SANSUM DIABETES
RESEARCH INSTITUTE

Name and Clinic Number

Approval Date: **October 23, 2020**
Not to be used after: **October 22, 2021**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Observational study of patient important outcomes in pregnant patients with type 1 diabetes mellitus on Insulin pump

IRB#: 18-007081

Site Principal Investigator: Dr. Jordan Pinsker

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. You will also be asked to review and sign a separate document titled "Experimental Subjects Bill of Rights" when first consenting to participate in this study. You will receive a copy of this signed and dated consent document, as well as a copy of your signed State of California "Experimental Subject's Bill of Rights" after completing it.

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CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigator: Dr. Jordan Pinsker **Study Team Contact:** Molly Piper	**Phone:** (805) 682-7640 ext 257 24 Hour Cell: (301) 830-0274 **Phone:** (805) 682 -7640 ext 214 **Institution Name and Address:** Sansum Diabetes Research Institute 2219 Bath St. Santa Barbara, CA 93105	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant
Research Subject Advocate **(The RSA is independent of the Study Team)**	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information

Other Information:

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

A description of this research study will also be available on https://www.mayo.edu/research/clinical-trials. This website will not include information that can identify you. You can search this website at any time.

1. Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you have type 1 diabetes (T1D), you are wearing or in the process of being trained to wear an insulin pump and you are pregnant. The goal of this research is to gather data regarding the changes which occur to your blood sugars and insulin requirements throughout your pregnancy. These data will be compared to a group of participants using an artificial pancreas system. We will also collect data about outcomes of your pregnancy and health status of your baby.

2. Why is this research study being done?

The purpose of this study is to gather information on insulin requirements and blood sugar levels during pregnancy. Pregnancy in T1D is associated with an increased risk of complications for mother and baby. High blood sugar levels in the mother increases this risk. Insulin requirements also change during pregnancy. The details of how these changes occur needs further study. This information will be used in the future to develop artificial pancreas algorithms, to compare your results to future study results of participants using artificial pancreas systems, and to provide additional information on glucose sensor satisfaction and results in pregnant women in comparison to finger stick levels.

3. Information you should know

Information Regarding Conflict of Interest:

Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

4. How long will you be in this research study?

You will be in the study until the end of your pregnancy, including one post-delivery visit, which is typically 6 weeks after delivery.

5. What will happen to you while you are in this research study?

If you agree to be in the study, you will be asked to participate in the following:

Screening visit:
After you provide informed consent, a study physician will perform a detailed history and physical examination with special emphasis on your diabetes history. We will record your body weight, height, and body mass index (BMI). Data from your insulin pump, blood glucose meters and continuous glucose monitor will be downloaded and archived using an electronic process to avoid data recording errors. We will obtain routine vital signs and collect information regarding your clinically available/ordered blood tests. This study is not meant to find out if the participant has any other diseases or problems. The study leaders will alert you if any of the research results are important to your health during the study.

You will be provided a study Dexcom G6 glucose sensor and supplies. You will be trained on proper insertion, calibration, and maintenance of the sensor (CGM). Training will be tailored to your individual experiences (which could include no prior CGM use or prior CGM use on different sensor).

You will be provided a study glucometer and supplies. You will be trained on the use of the meter including to perform fingersticks on clean, dry hands and to use only fingersticks for glucose assessments. You will be asked to perform finger sticks 8 times a day (before meals, after meals and bedtime) every 4 weeks throughout the study. We will also collect data from your glucometer throughout the study. The frequency of this will depend on your clinical team and your preference while using the Dexcom G6 system.

Follow up visits:
You will come to your regularly scheduled clinic follow up visits. Your usual care at these visits will not be affected. In addition, research staff will contact you every 14±4 days either coinciding with your regular visits for diabetes management or via phone. In addition, if you change pump settings, you will be asked to remotely upload your pump data.
CGM data and blood sugar (BG) readings will be downloaded at clinic and remotely for phone visits with the aim to have every week of pregnancy downloaded by the completion of the study. Food logs will be collected if available. Pregnancy complications will be recorded. At clinic visits, sensor sites will be inspected.

You will come to you regularly scheduled follow up visits which will occur monthly unless adjusted for medical reasons by you providers or for patient limitations. Hemoglobin A1C and/or fructosamine testing will be determined by the provider; records of blood draws will be collected.

Study personnel will be available at all times throughout the trial to answer any question or troubleshoot any sensor problem.

Postpartum visit:
After delivery, you will return study devices at the time of your routine post-partum follow up visit. Medical records including method of delivery, gestational age at delivery, neonatal intensive care unit (NICU) admissions, neonatal hypoglycemia, fetal weight, and length of hospital stay will be reviewed. You will also be asked to complete a survey about your satisfaction with CGM use. We hope that you will answer all of the questions, but you can skip any questions you don't want to answer. The questionnaires will take about 15 minutes to complete.

6. What are the possible risks or discomforts from being in this research study?

Risks associated with CGM sensor insertion include: bleeding (1.2%), swelling (0.2%), redness (0.5%), and bruising >1 cm (1.9%). Occasional participants may have sensitivity to adhesives associated with use of the CGM site resulting in skin irritation, redness, pain, blistering, scarring, systemic allergic reaction, or secondary skin infection.

Risks of BG testing include: pain at the site of lancet use (common), bleeding at the site of lancet use (expected), infection at the site of lancet use (rare), transmission of a communicable blood disease (rare if lancet used correctly and not shared) and incorrect information from a false low or false high BG reading (infrequent if following recommended procedures).

Risk of Device Reuse: the Dexcom G6 is labeled for single use only. The sensor (the component of the system that enters the skin) will be single use only. The transmitter and receiver may be reused. We will follow FDA guide on cleaning procedures for transmitters/receivers as part of the IDEs. The transmitter is attached to the sensor but does not enter the skin and the receiver is a hand held device. The transmitter and receiver will be cleaned adhering to FDA guide on cleaning procedures for transmitters/receivers.

Risk of emotional discomfort when answering items on questionnaires related to medical history, emotional status, or quality of life.

Risk of loss of privacy: The study team will make every effort to avoid compromising a participant's confidentially that may result in serious negative social, legal, or economic ramifications for the participant. The team will adhere to HIPAA regulations during this study.

Risk associated with enrolling pregnant subjects: Pregnant are at increased risk for hypoglycemia as they intensify glycemic control. Patient education and re-education and regular contact with study team will minimize risk of adverse events during the study.

Risk to fetus: The risk of congenital malformations is increased in women with T1D. Planned pregnancies have the potential to significantly decrease the risk. Glycemic control during pregnancy has the potential to decrease immediate risks such as large for gestational age babies, need for c-section, neonatal hypoglycemia, and long-term consequences such as obesity and early onset of type 2 diabetes.

7. Are there reasons you might leave this research study early?

If you decide to stop taking part in the study for any reason, we will ask you to make a final study visit. The final study visit will take about 1 hour. At this visit, we will:

- Collect your study devices,
- Download your pump,
- Collect the outcomes of your pregnancy
- And have you complete a survey about your satisfaction with CGM use.

In addition, the Principal Investigator, Mayo Clinic or Sansum Diabetes Research Institute may stop you from taking part in this study at any time:

- If it is in your best interest,
- If you don't follow the study procedures,
- If the study is stopped.

If you leave the research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

8. What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

9. What are the possible benefits from being in this research study?

This study may not make your health better. However, CGM use during pregnancy has been shown to improve time in range and decrease hypoglycemia in pregnant women with pre-existing T1D. There is the potential of benefit to participants from wearing the CGM, and having consultation and frequent contact with the study staff. Use of the CGM will provide predictive alarms indicating risk of hypoglycemia. The risk of hypoglycemia is often the number one fear

of patients who have T1D and often prevents optimal glycemic control. Therefore, there is a moderate short-term potential benefit and minimal risk for the participants.

10. What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

11. What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- *Dexcom G6 glucose sensor and supplies*
- *Study glucometer and supplies*

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

12. Will you be paid for taking part in this research study?

You will receive $10 per month for your participation in this study.

13. How will your privacy and the confidentiality of your records be protected?

Sansum Diabetes Research Institute is committed to protecting the confidentiality of information obtained about you in connection with this research study.

Information retrieved from patient's medical records will be kept confidential. Unless required by law, only the investigators as well as the institutional review board (IRB) will have direct

access to subject information. Collected personal information, research data, and related records will be coded, and this code will be used on all documents to prevent subject identification. Each patient will be assigned a unique code. One document only will relate patient identifiers to the unique codes. The principal investigator will ensure that this document is password-protected, and that both the document and the password are kept in a secure, private hard-drive. This document will be destroyed at the end of the research study. Subjects will not be identified in any publications or presentations that result from this study. Data will be entered into a separate database which will not contain any patient identifiers.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission.

Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Sansum Diabetes Research Institute research staff involved in this study.

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.

- A group that oversees the data (study information) and safety of this research.
- Other doctors caring for you who may need to know about the study device you are using.

Is your health information protected after it has been shared with others?

Sansum Diabetes Research Institute asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Sansum Diabetes Research Institute, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Sansum Diabetes Research Institute.

You can cancel your permission to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission lasts until the end of this study unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.

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Protected Health Information Authorization:
By signing, you authorize the use and disclosure of your protected health information. This information is collected as part of your participation in this study. You cannot be in this study if you do not provide this permission.

_____ / / : AM/PM
Signature Date Time

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ENROLLMENT AND PERMISSION SIGNATURES

Primary Health Care Provider/Endocrinologist/Diabetes Specialist Notification Option

I consent to having my/the participant's primary health care provider/endocrinologist/diabetes specialist notified by the study site of my participation in this study and/or any significant findings related to my health (please check yes or no).

☐ **Yes (if yes, please complete the information below)**

☐ **No**

Name and address of primary healthcare provider:

Name: _____

Address: _____

Phone: _____ **Fax:** _____

Name and address of endocrinologist/diabetes specialist:

Name: _____

Address: _____

Phone: _____ **Fax:** _____

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Study Participation

Your signature documents your permission to take part in this research.

	/ /	: AM/PM
Printed Name	Date	Time

Signature

Investigator's Certification

Person Obtaining Consent:

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

	/ /	: AM/PM
Printed Name	Date	Time

Signature

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HIPAA Authorization to Use and Disclose Protected Health Information

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Study Title: Observational study of patient important outcomes in pregnant patients with type 1 diabetes mellitus on Insulin pump

IRB#: 18-007081

Principal Investigator: Dr. Jordan Pinsker

During this research, information about your baby's health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your baby's health information for research and why they may need to do so. Information about your baby's health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission. You will be given a copy of this form.

Health information may be collected about your baby from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

This information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was done correctly.

If the results of this study are made public, information that identifies you or your baby will not be used.

Your baby's health information may be used or shared with:

- Sansum Diabetes Research Institute research staff involved in this study.

Your baby's health information may also be shared with:

- The Mayo Clinic Institutional Review Board that oversees the research.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.

- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

Protection of your baby's health information after it has been shared with others:

Sansum Diabetes Research Institute asks anyone who receives your baby's health information from us to protect your privacy; however, once this information is shared outside Sansum Diabetes Research Institute, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Privacy Rights

You do not have to sign this form, but if you do not, your baby cannot take part in this research study.

Your decision won't change the access to medical care or any other benefits your baby gets at Sansum Diabetes Research Institute now or in the future.

If you cancel your permission to use or share your baby's health information, your baby's participation in this study will end and no more information about your baby will be collected; however, information already collected about your baby in the study may continue to be used.

You can cancel your permission to use or share your baby's health information at any time by sending a letter to the address below:

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Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
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Rochester, MN 55905

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- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission lasts until the end of this study, unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.

Your signature documents your permission to use your baby's protected health information for this research.

	/ /	: AM/PM
Printed Name	Date	Time

_____
Signature