GLYCEMIC OPTIMIZATION ON DISCHARGE FROM THE EMERGENCY ROOM

NCT05197829

DATE: 9/29/23

1. TITLE

Glycemic Optimization On Discharge from the Emergency Room (GOOD-ER) program

2. EXTERNAL IRB REVIEW HISTORY*

NA

3. PRIOR APPROVALS:

NA

Conflict of Interest (COI):

The Study Investigators have no COI to disclose.

Clinical Engineering Department:

The continuous glucose monitor and reader have been inspected and approved by clinical engineering.

Biohazardous Agents:

NA

Radiation*:*

NA

Students as Subjects*:*

NA

Data Science Core & Recruitment Core:

The Data Science Core has been consulted and their services are not required for this protocol.

UMCCTS Protocol Review Committee (PRC)

This project has been reviewed by the PRC and approved for submission to the IRB. Several revisions were made to this ISP in response to the PRC comments. A document describing the PRC comments and the changes made is also included with the application.

4. OBJECTIVES*

Our goal is to help people with diabetes who are treated and then discharged from the emergency department (ED) achieve better health outcomes. Specifically, we are interested in determining whether or not continuous glucose monitoring after ED discharge is useful.

People living with diabetes, particularly those from disadvantaged socioeconomic backgrounds, frequently seek medical care through the emergency department (ED), but coordinated longitudinal follow up is often lacking. Almost 1 in 10 ED visits are related to diabetes (1), and rates of diabetes-related ED utilization are negatively correlated with household income (2, 3). Being evaluated in the ED can be a powerful motivator for patients, but this window of opportunity can be missed if patient activation is low or if access to ongoing medical care is limited. Interventions designed to improve continuity between the ED and diabetes specialty care have shown promise in terms of reducing hospitalizations and medical expenditures (4), but even at institutions with these programs in place, recurrent diabetes-related ED visits continue to be a problem (5). Overall, diabetes care for people in the ED remains fragmented and poorly studied.

As we attempt to help people seeking care for diabetes in the ED, we plan to study the potential role of continuous glucose monitoring (CGM) in this novel context. In the outpatient setting, CGM has been shown to cause clinically significant reductions in hemoglobin A1c as well as hyper- and hypoglycemia (6-8). It can also improve a patient's self-management skills and understanding of how food and activity affect blood sugar (9). CGM use, however, has never been studied as a tool to help people being discharged from the ED. It will be valuable to assess its usefulness in this setting, as patients are at high risk of recurrent hyper- or hypoglycemia during this transitional window (10, 11) and may be more engaged than at other times.

Our plan is to conduct a randomized controlled trial of unblinded CGM among people with diabetes who are discharged home after being treated in the ED for diabetes-related emergencies. In conjunction with research assistants, ED clinicians at the University Campus, Memorial Campus, Marlborough Campus, Clinton Campus, and Leominster Campus will identify patients with diabetes (type 1 or 2) and hyper- or hypoglycemia who would benefit from follow up in the UMass Diabetes Center of Excellence (DCOE). The ED physician will place a referral, if necessary, and study staff will help arrange this follow up, scheduling an appointment within 2-3 weeks. In addition to this care coordination, half of the participants will receive a CGM placed by the patient or study staff in the ED, and all patients will receive written instructions about how to handle recurrent hyper- or hypoglycemia.

The primary outcomes will be the rate of attendance at the follow-up visit and be the change in diabetes-related quality of life as measured by the PAID-5 scale and the DDS. We hypothesize that having a CGM will decrease the no-show rate and increase clinic attendance and improved diabetes-related quality of life. Secondary outcomes will include hemoglobin A1c levels over time, ED utilization, emergency medical services utilization, hospitalizations, and major cardiovascular events within 6 months. Finally, we will assess provider satisfaction in the DCOE via a brief survey.

Focusing on a common but rarely studied clinical problem – the ED-to-clinic transition for people with diabetes – this project will promote inter-departmental collaboration between the ED and the DCOE and will directly improve care for people with diabetes, particularly those from disadvantaged groups. In addition to improving care coordination, we will rigorously assess the

usefulness of CGM in a novel context, generating preliminary data for future work and serving as an example for other medical systems regionally and around the world.

5. BACKGROUND*

Emergency physicians and endocrinologists agree that the emergency department (ED) is not an optimal venue for delivering longitudinal medical care for people with diabetes, but diabetes-related ED visits remain common. In the United States in 2010, for example, approximately 10 percent of all ED visits – over 12 million in total – were for diabetes-related problems, the majority of which did not require hospital admission (1). Seeking emergency care for diabetes is associated with lower income and socioeconomic status (2, 3, 12), and this lack of continuity of care is associated with worse outcomes (13-15). Programs designed to improve care coordination between the ED and subspecialty diabetes care have shown promise (4, 5), at least in terms of reducing ED visits and expenditures, but significant works remains to be done, especially in terms of patient-centered outcomes.

Over the last decade, the emergence of continuous glucose monitoring (CGM) technology has changed how many people with diabetes manage their disease, but the ideal role for these devices is still being established. In outpatient settings, randomized trials have shown that CGM reduces hemoglobin A1c as well as hyper- and hypoglycemia (6-8, 16). There is also evidence that CGM use is associated with a reduction in hospitalizations and emergency diabetes-related events (17). From the patient perspective, CGM has been shown to improve diabetes-related quality of life (18) and diabetes self-management skills (9). Most of these studies, however, were conducted in ambulatory settings. CGM has never been studied as a tool to help people seeking diabetes-related care in the ED, a vulnerable population in which the potential benefit could be high.

At UMass Memorial Medical Center, we have an opportunity to implement and study new approaches to caring for people with diabetes-related emergencies. The UMass ED and the DCOE both serve large numbers of patients and exist within an academic environment conducive to patient-focused research. At the University Campus in 2019, over 1,000 people were treated for hyper- or hypoglycemia and then discharged home without being admitted to the hospital. Our goal is to help these patients avoid repeat ED visits and poor glycemic outcomes by bridging the gap between the ED and the DCOE. We believe that CGM during the high-risk period of time after ED discharge will help patients avoid recurrent glycemic problems while reducing their diabetes-related distress and helping their outpatient providers.

In addition to helping patients at UMass, we hope to pave the way for implementation of such programs on a broader scale, as there is great agreement among stakeholders that improvement is needed. Emergency physicians are motivated to reduce the number of patients seeking emergency care, as waiting rooms at UMass and elsewhere are frequently crowded, and diabetologists know that continuity of ambulatory care is in the best interests of their patients. Health systems work to keep expenses down, and of course, most importantly, patients prefer to avoid the ED when possible. We believe all these factors will make our program valuable and exciting to other systems.

The work we propose is innovative both in terms of its subjects and its methods. The population of people seeking care in the ED is more disadvantaged than the population as a whole, and it is

also a population that is studied far less often than outpatient populations. Most diabetes-related studies focus on patients affiliated with certain hospitals or group practices, potentially missing people who lack a secure relationship with longitudinal care. Our project is designed to improve outcomes for this large, at-risk group.

Our desire to study the effectiveness of CGM during the ED-to-clinic transition is also novel. The existing CGM literature is skewed towards studies of well-connected patients being followed as outpatients. We feel, however, that CGM could have value for other patients, such as those in the ED population who have already demonstrated their risk for severe hyper- or hypoglycemia. We will be the first group to rigorously study CGM as tool to help people being discharged from the ED, and thus our work will lay groundwork for future studies, hopefully both here at UMass and elsewhere.

6. INCLUSION AND EXCLUSION CRITERIA*

Patient Subjects:

Inclusion Criteria:

- Age 18 years or older
- Patients must be preparing for discharge from the emergency department after being treated for either hyperglycemia or hypoglycemia
- Patients must be either new referrals to the DCOE or existing DCOE patients in need of post-ED follow up
- Patients must have type 1 or type 2 diabetes
- Patients must be able to provide informed consent
- Patients must be fluent in English or Spanish

Exclusion Criteria:

- Current CGM use
- Need for hospital admission
- Upcoming computed tomography (CT) or magnetic resonance imaging (MRI) studies within 2 weeks, as these imaging modalities could potentially affect CGM performance
- Pregnant patients, as the device is not approved for pregnancy
- Any altered mental status, which would limit a patient's ability to consent to the study
- Patients who already have a longitudinal relationship with an outside endocrinologist
- Patients who have not been referred to the DCOE
- Prisoners
- Patients under age 18 years
- Patients who do not speak English or Spanish fluently

Justifications for Criteria:

-Our intervention targets patients with diabetes who are treated and discharged from the emergency department after being treated for either hyperglycemia or hypoglycemia.

-We will translate consent materials and patient instructions into Spanish. No additional languages are included as the CGM being used for the study and its associated reader only has English and Spanish menus and instructional manuals.

-Prisoners represent a special population that is routinely excluded from similar research studies. They represent an inaccessible population.

-Patients under eighteen are typically treated by pediatric endocrinologists and have different care regimens that are beyond the scope of this study.

-Pregnant women will not be included in this arm of the study as the CGM being utilized for this study is not FDA approved for use in pregnant women.

Provider Subjects:

Inclusion criteria for provider subjects will consist of licensed independent providers (NP, PA, MD, DO or MBBS) who provide subspecialty diabetes care to a patient subject enrolled in the study. Pregnant women may be included in this cohort as this study arm entails less than minimal risk and the study activities have no impact on pregnancy.

Exclusion criteria: Adults unable to consent, subjects under 18 and prisoners will be excluded from this study. Any subject that does not meet the inclusion criteria will be excluded. Trainees, including medical students, resident physicians, and fellows will be excluded from this study.

7. STUDY-WIDE NUMBER OF SUBJECTS*

NA

8. STUDY-WIDE RECRUITMENT METHODS*

NA

9. STUDY TIMELINES*

Patient Subject Participant Involvement Timeline:

- ***Enrollment & Intake Visit:*** *(Day 0)*
  - → Informed consent
  - → Non-biometric data – Contact information; Intake data points
  - → Five-question Problem Areas in Diabetes (PAID-5) scale as well as the 17-question Diabetes Distress Scale (DDS) and supplemental questions will be administered
  - → Device training (if randomized to CGM)

→ Care coordination to DCOE (all patients)

- ***Outpatient Blood Sugar Monitoring (for intervention group only) (day 0-14)***
  → Continuous Glucose Monitoring – Sensor worn 24 hours a day for up to 14 days. Data can be uploaded

- ***Follow Up:*** *(~Day 14-21 post ED visit)*
  → Study team will meet patient at follow-up appointment
  → Biometric data – Downloaded
  → Non-biometric data – Five-question Problem Areas in Diabetes (PAID) scale as well as the 17-question Diabetes Distress Scale (DDS) and supplemental survey questions will be administered
  → Compensation ($10)

- ***6 Months Follow up*** *(no active patient involvement)*
  → Follow-up data points abstracted from electronic health record (EHR)

Provider Subject Participant Involvement Timeline:

- ***Follow Up:*** *(~Day 14-21 post ED visit of patient subjects)*
  → Study team send survey questions to provider subjects immediately after they have a clinic encounter with a patient subject
  → This will be the only time point of participation for provider subjects

Study Timeline: We anticipate that recruitment will be complete by September 30, 2022. Primary data analysis will be complete by the end of March 2023.

10. STUDY ENDPOINTS*

Our primary outcome The primary outcomes will be the rate of attendance at the follow-up visit and be the change in diabetes-related quality of life as measured by the PAID-5 scale and the DDS.

Secondary outcomes will include A1c levels, recurrent ED or EMS utilization, hospitalizations, and major cardiovascular events. We will also query DCOE providers regarding their satisfaction with the program, including a question about whether the CGM data are helpful for each patient.

Expectation: Our hypothesis is that CGM use after ED discharge will reduce the clinic no-show rate and decrease diabetes-related distress compared to the group with care coordination only.

There are no primary or secondary safety measures being recorded for the purposes of this study.

Safety measures will include number of device questions/concerns expressed by subjects during enrollment through their two-week follow up appointment, reported blood sugar events,

(high/low values), and return visits to clinic/ED/hospitalizations within the 2 week window of enrollment.

11. PROCEDURES INVOLVED*

Enrollment & Intake Visit of patient subjects:

- ***Recruitment:*** *See Section 24*. Research personnel will confirm subjects' pregnancy status by subject self report.
    - → ***Documents:***
        - **HIPAA Waiver**
        - **Info Sheet**
        - **Screening Log**
        - **Declined/Ineligible Log**
- ***Consent:*** *See Sections 30 & 31*
    - → ***Documents:***
        - **Consent**
        - **HIPAA Authorization**

- ***Randomization*****:** Using the Redcap randomization module, patients will be randomized to the care coordination-only or care coordination plus CGM group

- **Master Code** ***Contact Information:*** Study Staff will obtain at least two ways (primary phone number and mailing address) to contact participants to schedule follow-up visits, completing a follow-up phone call if necessary, and to ensure the CGM equipment is returned.
    - → ***Documents:***
        - **Contact Info**
        - **Master Code**
- ***Intake:*** Study Staff will query EMRs to obtain the data points listed in the document below. Data collected will be verified with participants.
    - → ***Documents:***
        - **Intake Data- RA Facing**
        - **Intake Data- Patient Facing**
- ***Device Training for intervention arm (CGM Arm only):*** Half of the participants identified and enrolled as described above will be randomized to receive an unblinded CGM. We plan to use the 14-day Libre 2 CGM from Abbott. This device is a small disk (1.38 inches in diameter and 0.2 inches thick), and it weighs 0.18 ounces. After it is placed, a small (less than 0.4mm thick) sensor probe (not sharp) remains in the skin and can transmit continuous glucose data to a reader. The device can be submerged in water, and if it falls off, there will not be any significant bleeding. Study Staff will demonstrate the features and use of the CGM and sensor application (how the device should be worn, when it should be removed, the procedure to query the device for blood sugar readings using either a reader or smart phone application). After participants demonstrate an understanding of the use of the GCM, Study Staff will place the device on one of the participant's upper arms (patient choice) and monitoring will begin immediately after a

60-minute calibration period. They will be instructed to wear the CGM for two weeks continuously (including during sleep and hygiene), although they will also be advised that they can remove the sensor at any time if it causes any discomfort or distress. Subjects will not be removed from the study if they chose to remove the CGM. Participants will receive an informational sheet that explains the basic functionality of the CGM and lists Study Staff contact information in the event that they have questions about the CGM or its readings.

→ ***Documents:***

- **CGM Information for enrolled patients (CGM arm only)**

- ***Mobile Reader (CGM Arm only):*** Study Staff will set up the Libre dedicated reader for subjects. Study Staff will demonstrate the features and use of the device and provide participants with an informational sheet that explains how and when to use the reader. Currently, Abbott, the company the manufactures the Libre 2 CGM system, is developing a mobile phone-based app to replace the reader. This app is under FDA review but is not yet approved. If it is approved between now and the end of enrollment, we will give participants the choice of using either the designated reader or their phone, if they possess a compatible phone.

→ ***Documents:***

- **CGM Information for enrolled patients (CGM arm only)**

- ***Education on managing out of range blood sugars:*** All patients will receive information on how to respond to out of range blood sugars and emergency contact information

→ ***Documents:***

- **Information sheet: Hyperglycemia**
- **Information sheet: Hypoglycemia**

- ***Initial questionnaires: Patients will be administered*** the five-question Problem Areas in Diabetes (PAID) scale as well as the 17-question Diabetes Distress Scale (DDS), which produces a total score and four subscale scores (emotional burden, regimen distress, physician distress, and interpersonal distress). Finally, patients will be administered several supplemental questions pertaining to their perceptions of their healthcare and barriers to obtaining optimal glycemic control.

→ ***Paper Log:*** Study Staff will administer these questionnaires on tablets shared with patients

- ***Documents:***

» ***Problem Areas in Diabetes (PAID-5) scale/Diabetes Distress Scale*** **and supplemental questions**

- ***Diabetes Center of Excellence Care Coordination:*** Study Staff will follow up with ED provider to ensure that patients' have clinically indicated referral to diabetes center of excellence

→ ***Appointment scheduling:*** RA will make an appointment for the patient before ED discharge, if possible. If this is not possible, RA will contact the patient after discharge to arrange a follow-up appointment.

Outpatient Blood Sugar Monitoring: The CGM will be worn on the participants' upper arm continuously for 14 days (or until it falls off or the patient decides to remove it)

Visit #1 (~Day 14-21 Post-Discharge of patient subjects)

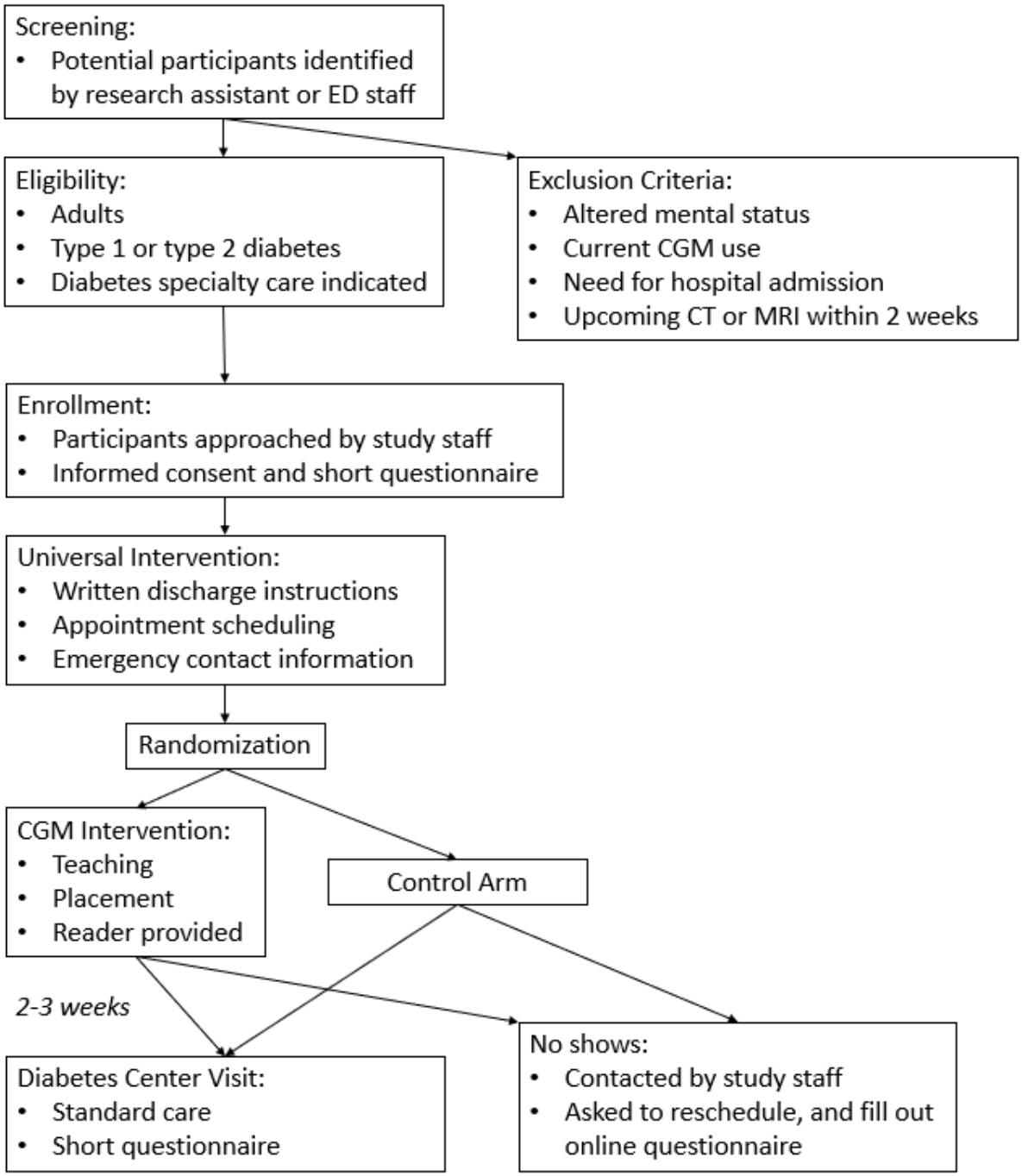
- ***Documents:***
  - → **Visit Data (RA facing)**
  - → ***Problem Areas in Diabetes (PAID-5) scale*/Diabetes Distress Scale and supplemental questions**
  - → **Fact sheet for provider subjects**
  - → **Provider satisfaction survey**

- ***CGM Data:*** Biosensor data will be downloaded and reviewed
- ***Material Collection:*** Study Staff will collect CGM readers
- ***Compensation:*** Participants will be offered $10 worth of gift cards to a retail store for completing visit #1.
- ***Provider Survey:*** immediately following an encounter with a patient subject, the provider taking care of each patient will be contacted by the study team as potential provider subjects. Potential provider subjects subsequently will be sent an email solicitation to participate in a Redcap survey. A fact sheet will be provided with that email. The survey will consist of 4 questions pertaining to their satisfaction with patient subject care coordination and/or their CGM utilization. Providers may be sent multiple surveys if they see multiple subjects who are enrolled in the study. This is the only involvement of the provider subjects.
- ***No Shows*:** *RAs will reach out to subjects who* miss their follow-up appointment to (1) help them reschedule and (2) ask that they fill out the post-intervention questionnaire via an online link (or mailed paper copy or via phone, if desired)

Follow up Data Collection (~6 months Post-Discharge)

- ***) Documents:***
  - → ***6 month follow up datasheet***
- ***Data Collection:*** The study team will query the EHR to collect follow up data points about enrolled subjects

Figure 1: Procedural Flow Sheet



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12. DATA AND SPECIMEN BANKING*

NA

13. Data Analysis and Management*

Feasibility: We have conducted a preliminary analysis of billing data from 2019 from the ED at the University Campus, and this analysis suggests that we will be able to target a large population of potential participants. In one year, there were 2,275 adult visits with a primary or secondary diagnosis of diabetes, hyper-, or hypoglycemia (Table 1). Over 60% of these patients were discharged home from the ED, and the majority had type 2 diabetes, although type 1 diabetes was over-represented (15%) compared to its frequency among cases of diabetes in the general population (less than 10%). Emergency physicians tend not to bill for diagnoses that do not require active ED management, so our numbers are likely not an overestimate. We suspect that only a fraction of these patients will be eligible for our study, but even if we were to recruit one out of every four, we would exceed our recruitment goal (200) within a year.

Sample Size: The primary outcomes are the clinic attendance rate and the change in diabetes-related distress, as measured by the Diabetes Distress Scale (DDS) and PAID-5 scale between the ED visit and the follow-up appointment date (19). Secondary outcomes include repeat ED/EMS utilization over 6 months, repeat hospitalizations, major cardiovascular events, and changes in hemoglobin A1c. For clinic attendance, we will aim to achieve attendance at 80% of the scheduled clinic visits. For a one-sided test at alpha=0.025 of a single proportion against a standard proportion (0.80), we will have 80% power to detect a difference of 0.13 (0.80 – 0.67) with a sample size of 83 subjects in the CGM group. Adjusted for 20% dropout, we will need approximately 100 subjects/group. For the DDS outcome, we will compare the change from baseline to the end of follow-up in the DDS between the two groups. Although we will fit the trajectory of the DDS change in each group using all DDS measures in a mixed effects model with repeated measures (MMRM), for simplicity in sample size estimation, we will calculate the sample size for an unadjusted comparison of the change between the two treatment groups. Based on a study of 267 subjects with diabetes (19), the standard deviation of the DDS was 1.0 across the three sites in that study. The DDS is a questionnaire of 17 questions, each scored on a Likert scale of 1 (not a serious problem) to 6 (serious problem), with the overall score calculated as the mean score across the 17 items. Thus, the range of the overall score is 1.0 – 6.0. With 100 subjects in each group, we can detect a difference of about 0.40 in the DDS change between the two groups. The literature on the DDS does not identify a clinically meaningful difference although Fisher, Polonsky, Hessler, Mullan (2012) suggest a difference of 0.5 as meaningful (20). Thus, our sample size will achieve power of greater than 80% to detect that difference.

Analysis Strategy: As indicted in the Sample Size section above, for the clinic attendance rate, we will conduct the initial unadjusted analyses using an exact test of the frequencies under the presumed population proportion (0.80) and the observed proportion. Adjusted analyses will be conducted using a logistic regression model for the proportion of clinic visits attended as the outcome in the intervention group with predictors including age, gender, time since diagnosis of diabetes, and other factors of interest.

For the outcome of change in DDS, we will conduct the initial unadjusted analysis as described above in the Sample Size section. For adjusted analyses, we will include each DDS score in the longitudinal MMRM, so that we can model the trajectory of change as well as the individual changes over the period of follow-up. The time metric in this model will be the time (months) since study enrollment with predictors including age, gender, time since diagnosis of diabetes and other factors of interest. We will also investigate subgroups of interest using a Forest plot approach. We will plot the means and confidence intervals for the outcome for the two groups using Forest plots to display the total groups and subgroups of interest. We will also generate

longitudinal plots of A1c over time with the means and appropriate exact 95% confidence intervals at each time point. In addition, with the DDS trajectories available, we are able to use machine-learning approaches, such as growth mixture models, to identify clusters of patients with similar trajectories but who are not members of previously defined subgroups. Finally, we will conduct sensitivity analyses to determine if missingness of DDS scores are missing at random or missing not at random. For these analyses, we will use several methods, including the jump-to-reference imputation and the pattern mixture model approaches, to determine if the results using the sensitivity analyses are consistent with the MMRM results, indicating that the missingness is missing at random.

For the secondary outcomes, the change in HbgA1c will be modeled as for the DDS above. The other secondary outcomes can be modeled as binary outcomes and will be modeled as longitudinal logistic models.

Data Management Plan:

All study data will be recorded on a REDCap database established on a secure encrypted server on AWS. All access to the database will be through permissions established by the IT REDCap administrator. Investigators will have to log into the REDCap database to enter or view data. The REDCap database will be developed and implemented by the data management staff of the UMMS Quantitative Methods Core (QMC) with the direction of Dr. Bruce Barton, QMC Director. Logic data checks will be built into the data entry process to help clean the data at entry. Quality control edits will be run to identify inconsistencies and questionable values in the data. The audit trail will be activated for the duration of the study.

Data for analysis will be downloaded directly from REDCap and converted to SAS datasets or R data frames for analysis. The downloaded datasets will be deidentified and are HIPPA as well as 21 CFR Part 11 compliant.

Provider Data:

We will present the data from the provider surveys in a descriptive fashion. For example, we will report the percentage of patients in the CGM arm whose provider found the data useful. We will also do subgroup analyses. Potential subgroups include the type of diabetes, whether or not the diabetes diagnosis is new, and whether or not the participant presented to the ED with hypo- or hyperglycemia.

14. PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF SUBJECTS*

In accordance with **HRP-801 Prompt Reporting Requirements**, any unanticipated adverse events will be reported and the PIs will closely monitor all aspects of the study.

The PIs will be responsible for monitoring adverse events during the study. If an adverse event occurs, their role will be to identify the concern, to develop an appropriate response to alleviate or minimize any adverse event, and to ensure that the adverse event is reported in a timely manner to the appropriate authority. Participants will be monitored for the occurrence of any

undesirable experience or unanticipated benefit. Events may occur during recruitment, during home CGM use, and during the initial follow-up visit. We anticipate that these effects will be limited. We will assess whether an undesirable experience (adverse event) occurred and will record details of all adverse events on an adverse event case report form. We do not anticipate that any serious adverse events (death, life threatening illness, new serious or permanent disability) will occur. However, should such an event occur, we will report the event within 24 hours to the University of Massachusetts Medical School (UMMS) Institutional Review Board.

The adverse event case report form will include a description of all undesirable experiences, required interventions, and an assessment of the participant after the event if possible. An estimate of the extent of injury and prevention strategies will be reported. The principal investigators will classify the relationship of the study protocol to the event as follows:

• Not related: The event is clearly related to factors not related to the study protocol.
• Remote: The event was most likely related to factors not related to the study protocol.
• Possible: The event follows a reasonable temporal sequence associated with participating in the study and/or is consistent with events related to the study protocol but is possibly related to factors such as the participant's clinical state.
• Probable: The event follows a reasonable temporal sequence associated with participating in the study and/or is consistent with events related to the study protocol and cannot be reasonably explained by factors such as the participant's clinical state.

The severity of an adverse event in both groups is defined as a qualitative assessment of the degree or intensity of an adverse event as determined by the principal investigator as follows:

• Mild: No impact (in any way) on the participant.
• Moderate: Impacts on the participant but is not life-threatening or incapacitating.
• Severe: Fatal, life threatening, permanently disabling; severely incapacitating; requires/prolongs inpatient hospitalization.

All adverse events will simultaneously be reported to institutional officials. The report will summarize the facts of the case, including the date and a description of the participant; whether the event is related to the study's protocols; the steps that have been taken to address the issue; whether the event provides emerging knowledge about the risks of the study that should be conveyed to participants; and whether the consent form should be revised.

Due to the relatively low risk of adverse events with using a CGM, which are FDA-approved for people with both type 1 and type 2 diabetes, and the relatively short duration of the study, we do not plan on having a data safety monitoring board review.

The frequency of data review for this study is summarized in the following table:

Data Type:	**Frequency of Review:**
Participant recruitment (adherence to protocol on inclusion & exclusion criteria)	The PI will directly observe recruitment for the first five cases, then will observe random

	cases bi-monthly once the study is established.
Data collection methods	The PI will directly observe data collection on the first five cases, then will observe random cases bi-monthly once the study is established.
Integrity of data storage procedures	The PI will directly monitor data storage the first five cases, and then will review all data monthly once the study is established.

15. WITHDRAWAL OF SUBJECTS WITHOUT THEIR CONSENT*

NA

16. RISKS TO SUBJECTS*

The main risks to participants in care coordination-only cohort are:

1) Loss of confidentiality or privacy given that their contact information will be collected
2) Psychological distress from filling out diabetes-related surveys.

The main risks to participants in the CGM arm include the risks above plus risks associated with the CGM. These risks include:

1) Local erythema (redness), local infection, inflammation, pain or discomfort, bleeding at the glucose sensor insertion site, bruising, itching, scarring or skin discoloration, hematoma, and adhesive irritation.
2) There is a remote risk of sensor or needle fracture during insertion, wear or removal, with fragments retained under the skin.
3) Distress from seeing abnormal values and potential confusion about how to treat abnormal values.

The main risks to participants in the provider subject cohort include:

1) Loss of confidentiality or privacy given that their contact information will be collected

Protections against the specific risks identified above include the following:

- **Loss of Privacy/Confidentiality**
    - Subjects will be approached privately in the ED and all data will be managed securely as noted above. The CGMs being used are small and unobtrusive. Because of the size of biosensor, we do not anticipate that a bystander would know that a patient is wearing a CGM nor would they be able to "eavesdrop" on the data being transmitted to the subject's phone or reader. Consequently, the use of CGM in a public location will not be problematic. We anticipate that the CGM

will attract little attention and will not lead to a loss of confidentiality, especially as these sensors are widely used in clinical practice for people with diabetes. We view this risk to be minimal. All data and personal information pertaining to subjects from both cohorts will be managed securely and accessible only by authorized members of the study team. All identifiers will be disposed of as soon as appropriate (see section 26).

- **Psychological Distress from Diabetes-Related Surveys**
  - The informed consent process will discuss the potential that filling out surveys related to diabetes could cause distressing rumination about living with a chronic disease. We will limit the length of surveys to approximately five minutes to minimize the effort that participants need to expend filling them out. We view this risk as minimal.

- **Physical Discomfort**
  - The CGM is comfortable to wear. Local reactions are rare and generally mild. If a participant no longer wishes to use or wear the CGM s/he can simply remove the sensors to truncate data collection while still being a participant in the study. We consider this risk to be minimal.

- **Psychological Effects of CGM**
  - Participants in the study may develop increased stress or awareness of their blood sugar as a response to the flow of data from the CGM. They may seek care or adjust their treatment regimen (correctional insulin, for example) based on CGM values. To mitigate this type of risk, all subjects will be supplied with extensive written information on how to manage hypo- and hyperglycemia, including clear instructions to check a finger-stick blood sugar level if there is any question of CGM inaccuracy, and will have the contact information for the study team if they have questions or concerns about the CGM or its readings. We have classified this risk to be minimal.
  - An endocrinologist will be "on call" 24 hours a day, 7 days a week, and the study pager number will be provided to all participants. The study pager will be carried during business hours by a study team member, who will pass all medical calls to the on-call doctor. After hours, the on-call endocrinologist will carry the pager. If subjects encounter a blood sugar value or other adverse event that they need assistance with, they will be encouraged to call their primary care physicians. If they are unable to reach their PCPs or don't have one, they will have the ability to page the provider on call, who will provide appropriate clinical guidance as to how to manage the adverse event. The provider on call will be a qualified endocrinologist who will be able to provide counseling on managing out of range blood sugars. If the complaint is too acute or complex to be managed on the telephone, the patient will be referred to the emergency department.

  - The CGM sensor to be used in the proposed study is a commercially available device and will be used to obtain patterns in blood glucose monitoring. The Libre,

made by Abbott, does not qualify as an implant or life-sustaining device, nor does it pose a serious health risk to study participants. Because of this, the Libre CGM meets requirements for a Non-Significant Risk Device under FDA 21 CFR 812.3(m).

17. POTENTIAL DIRECT BENEFITS TO SUBJECTS*

This project investigates an intervention that is intended to help people with diabetes navigate between the ED and specialty diabetes care. Within this program, we will provide care coordination and support for potentially vulnerable patients. We expect that patients will directly benefit from participating in the study because they will receive detailed written instructions relevant to diabetes and hyper- and hypoglycemia and will also receive assistance arranging the initial follow-up appointment. Subjects in the intervention group will benefit from closer monitoring of their blood glucose, which may help them avoid recurrent hyper- or hypoglycemia and will also provide real-time feedback about the impact of their dietary choices and exercise habits, which may impact their long-term lifestyle choices and empower them to participate more actively in their care management

As a thank you for their time and participation in this study, patients will also be gifted a $10.00 gift card

There is no anticipated direct benefit to the provider subject cohort.

18. VULNERABLE POPULATIONS*

No vulnerable populations will be included in this study. Pregnant patients, patients under 18, adults unable to consent, and prisoners are all excluded.

In the provider subject cohort, no subjects will be approached who are directly or indirectly supervised by any member of the study team.

19. MULTI-SITE RESEARCH*

NA

20. COMMUNITY-BASED PARTICIPATORY RESEARCH*

NA

21. SHARING OF RESEARCH RESULTS WITH SUBJECTS*

At subjects' follow up appointments in the DCOE, if subjects are randomized to the CGM arm, the results of their blood sugar readings will be reviewed and discussed with the subject. No other research results will be shared with subjects.

22. SETTING

- ***Enrollment & Intake Visit:*** UMMMC EDs (University Campus, Memorial Campus, Leominster Campus, Marlborough Campus, and Clinton Campus)
- ***Visits #1 and physician cohort recruitment:*** Diabetes Center of Excellence, University Campus
- ***Follow up data collection:*** Private offices at the University Campus in the departments of medicine and emergency medicine

23. RESOURCES AVAILABLE

Study Staff: All Study Staff members are up to date on CITI certification and are aware that this training must be renewed every three years. They will conduct this research in accordance with the current, IRB approved protocol.

- ***Study Investigators:***
  - → ***Principle Investigator (PI):*** The PIs are a board-certified Endocrinologist and Emergency Medicine physician with experience in human subjects' research.
    - ***Responsibilities:*** The PIs will be responsible for overseeing the entire study including, but not limited to (1) dissemination of the research protocol to all Study Staff; (2) recruitment; (3) enrollment; (4) data collection; (5) data analysis; and, (6) dissemination of results. The PI will ensure all Study Staff are adequately trained and monitor their progress to ensure they are following the protocol.
  - → ***Co-Investigators (Co-Is):*** The Co-Is are physicians from the departments of Emergency Medicine, and Endocrinology
    - ***Responsibilities:*** The Co-Is will assist the PI with all aspects of the study including, but not limited to: (1) recruitment; (2) enrollment; (3) administering questionnaires; (4) interpretation of results; and, (5) preparation of the resulting manuscripts.
- ***Additional Study Staff Roles:***
  - → ***Research Assistants (RAs):*** The RAs will have basic training in research methods and human subjects' research, as well as a bachelor's degree in a human science field or equivalent.
    - ***Responsibilities:*** They will be trained by the PI and Research Coordinator to complete most aspects of the study including, but not limited to: (1) explaining the study to eligible individuals; (2) obtaining informed consent; (3) training participants in the use of the CGM sensor and reader; (4) how to conduct a chart review; (5) data handling; (6) arranging follow-up visits; and, (7) administering questionnaires.
  - → ***Research Coordinator (RC):***
    - ***Responsibilities:*** In addition to the responsibilities described for the RAs, the RC will train and monitor the RAs and assist with regulatory requirements and communications with the IRB.

24. LOCAL RECRUITMENT METHODS

Patient Subjects

***Feasibility**:* As per Section 13, based on the number of patients presenting to the University ED with the qualifying chief complaint, the study team is confident that the appropriate number of subjects can be recruited during the study period.

Procedures: We have created a one-page basic *information sheet* to hand out to both potential and enrolled participants that outlines the study details in an easy-to-read format.

- Study staff will identify potentially eligible individuals through EHRs
- They will initially view:
    - → *(ED-Based)* The individual's name, age, sex, presenting complaint, ED bed location, and treating physician's name from the ED tracking board
    - → If the individual seems eligible based on the above information, Study Staff will query other portions of the EMR (medical history, current medications, past medications) to verify EMR-based eligibility.
    - → If the individual still seems eligible, the data points initially viewed will be recorded on the *Screening Log*.
    - → Study Staff will notify the potential participant's treating physician of eligibility, and ask if the treating physician plans to refer the patient to the DCOE
    - → If the physician is not familiar with the DCOE, the study staff member will educate the physician as to the purpose and availability of the DCOE to help the physician determine if a referral is appropriate for the patient. The study staff will also be prepared to show physicians how to place a referral order
    - → If the physician replies in the affirmative, the study staff will then request their permission to approach their patient and ensure that there are no additional barriers to enrollment from a clinical standpoint.
    - → Potential participants will be approached by a member of the Study Staff regarding this research. Study Staff will ask for the individuals' permission to explain our study, give them time to read our *information sheet* and offer them the opportunity to participate.

Destruction of Identifiers:

- ***Declined or Ineligible:*** Identifiers from the *Screening Log* will be deleted within 24 hours and de-identified demographic information, along with any noted barriers to participation, will be transferred to *Declined/Ineligible Log*.
- ***Agree to Participate:*** Following the enrollment and intake visit, identifiers from the *Screening Log* will be transferred to the *Master Code* and de-identified demographic information will be transferred to *Intake Data*. Medical record number (**MRN**) will be directly entered into the *Master Code*.

Compensation: Participants will be compensated for their time at their follow up each visit. A $10 Bank of America card will be given to each participant at his or her follow up visit. To be eligible to receive the research stipend - the subject's name, address, phone number, and type of

phone (mobile, landline) will be provided to the UMMS business office to procure the Bank of America card. Bank of America will mail the card directly to the subject. Once this information is provided to the business office – this identifying information will be destroyed by the PI.

Provider Referred Recruitment: We also plan to make the emergency providers aware of our program via announcements at resident conference and at monthly faculty meetings, and as has been done for prior ED-based studies, we will place signs in the "doc boxes" where charting takes place. These presentations and materials will include information about criteria that would make a DCOE referral appropriate. If an attending or resident identifies a potentially appropriate patient, they will page a member of our study staff, usually a research assistant (RA). When receiving a referred patient, the RA or other study staff member will proceed as above.

In a similar fashion, we will make the Diabetes Consult Service aware of our project as well so that potentially eligible patients can be referred.

Provider Subjects

Immediately following the office encounter with a patient subject, the study team will abstract in Redcap the provider taking care of each patient as potential provider subjects. Potential subjects subsequently will be sent an email solicitation to participate in a Redcap survey. A fact sheet will be provided with that email. The survey will consist of 4 questions pertaining to their satisfaction with patient subject care coordination and/or their GCM utilization. This is the only involvement of the provider subjects. The solicitation email, fact sheet, and provided survey are included with this application.

25. LOCAL NUMBER OF SUBJECTS

We expect to recruit patient 200 patients in the one-year period (100 in each arm). As per the power analysis described in section 13, this will allow us to measure our described outcomes. We expect to recruit approximately 8 provider subjects.

26. CONFIDENTIALITY

Procedures to Secure the Data:

- Participants will be assigned a unique Study ID# and most data related to a given participant will use this ID *(see table below)*.
- We may quote participant comments in presentations and publications; however, any direct quotations will be carefully reviewed to ensure that they do not include any potentially identifiable content.
- UMMS/UMMMC computers are password-protected and encrypted.
- Data will be stored in REDCap

	Coding	***Access***	***Storage***	***Destruction***
HIPAA Waiver	- N/A	- N/A	- N/A	- N/A
Info Sheet	- N/A	- N/A	- N/A	- N/A

Screening Log *1) While screening* *2) Status assigned – All data points will either be deleted or transferred to different documents (also see Section 24)*	1) *Identifiable information 2) N/A	1) Authorized Study Staff 2) N/A	1) Securely stored on a password-protected UMMMC/UMMS computer 2) N/A	1) *See Section 24* 2) N/A
Declined Ineligible - *De-identified demographic information will be transferred to this document from the Screening Log; Noted barriers to participation will be directly entered*	- Will not contain any of the 18 HIPAA identifiers	- Authorized Study Staff & Support Personnel	- Securely stored on a password-protected UMMMC/UMMS computer	- Will be archived once results have been published
Consent - *Written documentation*	- *Identifiable information	- Authorized Study Staff	- Securely stored in the PI's locked office	- In accordance with **HRP-800 Investigator Obligations**, paper forms will be retained for 3 years following completion of this research
HIPAA Authorization - *Written documentation*	- *Identifiable information	- Authorized Study Staff	- Securely stored in the PI's locked office	- In accordance with **HRP-800 Investigator Obligations**, paper forms will be retained for 6 years following completion of this research
Master Code - *Contact information will be collected using the paper form (Contact Info) and then transferred to the Master Code; Identifiers will be transferred to this document from the Screening Log; MRN will be directly entered*	- *Identifiable information; The only place that identifying information will be linked with Study ID#	- Authorized Study Staff	- Securely stored on a password-protected UMMMC/UMMS	- Contact information will be deleted for each participant once data collection is complete and the biosensor has been returned; MRN and name will be deleted upon data collection verification
Contact Info - *Contact information will be collected using the Redcap (Contact*	- *Identifiable information	- Authorized Study Staff	- N/A	- Contact information will be transferred to the *Master Code* following

Info) and then transferred to the Master Code				completion of the enrollment and intake visit and the Redcap form will be destroyed
Intake Data Collection Sheet – RA Facing *Collected using the Redcap form* **Also see Section 12*	Study ID# only	Authorized Study Staff	Directly entered by the RA into Recap	1) Destroyed upon completion of data collection verification 2) REDCap database will be archived once results have been published
Intake Data Collection Sheet- Patient Facing *Collected using the Redcap form* **Also see Section 12*	Study ID# only	Authorized Study Staff	Directly entered by the participant into a secure online database using survey mode (REDCap)	1) Destroyed upon completion of data collection verification 2) REDCap database will be archived once results have been published
Info Sheet- Hyperglycemia	- N/A	- N/A	- N/A	- N/A
Info Sheet- Hypoglycemia	- N/A	- N/A	- N/A	- N/A
Info Sheet- CGM	- N/A	- N/A	- N/A	- N/A
***Baseline Problem Areas in Diabetes (PAID) scale/* Baseline Diabetes Distress Scale and supplemental questions** *- Direct entry into REDCap*	- Study ID# only	- Authorized Study Staff & Support Personnel	- Directly entered by the participant into a secure online database using survey mode (REDCap)	- REDCap database will be archived once results have been published
2 Week Follow up Data Collection Sheet *1) Collected using the paper form* *2) Entered into REDCap* **Also see Section 12*	1) Study ID# only 2) *Same as above*	1) Authorized Study Staff 2) Authorized Study Staff & Support Personnel	1) Securely stored in the PI's locked office 2) Secure online database (REDCap)	1) Destroyed upon completion of data collection verification 2) REDCap database will be archived once results have been published
2 Week Problem Areas in Diabetes (PAID) scale/Diabetes Distress Scale and supplemental questions	- Study ID# only	- Authorized Study Staff & Support Personnel	- Directly entered by the participant into a secure online database using survey mode (REDCap)	- REDCap database will be archived once results have been published

- Direct entry into REDCap				
Provider subject email solicitation	-N/A	- Authorized Study Staff & Support Personnel	-N/A	-N/A
Provider Fact Sheet	-N/A	- Authorized Study Staff & Support Personnel	-N/A	-N/A
Provider Survey *-Direct entry into REDCap*	- Study ID# only	- Authorized Study Staff & Support Personnel	- Directly entered by the participant into a secure online database using survey mode (REDCap)	- REDCap database will be archived once results have been published
Follow up Data Collection Sheet *- Direct entry into REDCap*	Study ID# only	1) Authorized Study Staff 2) Authorized Study Staff & Support Personnel	1) Securely stored in the PI's locked office 2) Secure online database (REDCap)	1) Destroyed upon completion of data collection verification 2) REDCap database will be archived once results have been published
Devices: **CGMs** **CGM Readers** **Tablets**	- N/A	- Authorized Study Staff	- Stored in the PI's locked office when not in use	- N/A

27. PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF SUBJECTS

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Procedures to Protect Subjects:

- To make participants feel at ease, Study Staff will clearly explain the function of the ED care coordination program and the CGM if applicable
- Participants will be informed that they can remove or the CGM at any time if they feel uncomfortable or have concerns, and can skip any question in the questionnaires that they feel uncomfortable answering.
- Study Staff will remind participants that their participation is voluntary and withdrawal of participation at any time will not involve any penalty or loss of benefits to which they are otherwise entitled.
- Participants will be offered copies of all signed forms *(Consent* and *HIPAA Authorization)* and given contact information for Study Staff should they have any questions or concerns at any time while wearing the CGM, or if they wish to withdraw from the study.
- Study Staff members directly involved with recruiting and consenting participants will not be involved in their clinical care.

- The collection of sensitive information (e.g., questions regarding substance use history) will be limited to the information that is necessary to conduct this research.

Protected Health Information:

- A *HIPAA Waiver of Authorization* has been obtained to allow Study Staff to query EMRs to identify eligible participants for recruitment *(see Section 24)*.
- Following consent, a signed *HIPAA Authorization* will be obtained to access and record additional information from the participant's EMR. This information will be limited to information directly related to the study.

28. Compensation for Research-Related Injury

No funds have been set aside for research related injury.

29. Economic Burden to Subjects

There are no anticipated costs for which participants will be responsible because of participation in this research. Follow-up visits in the DCOE will take place as part of routine clinic care. Any charges associated with the CGM, such as physician interpretation of the CGM, will be covered by the study.

30. Consent Process

Study Staff Education: Only Study Staff with prior approval who have reviewed **HRP-802 Informed Consent** will be obtaining consent.

Consent Process:

- We will be obtaining informed consent.
- All of the potential risks, reasoning, and goals of this research will be explained to each individual prior to obtaining consent. They will be informed that enrollment is voluntary and declining to participate will not affect their treatment. Ample time will be given to answer any questions and they will be informed that they may opt out of this voluntary study at any point.
- All consent will be collected electronically via the Redcap application. Patients will be able to review, sign, and date consent electronically
- -A printed copy of the consent will be provided to patients after the electronic signature
    - The electronic consent document/process allows subjects to proceed forward or backward or pause for review later if they choose.
    - Several measures are present to ensure that subjects have access to all of the consent related materials, including hyperlinks or other external documents. These measures include active guidance from the study team while reviewing the consent form to point out salient sections and key language, and access to paper

copies of all relevant documents that patients may need to make their decision about participation. Patient will be allowed to read a paper copy of the consent before signing electronically if they prefer.

Non-English Speaking Patients

- The full consent form and all subject facing materials will be available in Spanish
- Recruitment and consent will be obtained with assistance from live or video/audio certified medical interpreters who will also be available at all follow up visits

31. Process to Document Consent in Writing

Study Staff Education: Only Study Staff with prior approval who have reviewed **HRP-803 Documentation of Informed Consent** will be obtaining consent.

Documentation of Consent: Informed consent will be documented in writing for patient subjects. Written consent will not be obtained for provider subjects as the study activities for this cohort entail less than minimal risk and do not entail any activities that would normally require written consent outside of the research setting. We request a waiver of written consent for provider subjects.

32. Drugs or Devices

Abbott Libre 2

→ The device is FDA-approved for people with type 1 and type 2 diabetes

→ The device does not qualify as an implant or life-sustaining device, nor does it pose a serious health risk to study participants. Therefore, the E4 meets requirements for a non-significant risk device under **FDA 21CFR 812.2(b)**.

- ***Additional Device Information:*** The Abbot Libre 2 *(Figure 3)*, which is a clinical grade commercially available device, is a small disk (1.38 inches in diameter and 0.2 inches thick), and it weighs 0.18 ounces. After it is placed, a small (less than 0.4mm thick) sensor probe (not sharp) remains in the skin and can transmit continuous glucose data to a reader. The device can be submerged in water, and can be worn continuously for up to 2 weeks.
- The device can wirelessly stream data to a smart phone application or dedicated reader device Bluetooth

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