Study Title: Does the use of continuous glucose monitoring (CGM) in the immediate postpartum period in women with pregestational diabetes admitted to the hospital decrease hypoglycemic episodes?

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PI: Andrea Greiner, MD

INFORMED CONSENT DOCUMENT

Project Title: **Does the use of continuous glucose monitoring (CGM) in the immediate postpartum period in women with pregestational diabetes admitted to the hospital decrease hypoglycemic episodes?**

Principal Investigator: Nicole Masse

Research Team Contact: Nicole Masse (319-356-7189)

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you are a type I or type II diabetic and are currently pregnant.

The purpose of this research study is to determine if the use of continuous blood glucose monitors during hospitalization in the immediate postpartum period is more effective at identifying hypoglycemia when compared to traditional point of care glucose testing.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 40 will take part in this study conducted by investigators at the University of Iowa.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for the duration of your inpatient postpartum stay after delivery of your child which will be approximately 48-72 hours.

WHAT WILL HAPPEN DURING THIS STUDY?

If you opt to participate in this study, a continuous blood glucose monitor (CGM) will be placed following your arrival to labor and delivery for delivery of your infant. Glucose values from the CGM device will then be available to your nurse through the Samsung phone with a CGM share/follow app. Your nurse will be able to see your current glucose data and would receive alarms to indicate hypoglycemia or impending hypoglycemia. Your nurse will be provided with instructions on how to appropriately respond to the alarms. Your nurse will continue to perform standard of care blood glucose

monitoring per routine hospital protocol but will also obtain a finger stick to validate a blood glucose level whenever a low CGM alarm sounds. Low blood glucose values <70 mg/dl will be treated per nursing policy. Monitoring of blood sugars through the CGM device will continue throughout your postpartum hospital stay. The CGM device will be removed prior to discharge from the hospital.

No additional long-term follow up will be needed.

We will collect information from your medical chart about: type of pregestational diabetes (DM1 vs DM2), blood glucose values, number of hypoglycemic events, number of times treated for hypoglycemia.

Your information collected as part of this research, even if identifiers are removed, will not be used or distributed for future research studies.

Data will not be used for commercial purposes.

WILL I BE NOTIFIED IF MY [DATA\BIOSPECIMENS\IMAGES] RESULT(S) IN AN UNEXPECTED FINDING?

We may learn things about you from the study activities which could be important to your health or to your treatment. If this happens, you can decide whether you want this information to be provided to you. If you choose to have this shared, you will be informed of any unexpected findings of possible clinical significance that may be discovered during review of results from your point of care glucose monitoring collected through the CGM device. The results from the **data]** we collect in this research study **are not]** the same quality as what you would receive as part of your health care. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as feeling worried about a finding for which no treatment is available). The CGM device will alert your nurse of a low blood sugar concerning for hypoglycemia. If this occurs, a standard point of care glucose fingerstick will be measured. If hypoglycemia if confirmed on point of care testing, you will be treated for hypoglycemia per our standard of care protocol.

The data will**]** be reviewed by a physician who normally reads such results and they will inform us if there are any unexpected findings. We will provide you with this information so that you may discuss it with your primary care physician. However, if you believe you are having symptoms that may require care prior to receiving any information from this study, you should contact your primary care physician. The study team/study will not cover the costs of any follow-up consultations or actions.

Please initial one of the following options:

_____ Yes, I want to be provided with this information.
_____ No, I do NOT want to be provided with this information.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Risks related to this study are rare. Potential risks include irritation from placement of the CGM device and the potential risk for infection. If you were to experience irritation from the CGM device, the device will be removed immediately, and you will be excluded from the study. To minimize the risk of infection from the CGM device, the skin area is cleaned with an alcohol swab prior to placement of the device. If there are concerns for a skin infection from the CGM device, the CGM device will be immediately removed. There is also a risk of loss of confidentiality of data. Measures in place to minimize this risk are indicated in the 'What About Confidentiality' section later in this document.

WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will benefit from being in this study. If hypoglycemia is in fact detected sooner by your healthcare team using a CGM device (as compared to standard point of care testing), you may be treated for hypoglycemia more promptly which would potentially avoid severe hypoglycemic events.

In the future, other people might benefit from this study because use of a CGM during the postpartum period in hospitalized patients may result in more prompt treatment of hypoglycemia as compared to the standard point of care glucose testing.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could receive the standard of care treatment which includes the standard point of care glucose testing.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will be mailed a $25.00 e-voucher for participation in this study.

WHO IS FUNDING THIS STUDY?

The University and the research team are receiving a grant from the Swift Family Foundation to conduct this research study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- The University of Iowa does not plan to provide free medical care or payment for treatment of any

illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will be collecting the minimal amount of data needed to answer the research question. All records containing protected health information will be transported in a manner that no identifiable information is visible. All hard copy material will be kept in a secure office within a locked cabinet. Electronic data will be collecting by reviewing your medical chart through EPIC. All protected health information will be stored through REDCAP a secure web-based interface for storing study information. At the end of the study, all study material will be destroyed. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

The University of Iowa Hospitals and Clinics generally requires that we document your participation in research occurring in a University of Iowa Health Care facility. This documentation will be in either your medical record or a database maintained on behalf of the institution reflecting that you are participating in this study. The information included will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires University of Iowa Health Care to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study and for your treatment. Once University of Iowa Health Care has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes University of Iowa Health Care to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Nicole Masse MD in the department of OBGYN at 200 Hawkins Drive, Iowa City 52242. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I Decide to Drop Out of the Study?

If you decide to leave the study early, we will ask that are nurses remove the continuous glucose monitor and you will be excluded from the study.

Will I Receive New Information About the Study while Participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can Someone Else End my Participation in this Study?

Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen if we determine it is unsafe for you to continue wearing the CGM device (i.e. in the event of an adverse skin reaction or a skin infection) you develop an adverse skin reaction or skin infection from the continuous glucose monitor.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Nicole Masse MD at (319) 356- 7189. If you experience a research-related injury, please contact: Nicole Masse MD at (319) 356- 7189.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences,

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600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

_____

Subject's Name (printed):

_____

(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____

(Signature of Person who Obtained Consent) (Date)