**Use of Continuous Glucose Monitors in COVID-19 ICU and Potential Inpatient Settings**

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**PROTOCOL TITLE:**
Use of Continuous Glucose Monitors in COVID-19 ICU and Potential Inpatient Settings

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☐ Division of Critical Care Medicine
☐ Harrington Heart and Vascular Institute

**DATE**:
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## Objectives

● To improve glycemic control in inpatient/ICU settings using real- time continuous glucose monitors (CGM) data for insulin titration.
● To use (CGM) as a means to reduce COVID-19 patient contact with healthcare workers

## Hypothesis

● Use of real time and retrospective data of CGM can be utilized with inpatients/ ICU settings to increase time spent in target glycemic range (1).
● CGM real time data access can reduce frequency of healthcare worker exposure to COVID- 19 patients without compromising glycemic control.

## Background

Due to the increasing need for acute care of COVID-19 patients in ICU settings, the use of continuous glucose monitors (CGM) as a means to reduce patient contact and remotely improve glycemic control for diabetic COVID-19 patients' needs to be explored. As demonstrated by recent data published in China, Wuhan province patients with diabetes made up 22.2% of COVID-19 ICU patient populations with a subsequent mortality of 7.3% (3). Not only during COVID-19 pandemic but also previous experiences with SARS and influenza viral respiratory infections demonstrated increased mortality in those patients with hyperglycemia (4).

Using CGMs provides timely access to glucose trends, commonly used to determine insulin dosing decisions in outpatient settings (5). Implementing their use for hospitalized patients could be expected to improve healthcare worker insight into glycemic control therapies.

Considering the ease of transmission of the SARS-Cov-2 virus, it is important to minimize duration and frequency of patient contact in order to maintain the safety of COVID-19 healthcare workers without compromising on their glycemic control. On April 1st 2020, the FDA released a statement to announce that they "will not object" to the use of CGM's in COVID-19 positive hospital patients. The WHO recommends that any healthcare provider coming into direct contact with COVID-19 patients should be utilizing appropriate personal protective equipment (PPE) for each encounter. In this time of limited PPE supply (6), remote glucose monitoring can allow for rational use of these limited resources. With appropriate training on CGM data interpretation, nursing and ordering providers could expect to develop and implement more efficient insulin plans, requiring less frequent physical contact with COVID-19 positive patients.

## Inclusion and Exclusion Criteria

### Inclusion Criteria for COVID 19 Participants

1. COVID-19 tested positive patient
2. Age over 18 years
3. Admitted to COVID-19 specific ICU, with possible transfer to inpatient unit when stable
4. Patients with known or acquired Type 1 or Type 2 Diabetesrequiring insulin therapy during admission
5. Patients who already have or may require CGM use

### Exclusion Criteria for COVID 19 Participants

1. In state of active diabetic ketoacidosis (DKA) at time of enrollment
2. Two or more vasopressors in use at time of sensor placement
3. Unable to use at predetermined sensor site based on assessment of skin health

**Inclusion Criteria For Heart Failure ICU Patients**

1. Age over 18 years
2. Admitted to Heart Failure ICU, with possible transfer to inpatient unit when stable
3. Patients with known or acquired Type 1 or Type 2 Diabetes requiring insulin therapy during admission

**Exclusion Criteria For Heart Failure ICU Patients**

1. In state of active diabetic ketoacidosis (DKA) at time of enrollment
2. Two or more vasopressors in use at time of sensor placement
3. Unable to use at predetermined sensor site based on assessment of skin health

# Number of Research Participants

We will enroll 46 subjects at UHCMC and plan to enroll 100 subjects study wide. Approximately 18 patients from UH Ahuja Medical Center, 18 from UH Geauga Medical Center, and 18 from UH Portage Medical Center are intended to make up the remaining 100 participants.

Out of the 46 at UHCMC, 6 participants will be enrolled from UHCMC heart failure ICU to provide a nonCOVID-19 participant set. Heart failure and COVID-19 participants will be enrolled concurrently.

# Recruitment Methods

1) Patients will be selected from the COVID-19 specific ICU patient population or Heart Failure ICU, identified as requiring frequent glucose monitoring for insulin management by their critical care providers. Patients in the COVID-19 ICU who already have or may require CGM use, should be selected for recruitment. Of note, Heart Failure ICU patients are not covered under the FDA's non-objectionable use of CGM statement due to their COVID negative status. Heart Failure ICU participants will only have access to CGM after consented enrollment into study.

2)Critical care team will contact the study personnel via phone and pager numbers or Doc Halo secure messaging available 24hrs a day, 7 days a week. Study personnel will review patient EMR to evaluate for inclusion/exclusion criteria.

3) To promote physician to physician recruitment, flyers will be posted within the COVID ICU at the reception desk and 4 provider workstations in plain view for providers who may wish to contact study personnel. This flyer includes inclusion/exclusion criteria, brief study summary, and study personnel contact information.

4) Evaluation of decision making capacity of potential participants. If the participant has met the inclusion criteria, they will then undergo the assessment for decision making capacity. This will be conducted by study personnel asking the following questions:

*1. Is the participant alert and able to communicate with the investigator/study team?*
*2. Is the participant sufficiently comfortable to be able to communicate?*
*3. Is the participant medically stable such that a consent process is feasible?*

If the participant is unable to complete any of these three steps, the study team will consider whether it is possible to return to the potential participant to repeat the assessment within 24 hours. If not possible, then the study team will call upon the legally authorized representative (LAR)/next of kin of the potential participant to consent. The contact information of the LAR/next of kin will be obtained from the primary ICU team of the potential participant.

If the potential participant fulfills all three decision making criteria, and the study team has established the method of communication, the study team will engage in the consent process with the potential participant if he/she is willing.

· If the individual declines, no further engagement is pursued.

· If the individual agrees, we will conduct a post-consent quiz following the consent process and we will document the results of the post-consent quiz.

o If the potential participant does not pass, the study team will review the material with the individual and re-administer the quiz one more time.

o If the individual does not pass the second time, but is still interested in participating, the legally authorized representative of the potential participant will be sought.

The post-consent quiz: (participant will have to answer all 4 questions correctly to pass)
1) “Can you tell me what will happen if you decide to be in this study?”
2) “How will being in this study help you?”
3) “Can anything bad happen to you by being in the study?”
4) “What do you need to do (who do you talk to) if you change your decision?”.

At this point, the investigator establishes whether the participant has the decision making capacity or not. A written consent will be obtained by following the study consent process, once the patient is established to have capacity and agreeable to participate in the study.

If the patient is not able to provide written consent due to mechanical issues in writing a verbal consent will be obtained in the presence of a witness. The signature of the witness will be obtained as well.

The investigator will continue once daily assessment of participants' decision making capacity. This will be repeated until the completion of study participation. Should the participant regain decision capacity, the consent process will be repeated directly with the participant.

5) COVID-19 Recruitment:

The study personnel will approach the patient who has met the inclusion criteria via their hospital phone or cell phone to reduce PPE use. The study team will introduce the study, allow for any questions, and see if the patient is interested. If they are, the potential participant will be provided a full IRB-approved informed consent document. This will be transmitted by email or text as a link to RedCap full consent form. The potential participant may receive a paper copy on request, which will be transferred to them by their nurse upon next planned room entry. The study team will arrange a mutually convenient time for a full informed consent process with the potential participant. The platform doxy.me will be utilized for virtual interaction. At the arranged virtual meeting time, the study team member who will be consenting sends a text message or email “invitation” to the potential participant along with the REDCap e-consent link with the full consent form for the participant to view. Once both parties are on the virtual visit, the study team member will verify patient identification. The potential participant will be asked his/her full name and date of birth. Once identity has been verified, the full informed consent process will take place during the virtual visit. If the participant decides to enroll, an electronic signature can be obtained from the REDCap e-consent link during the virtual visit. If the potential participant is unable to utilize the electronic format signature, he/she can sign a paper copy during the virtual visit and can take a picture of the signature page and send that to the study team at the end of the virtual visit.

6) Heart Failure ICU Recruitment:

The study personnel will approach the patient who has met the inclusion criteria in their ICU room to introduce the study and give the patient a paper copy of the consent form to review. The review of the consent form will be done in the patient's room. The patient will be given more than 1 hour to review the consent form and study details in private. The patient and study personnel will set a time window for return to the ICU room the same day for review and discussion of the study. The study personnel will return to the patient's room at the previously set appointment time. If the participant decides to enroll, the consent process will take place.

7) Adults unable to consent/ LAR/next of Kin Recruitment:

The study personnel will approach the LAR/Next of Kin for the potential participant who has met the inclusion criteria by telephone number. The identity of and contact information for LAR/Next of Kin will be obtained from the critical care team. The potential participant's LAR/ next of kin will be provided a full IRB-approved informed consent document. This will be transmitted by email or text as a link to RedCap full consent form. The study team will arrange a mutually convenient time for a full informed consent process with potential participant's LAR/ next of kin. The platform doxy.me will be utilized for virtual interaction. Once the time is arranged ahead, the study team member who will be consenting sends a text message or email "invitation" to the LAR/ next of kin of the potential participant along with the REDCap e-consent link with the full consent form. Once both parties are on the virtual visit, the study team member will verify LAR/next of kin's identification. The potential participant's LAR will be asked his/her full name, date of birth, and to display their driver's license. If not available, any state or government-issued picture identification card is allowed. Once identity has been verified, the full informed consent process will take place during the virtual visit. If the participant decides to enroll, an electronic signature can be obtained from the REDCap e-consent link during the virtual visit. If the LAR/next of kin is unable to utilize the electronic format signature, he/she can sign a paper copy during the virtual visit and can take a picture of the signature page and send that to the study team at the end of the virtual visit.

## Setting

1) UH CMC, potentially UH Ahuja Medical Center, UH Geauga Medical Center, and UH Portage Medical Center

2) In the COVID specific ICU and Heart Failure ICU, patients will be identified and recruited as potential research participants.

## Consent Process

Consent Process for COVID positive patients:

● The study personnel will approach the patient who has met the inclusion criterion at their ICU room from outside the door by calling their room phone or personal cell phone.
● Patient will view electronic consent form and video chat on their personal smart phone or on an ipad from the ICU. Nurse will bring in ICU ipad at next planned room entry.
● At this point, the potential participant will be provided a full IRB-approved informed consent document. This will be transmitted by email or text as a link to RedCap full consent form. The potential

participant may receive a paper copy on request. In the case of COVID ICU, the nurse will hand the patient the consent form at the next planned room entry.

- The study team will arrange a mutually convenient time for a full informed consent process with the potential participant.
- The platform doxy.me will be utilized for virtual interaction. Once the time is arranged ahead, the study team member who will be consenting sends a text message or email "invitation" to the potential participant along with the REDCap e-consent link with the full consent form for the participant/LAR to view.
- Once both parties are on the virtual visit, the study team member will verify patient identification. The potential participant will be asked his/her full name and date of birth.
- Once identity has been verified, the full informed consent process will take place during the virtual visit. If the participant decides to enroll, an electronic signature can be obtained from the REDCap e-consent link during the virtual visit.
- The consent discussion will include:
    - Key ideas of the study
    - Key study procedure
    - Alternatives to study participation
    - Risks of study participation
    - Benefits of study participation
    - Financial cost or reimbursement (which is none)
- If the patient needs more time to read/review the full consent form, the patient and study personnel will set a time window for resuming virtual consent. Flexible time window set to allow for patient occupied by procedure or imaging.
- Patient will be asked to summarize the key ideas and key procedures of the study to confirm comprehension.
- If the potential participant is unable to utilize the electronic format signature, he/she can sign a paper copy during the virtual visit and can take a picture of the signature page and send that to the study team at the end of the virtual visit.
- Study personnel will co-sign form thereafter.
- Should the patient elect not to participate, their questions will be answered regarding alternatives to participation.

Consent process for Heart Failure ICU

- The study personnel will approach the patient who has met the inclusion criterion in their ICU room
- A paper copy of the consent form will be provided to the patient, this will then be read together with the patient and study personnel
- The consent discussion will include:
    - Key ideas of the study
    - Key study procedure
    - Alternatives to study participation
    - Risks of study participation
    - Benefits of study participation
    - Financial cost or reimbursement (which is none)
- If the patient needs more time to read/review the full consent form, the patient and study personnel will set a time window for return to the ICU room the same day for further review and discussion of the study. Flexible return window set to allow for patient occupied by procedure or imaging.
- Patient will be asked to summarize the key ideas and key procedures of the study to confirm comprehension.

● Study personnel will collect the patient's signature once all questions are answered and if the patient agrees to consent.
● Study personnel will co-sign form thereafter.
● Should the patient elect not to participate, their questions will be answered regarding alternatives to participation.

Consent Process for adults Unable to Consent
● The study personnel will approach the LAR/Next of Kin for the potential participant who has met the inclusion criteria by telephone number. The identity of and contact information for LAR/Next of Kin will be obtained from the critical care team.
● The study team will arrange a mutually convenient time for a full informed consent process with the potential participant's LAR/Next of Kin.
● The platform doxy.me will be utilized for virtual interaction. Once the time is arranged ahead, the study team member who will be consenting sends a text message or email "invitation" to the LAR/next of kin along with the REDCap e-consent link with the full consent form for the LAR to view.
● LAR/next of kin will view electronic consent form and video chat on their personal video chatcapable device, such as a smartphone.
● Once both parties are on the virtual visit, the study team member will verify patient identification. LAR/ next of kin will be asked his/her full name, date of birth, and to display their driver's license. If not available, any state or government-issued picture identification card is allowed.
● Once identity has been verified, the full informed consent process will take place during the virtual visit. If the participant's LAR decides to enroll, an electronic signature can be obtained from the REDCap e-consent link during the virtual visit.
● At this point, the potential participant's LAR/Next of Kin will be provided a full IRB-approved informed consent document. This will be transmitted by email or text as a link to RedCap full consent form.
● The consent discussion will include:
    ○ Key ideas of the study ○ Key study procedure
    ○ Alternatives to study participation ○ Risks of study participation
    ○ Benefits of study participation
    ○ Financial cost or reimbursement (which is none)
● They will be asked to summarize the key ideas and key procedures of the study to confirm comprehension.
● If they are unable to utilize the electronic format signature, they can sign a paper copy during the virtual visit and can take a picture of the signature page and send that to the study team at the end of the virtual visit.
● Study personnel will co-sign form thereafter.
● Should the LAR/Next of Kin elect not to participate, their questions will be answered regarding alternatives to participation.

## Sharing of Results with Research Participants

The CGM data collection and interpretation will be shared with the staff of the department of endocrinology and COVID or Heart Failure critical care team involved in the direct care of the study participant.

☐ Results will not be shared with research participants
☐ Results will not be shared with research participants' doctors

## Study Design

Prospective, pragmatic real time study investigating off-label device application

## Study Procedures

- Prior to CGM implementation by non-study personnel, COVID ICU or Heart Failure team involved in use and interpretation of CGMs will be given training lectures via WebEx for remote viewing. Lectures are created by study personnel and Dexcom. These lectures will be made available on WebEx several times each week so that involved team members may participate at their convenience, but before they use Dexcom G6 device with a patient in their care.
- Patients will be selected from the COVID-19 specific or Heart Failure ICU patient populations, identified as requiring frequent glucose monitoring for insulin management by their critical care providers.
    - Critical care team will contact the study personnel via phone and pager numbers or Doc Halo secure messaging available 24 hours a day, 7 days a week. Study personnel will review patient EMR to evaluate for inclusion/exclusion criteria.
    - Flyers describing the study with study personnel contact information will be placed in ICU workspace for employee viewing.
- Patients in the COVID-19 ICU who already have or may require CGM use, will be selected for recruitment. Heart Failure ICU participants will only have access to CGM after consented enrollment into study.
- Study personnel will follow the consent process as described above.
- The COVID ICU staff trained by study personnel will perform the following steps:
    - Transmitter ID syncing
        - Enter “SN” number on the back of the transmitter into the display device before entering patient’s room
    - Sensor Placement
        - No numbing agents are required for sensor placement
        - The ICU healthcare provider will need to wash their hands and wear PPE as per COVID ICU protocol and gloves in the Heart Failure ICU.
        - The insertion site is cleaned with an alcohol pad at the point of an imaginary line of the mid axillary at the level of the umbilicus. Let dry.
        - The applicator is taken from the sensor packaging. The Sensor packaging is kept until the sensor session is complete.
        - The sensor is checked for damage
        - The adhesive labels are pulled off while not touching the adhesive.
        - The applicator is placed horizontally, not vertically, on skin.
        - The adhesive is firmly pressed down to the cleaned skin.
        - The safety guard is folded and broken from the applicator and thrown away.
        - The insertion button is pressed and released to insert the sensor.
        - The applicator is removed and thrown out.
    - Transmitter Attachment
        - The bottom of the transmitter is wiped with alcohol wipe and allowed dry. The metal dots on the bottom should not be touched other than alcohol wipe.
        - The transmitter tab is then slid into the slot at the narrow end of the holder on the sensor patch.
        - The wide end of the transmitter is pressed until it clicks into the holder.

        ■ It is secured in place by rubbing fingers around the adhesive patch three times.
    ○ Glucose data transmission
        ■ After the insertion of the sensor and attachment of the transmitter, the transmitter will automatically pair with the display device via bluetooth connection.
        ■ The sensor will have a 2 hour warmup period before glucose data is collected. After warm up Dexcom data will include only interstitial glucose levels, which are recorded every 5 minutes by display device
        ■ The ICU staff will be prompted by display device to do initial calibration based on finger stick glucose once the 2-hour warmup is finished, then calibrate every 24 hours after that time as prompted by display device.
        ■ The ICU staff will record CGM glucose data as displayed on CGM receiver into the "Point of Care" free text flowsheet every 2 hours in the patient's chart
        ■ The ICU nursing staff will additionally collect point of care finger glucose readings every 4 hours or as they are scheduled to enter the patient's room for standard of care in ICU setting.
        ■ CGM data is saved in the receiver component of the device until downloaded at the end of device use. Download will be saved as an electronic copy with participant's anonymised ID code as the file name. This file will be stored in the secured shared drive accessible only to study personnel.

● CGM sensor will transmit glucose data in real-time to the receiver placed within a 20 foot distance from the patient on the glass door outside the ICU room. Glucose data can then be viewed in real time by the healthcare team.
● Dexcom will also provide glucose telemetry software which will allow for remote viewing of glucose data from all the patients on CGM.
● The sensor is a single use, disposable device while the transmitter and the display device will be cleaned with alcohol and glucose data downloaded and cleared from the device between participants. This data download is facilitated via Dexcom Clarity App.
● CGM sensors may be worn for a maximum of 10 days at a time throughout the participants' ICU admission. If a patient's ICU stay exceeds 10 days, the sensor will be removed by peeling off the adhesive. Nurse will replace it with a new sensor on the patient's opposite side at the point of an imaginary line of the mid axillary at the level of the umbilicus. The same transmitter is reattached to the new sensor after being clean with alcohol wipe. 2 hour warm up period will repeat and use of CGM will resume as before. Total maximum use for study purposes is 20 days (2 sensor uses).
● Point of care finger glucose readings will be collected every 4 hours. Of these, one fingerstick reading daily will be used for calibration of CGM device at the time prompted by CGM receiver.
● Any CGM glucose readings suggestive of hypoglycemia measuring less than 70 mg/dL, provider/nurse is to confirm with fingerstick glucose reading, then treat according to UH hypoglycemia protocol.
● Any CGM glucose readings suggestive of hyperglycemia measuring greater than 300 mg/dL, care provider is to confirm with fingerstick glucose reading, notify ordering provider then treat according to insulin order placed by care team.
● Enrolled participant's information will be collected from UH Inpatient EMR. This information will include patient name, MRN, DOB, height, weight, gender, ethnicity, type of diabetes and diabetic complications, past medical history of lung disease or cancer, home diabetic medications, in-hospital diabetic medications, history of smoking and alcohol use, symptoms on admission to the hospital, daily vital signs, blood electrolytes, chemistries including renal and

hepatic function, Coronavirus test results, blood cell counts, Hemoglobin A1c, laboratory blood glucose, finger stick glucose, daily insulin requirement, inotropic support, mechanical ventilation status, renal replacement therapy, antibiotic and glucocorticoid use, length of hospital stay, length of ICU admission, imaging modalities used, any adverse events including hypoglycemia and death.

● At the removal of each CGM device, the sensor will be discarded and the transmitter along with the receiver/display device will be cleaned with alcohol pads appropriately before using it with another patient.

● Imaging considerations

○ CGM should not be used during MRI. Both the transmitter and the sensor must be removed prior to MRI.

○ It is not harmful to the patient to wear a CGM during x-ray or CT scan. In order to maintain sensor and transmitter integrity, these devices should be shielded with lead during CT or x-ray, so long as the intended imaging field is not disrupted.

## Study Timeline

● Each study subject will be included for a minimum of 24 hours and maximum of 20 days. If patient's ICU stay exceeds 20 days, the ICU care team may elect to continue CGM use, but no further CGM data will be downloaded or preserved for study purposes.

● Data will be downloaded at the end of each CGM device use for each individual study participant.

● Study will be conducted until the minimum goal of 46 subjects is reached.

## Data to be collected for your study (AFTER consent and HIPAA Authorization have been obtained)

- % of time spent in target glucose range of 140-180mg/dL
- Variability of glucose level between CGM, POCT glucose, and serum lab glucose level
- Duration of hospital stay vs % time spent in target glucose range
- % time spent in hypoglycemia (< 54mg/dL)
- % of time spend in low (180mg/dL)
- Number of hypoglycemic excursions (sensor = 20 minutes)
- Glucose variability assessed by:
    - %coefficient of variation (%CV)
    - Mean absolute glucose (MAG)
    - Low blood glucose index
- In hospital mortality
- length of ICU stay
- total admission duration
- Point of care glucose

-venous blood glucose

- Reduction in patient contact for exclusive purpose of glucose measurement/intervention as compared to q2hr, q4hr, and q6hr POCT glucose checks
- Enrolled participant's information will be collected from UH Inpatient EMR. This information will include patient name, MRN, DOB, height, weight, gender, ethnicity, type of diabetes and diabetic complications, past medical history of lung disease or cancer, home diabetic medications, in-hospital diabetic medications, history of smoking

and alcohol use, symptoms on admission to the hospital, daily vital signs, blood electrolytes, chemistries including renal and hepatic function, Coronavirus test results, blood cell counts, Hemoglobin A1c, laboratory blood glucose, finger stick glucose, daily insulin requirement, inotropic support, mechanical ventilation status, renal replacement therapy, antibiotic and glucocorticoid use, length of hospital stay, length of ICU admission, imaging modalities used, any adverse events including hypoglycemia and death.

## Data Analysis Plan

Each patient's CGM data will be aggregated (e.g., across repeated measures) by Dexcom Clarity App. As a largely descriptive study, standard summary statistics will be computed. Means and standard deviations will be used to summarize the primary outcome (% of time spent in target glucose range of 140-180mg/dL) as well as all other continuous variables. Frequencies and percentages will be used to summarize categorical variables. Poisson regression will be used to determine whether use of CGM reduced the number of times healthcare workers were in contact with COVID-19 patients compared to q2hr, q4hr, and q6hr POCT glucose checks. Univariate and multivariate regression models will be used to explore potential associations between % of time spent in target range and secondary outcomes (e.g., length of stay in the hospital and ICU) while controlling for relevant covariates.

## Risks to Research Participants

Sensors may fracture on rare occasions. There is a potential rare risk of sensor breakage and part of it may remain under the skin causing symptoms of infection or inflammation—redness, swelling or pain— at the insertion site. (8) CGM sensor readings may be affected by some of the conditions seen in ICU patients. Volume contraction, renal dialysis, use of vasopressor medications, and metabolic acidosis are examples of physical conditions which may impact sensor readings. In the event that CMG data is discordant to clinical presentation, an alternate glucose reading from fingerstick or lab will be considered. There is also a risk of breach of confidentiality.

### Protect the Privacy Interests of Research Participants

Primary identification for recruitment will be provided by the critical care team directly related to the patient's care. These patients will be presented to study personnel for evaluation of inclusion/exclusion criteria confirmation. Once confirmed as a potential participant, an anonymised code will be assigned to that patient's MRN. The anonymised code log sheet will be maintained only in a secured shared drive. Confidentiality of data will be preserved during data transmission via the use of anonymised codes. Participants will be assigned codes based on order and location of enrollment. Identifiable personal information will be stored securely in a locked room at the Department of Endocrinology at UHCMC. Electronic versions will be saved on a desktop computer at University Hospitals using password protected security measures. Data will be accessible only to the Research Team and for audit in a secured shared folder.

## Potential Benefit to Research Participants

Benefit for COVID- 19 positive participants

- Increased frequency of glucose monitoring may improve insulin management
- Opportunity for the participants to learn about a device which you may use at home if covered by health insurance.
- Alerts offer improved glycemic variation awareness
- Help to establish effective inpatient methods of CGM use for general diabetic patient admissions
- Potential benefit to healthcare providers by reducing exposure to SARS-CoV-2 virus

Benefits for COVID-19 Negative participants (participants in HFICU)

- Detailed information about glucose patterns available to healthcare team which may improve insulin management.
- Opportunity for the participant to learn about a device which you may use at home if covered by health insurance.
- Alerts offer improved glycemic variation awareness
- Help to establish effective inpatient methods of CGM use for general diabetic patient admissions

## Withdrawal of Research Participants

If the subject has serious event related to study
Investigator initiated discontinuation due to participation or equipment concerns
Patient withdrawal of consent
Data collected up until the point of withdrawal may be included in the study
Patient no longer requires glucose monitoring for their care

## Alternatives to Participation

Patient may elect to use POCT finger stick glucose measurement 4 to 6 times daily
Patient may use CGM for glucose monitoring without permitting data download
Alternative not to participate

## Costs to Research Participants

There is no monetary cost to participants. Cost of study supplies will be funded by the Department of Critical Care Medicine.

## Research Participant Compensation

Participants will not receive any monetary compensation for their participation.

## Provisions to Monitor the Data to Ensure the Safety of Research Participants

1. Study principal investigator will be responsible for monitoring the data weekly for completeness, accuracy, and adherence to the protocol.

2. There will not be a Data and Safety Monitoring Board or Committee.

## Drugs or Devices

Dexcom G6 Personal CGM

## Community-Based Participatory Research

This study is in the inpatient setting only so this does not apply to our study.

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