real time to assist them with managing their diabetes

What are the potential benefit(s) of the study (e.g., benefits to society, increased knowledge of the particular disease, increased scientific knowledge, etc.)?

The benefit to the researchers is to help provide better management of diabetes in transplant patients in the future.

28. PRIVACY AND CONFIDENTIALITY

Select the identifiers.

☑ Names

☑ All geographical subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000

☑ All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older

☐ Phone Numbers

☐ Fax Numbers

☐ Email Addresses

- [ ] Social Security Numbers
- [x] Medical Record Numbers
- [ ] Health plan beneficiary numbers
- [ ] Account numbers
- [ ] Certificate/license numbers
- [ ] Vehicle identifiers and serial numbers, including license plate numbers
- [ ] Device identifiers and serial numbers
- [ ] Web universal resource locators (URLs)
- [ ] Internet protocol (IP) addresses
- [ ] Biometric identifiers, including finger and voice prints
- [ ] Full face photographic images and any comparable images
- [ ] Any other unique identifying number, characteristic, or code
- [x] Medical history
- [x] Surgical history
- [x] Laboratory results
- [ ] Other

Provide the length of time the identifiers will be stored or retained.

for the duration of the study (anticipated 24 months)

Describe how data will be collected, recorded, and shared, including the specific safeguards to protect the confidentiality of data. Select all that apply.

- [ ] Working with an entity outside of UAB to collect, record, share, or otherwise utilize the data.
- [ ] Data will be stored in REDCap.
- [ ] Data will be stored in ShareFile
- [x] Data will be kept on a UAB encrypted device (i.e., computer, tablet, etc.).

[ ] Yes [x] No * Will anyone other than the study team have access to the device?

- [x] Data will be stored on a UAB encrypted server.
- [ ] Data will be stored in the UAB Cheaha Supercomputer
- [x] Data will be recorded on paper.

Where will the paper records be stored?

in the PI's locked administrative office in FOT 754

- [x] Data will be coded.

[x] Yes [ ] No * Will a key to the code be maintained?

Who will have access to the key?

only personnel listing on the IRB personnel listing

- [ ] Data will be kept in a locked office/filing cabinet.
- [ ] Data will be stored on a password protected computer/drive not maintained by UAB.
- [ ] Data will be stored in a location not described above.
- [ ] Data will NOT be coded.

Describe the plan to destroy the subject identifiers at the earliest opportunity consistent with the conduct of research, unless retention is required for reasons of health, research, or law (including the methods that will be used to discard data at the end of the study life cycle). NOTE: Research records must be retained and subsequently discarded in accordance with applicable regulatory guidelines.

Paper records will be kept in the locked department research office for a minimum of 3 years or until a time is decided that they can be destroyed. Electronic records will be stored on a password-protected server behind the UAB firewall. At a time after at least 3 years, if it is determined that the data should be deleted, all study data will be destroyed. Electronic data will be wiped from the server following UAB IT policies and procedures, and any paper documents will be securely shredded following UAB's research documentation policies and procedures.

HIPAA Authorization

Indicate whether you will obtain HIPAA Authorization, a HIPAA waiver, whether the data meet the specifications for a Limited Data Set, or whether the study does not involve access, review, or disclosure of Protected Health Information (PHI). Select all that apply.

- [x] Request for partial HIPAA waiver for recruitment/screening purposes.

Indicate which identifiers will be included *under the request for partial HIPAA waiver* for recruitment/screening purposes.

- [x] All geographical subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
- [x] All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
- [ ] Phone numbers

- ☐ Fax numbers
- ☐ Email addresses
- ☐ Social Security numbers
- ☑ Medical record numbers
- ☐ Health plan beneficiary numbers
- ☐ Account numbers
- ☐ Certificate/license numbers
- ☐ Vehicle identifiers and serial numbers, including license plate numbers
- ☐ Device identifiers and serial numbers
- ☐ Web universal resource locators (URLs)
- ☐ Internet protocol (IP) addresses
- ☐ Biometric identifiers, including finger and voice prints
- ☐ Full face photographic images and any comparable images
- ☐ Any other unique identifying number, characteristic, or code
- ☑ Medical history with no other identifiers or PHI
- ☑ Surgical history with no other identifiers or PHI
- ☑ Laboratory results with no other identifiers or PHI
- ☐ Other
- ☐ HIPAA Authorization will be obtained for some or all of the subjects.
- ☐ Request for HIPAA waiver for some or all of the subjects (e.g., for retrospective review of PHI, and/or to review PHI for recruitment purposes and obtain HIPAA authorization during enrollment)
- ☐ The data meet the specifications for a limited data set. NOTE: A limited data set will only apply if you receive data from an outside source as a limited data set or if you are sending data to an outside source as a limited data set (in which case, documentation of authorization or a Waiver of Authorization will be required). A Data Use Agreement (DUA) is required for this option.

HIPAA Covered Entities

Indicate which of the entities would provide health information for this protocol, maintain health information as it was collected for this protocol, and/or store health information after it has been collected for this protocol.

- ☑ UAB Hospital or UAB Hospital - Highlands
- ☑ The Kirklin Clinic of UAB Hospital or Acton Road (and/or associated clinics)
- ☐ UAB Callahan Eye Hospital
- ☐ Children's of Alabama
- ☐ Jefferson County Department of Health
- ☐ School of Dentistry
- ☐ School of Health Professions
- ☑ School of Medicine
- ☐ School of Nursing
- ☐ School of Optometry
- ☐ University of Alabama Health Services Foundation
- ☐ Valley Foundation
- ☐ Medical West - UAB Health System Affiliate
- ☐ Birmingham Veteran's Affairs Medical Center
- ☐ Yes ☑ No Is the principal investigator requesting that the UAB IRB waive patient HIPAA authorization from another institution or entity (e.g., insurance company, collaborating institution)?

29. CONSENT

Informed Consent

Indicate all that apply to the informed consent process.

- ☑ Informed consent with written documentation will be obtained from all or some of the subjects.

Select all types of consent forms that will be used.

Consent Form Types	Description of Document (50 words or less)	Clean Copy	Tracked Copy
Main Consent 1	revised 5/27/22		

All * Will written informed consent be obtained from all or some of the subjects?

Describe how written informed consent will be obtained, including confirmation that a copy of the signed consent document will be given to the individual who will sign it.

Potential participants will be approached during their hospitalization following transplant. They will be told about the study and given the chance to ask questions prior to being offered enrollment. The consent will be reviewed in its entirety and signed prior to any study procedures being performed. A signed copy will be provided to the patient. A checklist will be completed by the research staff involved in the consent process verifying that the consent was reviewed and signed, all questions were answered, and a signed copy was provided to the patient. If one of these items was not completed, an explanation will be provided on the checklist. This checklist will be signed by the research staff and placed with the paper research records stored in the locked PI's administrative office in FOT 754.

Describe how the study team will ensure the subjects understand the information presented.

The participant will be contacted and the study will be introduced to them by the investigator or study coordinator. If they are interested, a copy of the consent form will be given to them for their review. The investigator or study coordinator will go over the consent form in detail and give the participant the chance to ask any questions they may have.

What language will the prospective participant understand?

English

What language will be used to obtain consent?

English

☐ Yes ☑ No Will any potential participants be, or have been, in a stressful, painful, or drugged condition before or during the consent process?

☐ Request a Waiver of Documentation of Informed Consent (e.g., subject may not sign an informed consent document, but will be given an information sheet)

☐ Request a Waiver or Alteration of some or all elements of informed consent or a FULL waiver of informed consent.

31. ATTACHMENTS

Attachments

Document Name	Document Type	Description	Clean Copy	Tracked Copy
Protocol Oversight Review Form	IRB Submission Form			
Data Collection Sheet	Data Collection			
Survey/Questionnaire	Data Collection	Diabetes Treatment Satisfaction Questionnaire (DTSQ)		
Survey/Questionnaire	Data Collection	Hypoglycemic Confidence Scale (HCS)		
Recruitment Letter	Participant Communications			
Other Relevant Documents	Other	grant application		
Other Relevant Documents	Other	schedule of events for participants		
Response Memorandum	IRB Submission Form	response to Determination Letter dated 5/27/22		

Updated By: Deborah K. Lowman @ 27-May-2022 12:19:10 PM

Data collection variables for IRB-300009227: Continuous Glucose Monitoring (CGM) in Kidney-Transplanted Adults

- Name
- Date of birth
- Age
- Gender
- Race
- Date of diabetes diagnosis
- Date of kidney transplant
- Subacute rejection rates – data collected from SOC kidney biopsy
- Steroid & immunosuppressive regimen during study period
- CGM data to be collected:
    - fructosamine/albumin ratio
    - CGM-measured Time in Range (TIR) of 70 to 180 mg/dL
    - time with glucose level at greater than 180 mg/dL
    - time with glucose level at lower than 70 mg/dL
    - time with glucose level at lower than 54 mg/dL,
    - Mean Glucose Level,
    - Glucose Variability (GV),
    - Glucose Management Indicator (GMI)
    - microalbuminuria