SANSUM DIABETES RESEARCH INSTITUTE

Approval Date: **June 30, 2022**
Not to be used after: **June 29, 2023**

Name and Clinic Number

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Supervised Safety and Feasibility Evaluation of the Zone-MPC Control Algorithm Integrated into the iAPS in Pregnant Patients with Type 1 Diabetes with Extension into Outpatient at Home

IRB#: 19-012342

Principal Investigator: Kristin Castorino and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to test the safety and effectiveness of the interoperable Artificial Pancreas System Smartphone App (iAPS) in managing blood sugars in pregnant patients with type 1 diabetes. You have been asked to take part in this research because you are pregnant and have type 1diabetes. In this study, you will use an artificial pancreas system in a supervised outpatient environment with medical staff present. The system uses a Dexcom continuous glucose monitor (CGM) and an insulin pump to automatically dispense insulin and control blood sugar.

What's Involved	Study participation involves a screening visit to determine eligibility. One to two weeks of sensor augmented insulin pump data collection will then occur, with you using your own insulin pump, and a study provided continuous glucose monitor. You will then use the iAPS with a study insulin pump for a 48-60 hours closed-loop (CL) session in a supervised outpatient environment with medical staff present. During the session, you will bolus for all meals and snacks, and will perform your usual daily activities while being accompanied by study medical staff. Two hours after discharge from the CL session, you will receive a follow-up phone call to make sure you have safely transitioned back to your own insulin pump. In addition, you will have the choice to take the iAPS study system home with you, after the closed-loop session, to use for the duration of your pregnancy. If you choose to do this, you will also need to have a designated study contact (care partner) who resides in your house each night in case the study team cannot contact you. Your care partner will be trained on emergency diabetes care and how to turn off the study system in case you need assistance in an emergency. You will have a phone or video visit at 24, 48 and 72 hours after bringing the system home and each week thereafter. At each visit, the study team will assess how you are doing with the system to ensure your safety.
Key Information	This study requires you to use either lispro (Humalog) or aspart (Novolog) insulin for the duration of closed-loop use. If you are not currently using one of these types of insulin, you must be willing to switch to one of these types of insulin for the duration of the study. This study also requires you to wear a CGM device and come to the study center for 48-60 hour CL session, and your care partner to be trained at the center by video visit or in person during that same session. You should consider whether you are willing to commit to doing these things to the best of your ability. A change in your insulin doses and diet may cause you to experience symptoms of hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose). Additionally, hypoglycemia or hyperglycemia could occur if there is a device malfunction and the system delivers too much or too little insulin.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

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.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Dr. Kristin Castorino **Phone:** (805) 708-2630 **Study Team Contact:** Mei Mei Church, NP **Phone:** (805) 335-0504 **Institution Name and Address:** Sansum Diabetes Research Institute 2219 Bath St. Santa Barbara, CA 93105
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu

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

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

You have been asked to take part in this research because you are pregnant and have type 1 diabetes. In this study, you will use an artificial pancreas system in a supervised outpatient environment with medical staff present and the option to then use the system at home. The system uses a continuous glucose monitor (CGM) and an insulin pump to automatically dispense insulin and control blood sugar.

Why is this research study being done?

The purpose of this research study is to:

- Test the safety and effectiveness of the interoperable Artificial Pancreas System Smartphone App (iAPS) in managing blood sugars in pregnant patients with type 1 diabetes in a supervised outpatient environment with medical staff present.

iAPS has been tested before in both the inpatient and outpatient setting in people with type 1 diabetes. In this study you will test it for 48-60 hours in a supervised outpatient environment with medical staff present. Additionally, you will then have the option to use this system at home for the duration of your pregnancy. The system consists of (1) a CGM that measures blood glucose levels every 5 minutes, (2) a study provided cellular phone that calculates how much insulin is needed, and (3) an insulin pump that delivers the insulin based on the recommended doses. The CGM sensor is inserted just beneath the skin. It measures the glucose in the fluid beneath the skin and shows the measurement on the phone screen every 5 minutes. The sensor needs to be replaced every 10 days. The insulin pump has a tiny tube that is inserted beneath the skin. It needs to be replaced about every 2-3 days.

The interoperable Artificial Pancreas System (iAPS) is an investigation device. The United States Food and Drug Administration (FDA) has approved its use in this research study.

Information you should know

Who is Funding the Study?
This study is being funded by the National Institute of Diabetes and Digestive and Kidney Diseases and The Leona M. & Harry B. Helmsley Charitable Trust.

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.

How long will you be in this research study?

You will be in the study for about three weeks, with the option to extend your participation for the duration of your pregnancy until delivery.

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
Before any study-related tests and procedures are performed, you will be asked to read and sign this consent document. The following screening tests and procedures will then be performed to determine if you qualify to take part in this study:

- Demographics (date of birth, gender, race and ethnicity)
- Contact information (retained at the site)
- Name and contact information of a care partner who will be trained how to assist you in the event of an emergency
- Diabetes history, including history of diabetic ketoacidosis or severe hypoglycemia
- Medical history, including any relevant data related to current pregnancy, significant kidney disease, liver disease, adrenal insufficiency, or new thyroid disorder
- Medications, including recent high dose steroid use
- Physical examination to include:
    - Weight,
    - Height
- Vital signs including measurement of blood pressure and pulse
- Download of diabetes devices (pump, CGM, glucometer)
- HbA1c level measured using the DCA2000 or comparable point of care device or local lab

- Additional screening laboratory measurements of creatinine and transaminase. Measurements performed as part of usual clinical care prior to obtaining informed consent for participation in the trial may be used if completed within the last 3 months.

Screening procedures will last approximately 2 hours.

This study requires you to use either lispro (Humalog) or aspart (Novolog) insulin for the duration of the study. If you are not currently using one of these types of insulin, you must be willing to switch to one of these types of insulin for the duration of the study.

Sensor Augmented Insulin Pump Data Collection
You will have a training visit where you will be taught how to use the study glucometer and the Dexcom G6 continuous glucose monitor. You will practice using the monitor for 1-2 weeks. In this study you will be asked to wear the CGM system on your upper arm. Look for a place on your upper arm where you have some padding to place the sensor. Study staff may contact you more frequently, use the Dexcom Follow app to monitor your data, and/or simply review your diabetes care on the phone during this time. During this phase, your basal rates, carbohydrate ratios and/or insulin sensitivity factors may be adjusted as needed based on study clinician discretion to optimize pump settings prior to entering the hybrid closed-loop phase.

Hybrid Closed-Loop Phase (~48-60 Hours)
You will be instructed to insert a new CGM sensor at least 24 hours prior to arrival to the supervised outpatient environment, which may be similar to a hotel. Prior to initiating the closed-loop study, baby's heart rate will be documented using a portable hand-held baby monitor called a Doptone if you are at greater than ~23 weeks gestation.

The study insulin pump that you will wear during the closed-loop session is made by a company called Tandem. It is called the Tandem t: AP pump. It has an infusion set that the study staff will help you insert in your skin. Study staff will help you change this infusion set every 3 days or sooner if it stops working correctly. The study CGM is made by Dexcom. It is called the Dexcom G6. It includes two parts: the sensor and the plastic transmitter. The Dexcom G6 uses a small sensor that is placed under the skin. It measures sugar levels every five minutes.

There is no approved wear site for the Dexcom G6 sensor in pregnancy, as the device is not yet approved or cleared by FDA for pregnant women. For this study, the specified sensor location during this study will be the upper arm. Your study physician will review with you how to place the sensor in this location. The Dexcom G6 sensor will need to be replaced every 10 days, or sooner if it comes out or stops working.

Although the iAPS closed-loop system can be used with different insulin pumps and CGM systems, in this study you will only be using the Dexcom G6 CGM and the Tandem t:AP insulin pump while you are using the iAPS.

During the closed-loop session, you will be supervised at all times by study staff who are clinically trained in treating hypoglycemic and hyperglycemic emergencies. Fingerstick glucose measurements will be performed before all meals, 2 hours after meals, at bedtime, and as needed per yours or the study investigators request.

During the closed-loop session, you will be allowed to snack at any time and bolus appropriately per your home routine, with the goal to pre-bolus 15-30 minutes ahead of time to minimize high blood sugars after a meal. You will be required to enter the carbohydrate content of all meals/snacks into the iAPS while supervised by the study staff for all meals and snacks requiring insulin.

If a CGM sensor fails or comes loose at any point during this phase, the sensor will be replaced and closed-loop mode will resume once the sensor has completed warm-up. Skin Tac or other similar agents may be used to ensure adequate adherence of the CGM sensor to the skin.

You will be allowed to perform light exercise (e.g., walking, stretching, yoga) per your usual home routine at any time during the closed-loop phase, and may take additional carbohydrates for exercise as per your usual home routine. Any additional carbohydrates or activity will be documented in your chart. You will be encouraged to eat your usual prescribed diet while using the system.

You will have the option of continuing onto the extension phase after completion of the supervised closed-loop phase. To prepare for home use, study staff will use the supervised closed-loop session to provide you (and your care partner) device training on how to start the system, how to stop the system as well as troubleshooting potential device issues, alarms and notifications.

<u>Training for Home Use</u>
During the supervised closed-loop phase you will be asked to practice using the system until you feel confident using the system at home. You will also be trained on when to contact study staff for device trouble shooting. Upon completion of the supervised closed-loop session, with the completed home use training, the healthcare team will determine if you are still a good candidate for home use.

Training of your care partner will be completed either in person or via video visit during a portion of the 48-hour study session, prior to leaving the supervised setting with the system for home use. Your care partner should feel comfortable with knowing your whereabouts and helping study staff reach you if you do not respond to alerts or phone calls that may occur both day and night.

Your care partner must reside in the same dwelling as you during the night, be agreeable to all device training during the supervised session and additional training on hyper- and hypoglycemia treatment, and feel comfortable assisting with emergency care if needed, such as transportation to the hospital or emergency department.

1. I agree to participate in the extension home phase of the hybrid closed-loop system. I agree that I may be a good candidate for home use and would like to receive training on home use during the supervised session.

   ☐ Yes ☐ No Please initial here: _____Date: _____

2. I agree to having a care partner with me throughout the study.

   ☐ Yes ☐ No Please initial here: _____Date: _____

Name of care partner:_____ Relationship:_____

With your permission, we may photograph or videotape your participation in this trial. Photographs and video may be used in presentations at conferences and shown to potential study subjects, as well as potential research donors. Photos or videos would include your face, body, and study devices. Your willingness to have photos taken is independent of your participation in this trial. Your photo or videotape will not be used without your consent. Your identity can remain anonymous, and your name will not be used or associated with any photographs or videos used.

1. I agree to be photographed/videotaped during this trial.

   ☐ Yes ☐ No Please initial here: _____Date: _____

2. I agree to be photographed/videotaped during this trial but would like to remain anonymous (face not shown).

   ☐ Yes ☐ No Please initial here: _____Date: _____

<u>Follow Up Phone Call</u>
Study staff will call you approximately 2 hours after discharge from the closed-loop session to ensure you have safely transitioned to the study system or back to your own insulin pump and to see if you have any additional questions. If you choose to not participate in the extension home phase, this will be your final study visit.

Extension Home Phase

You will have the option to use the study system at home for the duration of your pregnancy. If you choose to take this system home, you will be trained on how to use all study devices during the 48 hour closed-loop session.

You will have phone calls at 24, 48, 72 hours after you have left the clinic with the system and then weekly follow up visits that can be completed via phone or video visit. Additional unscheduled visits may be needed during the home use phase. At each of these visits, a study team member will review your pump and CGM information with you. We will address any concerns you may have and provide advice for glucose management, if applicable, on your follow up visit calls. Based on this information, the study team will assess your safety using this system at home. If the team thinks it is safe for you to continue, you will be able to wear the system for another week. If your study doctor is concerned the system may not be working well for you, of if you develop Diabetic Ketoacidosis (DKA) or have a severe low blood sugar (hypoglycemic event) you will need to stop using the system, and you will end participation in the study.

During the home use phase fingerstick glucose measurements will be performed before all meals, 2 hours after meals, at bedtime, and as needed per yours or the study investigators' request. After at least two weeks of home use fingerstick glucose measurement frequency may be reduced after review by study staff.

To continue using the system at home, you must have a care partner/other responsible adult, willing to share their contact information with the study team, who can be available to physically find you and assist if you do not respond to contacts from the study team.

You will be provided enough study supplies to for the duration of this phase.

During this phase, you will be required to have an emergency home glucagon kit for the duration of the study. If you do not have one, you will be given a prescription for one. You will also have an A1c or other similar lab testing performed every 4 weeks either as part of clinical care or by the study team.

Your care partner should be comfortable with helping you treat high and low blood sugar values as well as assisting for emergency care if needed, such as transportation to the hospital or emergency department.

You will stop use of the study system if you are admitted to a hospital, including for labor and delivery. The study team will discuss the removal of the study system requirement with your obstetrician. You will be contacted after delivery to ensure safe transition to your home insulin pump. 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.

Expectations

If you participate in this extension portion of the study, you will be expected to:

- Attend each scheduled study visit
- Be available by phone or video for the scheduled study phone or video visits
- Provide updates regarding your obstetrical care at each study contact
- Contact study staff for any device issues, safety concerns or hospital visits
- Have a care partner who is trained by study staff.

If there are clinical meaningful research results that pertain to you that occur in this study, we will notify you and your regular care providers if you give us permission to do so.

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

All study procedures may involve risks that are unknown. Besides the risks described below, there may be other discomforts or risks to you from this investigational study that we do not yet know about.

Risks associated with CGM sensor insertion include: bleeding (1.2%), swelling (0.2%), redness (0.5%), and bruising >1 cm (1.9%). Occasionally, 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 venipuncture include: common reactions like pain, bruising, or redness at the sampling site. Less common reactions include bleeding from the sampling site, formation of a small blood clot or swelling of the vein and surrounding tissues, and fainting.

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 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 of hypoglycemia: There is always a risk of having a low blood sugar (hypoglycemia). The frequency of hypoglycemia should be no more and possibly less than it would be as part of daily living. Symptoms of hypoglycemia can include sweating, jitteriness, and not feeling well. Just as at home, there is the possibility of fainting or seizures (convulsions) and that for a few days the participant may not be as aware of symptoms of hypoglycemia. A CGM functioning poorly and significantly over-reading glucose values could lead to inappropriate insulin delivery. Fetal microsomia or small for gestational age babies has been reported in pregnant women with excessive hypoglycemia using multiple daily injections or sensor augmented or standard insulin pump therapy.

Risk of hyperglycemia: Chronically high blood sugars (hyperglycemia) can increase the risk of fetal macrosomia, polyhydramnios and hypoglycemia in the newborn fetus at the time of delivery. These are the same risks that occur in pregnant women utilizing MDI or sensor augmented or standard insulin pump therapy. Acute hyperglycemia can lead to DKA that puts the fetus at acute risk of acidosis and demise. Furthermore, DKA in pregnancy can occur at lower glucose levels than in the non-pregnant state, hence the need to be vigilant and intervene when the glucose level reaches 180 mg/dL.

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 guidance on cleaning procedures for transmitters/receivers. 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 guidance on cleaning procedures for transmitters/receivers.

The study insulin pump is labeled for single-patient use. During the study, this device may be reused after cleaning adhering to a hospital-approved cleaning procedure. All infusion set equipment will be single patient use only (infusion set insertion kits, tubing, cartridges etc.).

The study phone may be reused after cleaning adhering to a hospital-approved cleaning procedure.

The study blood glucose meter and blood ketone meter are labeled for single-patient use. During the study, all blood glucose and ketone meters will be single patient use only.

Risk associated with enrolling pregnant subjects: Pregnant women 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 abnormal organ development 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

babies, need for C-section, hypoglycemia in the baby at birth, and long-term consequences to the baby such as obesity and early onset of type 2 diabetes.

Unforeseen Risks
Since the study device (iAPS) is investigational, there may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus since you are pregnant.

Are there reasons you might leave this research study early?

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

The Investigator can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

The investigator will ask you to pause the use of the system if you are admitted to the hospital for inpatient care. You will be asked to have your personal pump and diabetes supplies ready to go in the case of an unexpected hospital visit.

The investigator will ask you to pause the use of the system if you require steroids during your pregnancy until the effect of these medications have worn off. You will also be asked to pause use of the system if you are admitted to hospital during your pregnancy.

If you leave the study for any reason, the Investigator may ask you to have some end-of-study tests for your safety.

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

Where to get help:
If you are hurt by this research, or have an emergency after hours, you may call Dr. Castorino on her cell phone at (805) 708-2630 and she will help you arrange medical care.

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. Sansum Diabetes Research Institute does not have any program to provide compensation for persons who may experience injury while participating in research projects.

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

There is no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future.

This study may result in better glucose control for you. You may gain a better understanding of how to measure and control your blood-glucose levels. You will also learn how to adjust your basal rates, carbohydrate ratios and correction factors, and what your optimal basal rates, carbohydrate ratios and correction factors are. Information obtained from this study may benefit patients in the future. There will be no cost to you for any of the procedures that are part of this study, including the doctor examinations and laboratory tests. You will be provided with continuous glucose sensors, a glucose meter, a ketone meter and test strips during the study.

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

You do not have to be in this study to receive treatment for type 1 diabetes during your pregnancy. You may choose not to participate in this study and still continue your regular care with your personal physician. Please talk to the study doctor about your options before you decide whether or not you will take part in this study.

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

There will be no charge to you for your participation in this study.

The study devices, laboratory / point-of-care testing, study-related procedures, and study visits will be provided at no charge to you or your insurance company.

You must provide your own insulin for the study. The study requires you to use either lispro (Humalog) or aspart (Novolog) insulin for the duration of the study. If you are not currently using one of these types of insulin, you will be provided with a prescription to purchase one of these types of insulin. If this occurs, the study team may cover the cost of this insulin as long as you are in the 48 hour. Insulin use during the outpatient extension phase is not covered by the study.

In addition, you will be required to have an emergency home glucagon kit for the duration of the study. If you do not have one, you will be given a prescription for one.

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

You will be paid up to a total of $400.00 if you complete this study. You will be paid for the visits you complete according to the following schedule:

- Screening Visit: $50
- Sensor Augmented Insulin Pump Data Collection: $50
- Hybrid Closed-Loop Phase: $300
- There is no additional payment if you choose to take the study system home with you for the extension home phase.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Accounts Payable at Sansum Diabetes Research Institute will be given your name, address and Social Security number in order to issue a check for your study participation. If you receive research payments totaling $600 or more in a calendar year, a tax Form 1099 will be sent to you. For Sansum Diabetes Research Institute employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W2 after calendar year-end.

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

You will be paid when you complete the study. All devices need to be returned at the completion of the study.

If you have any questions regarding your compensation for participation, please contact the study staff.

Will your information or samples be used for future research?

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

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.

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. Additionally, parts of your health information that pertain to your participation in this study may be photocopied. Confidentiality will be maintained by using your study number and/or initials as an identifier on the photocopies. If the results of this study are published or presented at meetings, you will not be identified. The investigator is required by law to retain your research-related records for a period of 2 years after the latter of a) the date that the records are no longer required for purposes of supporting a premarket approval application or b) a notice of completion of a product development protocol (21CFR812.140).

There are some situations where the information from the study may need to be shared and will not have a code number or be otherwise de-identified, and may have your name, address, telephone number or social security number on it (PHI). For example, other doctors who are

assisting in your medical care outside of the study may need to know what medications you are taking and your insulin doses. They may need to see your PHI. They may not be covered the by the law. Everyone who needs to see your information will be told it is confidential, but we cannot guarantee full confidentiality once it leaves the Sansum Diabetes Research Institute.

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 (or "authorization") to Sansum Diabetes Research Institute.

Your health information may be collected from:

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

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Sansum Diabetes Research Institute research staff involved in this study.
- Other Sansum Diabetes Research Institute staff involved in your clinical care.
- Researchers involved in this study at other institutions.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- 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.
- A group that oversees the data (study information) and safety of this research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Sansum Diabetes Research Institute. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media) information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Sansum Diabetes Research Institute may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Sansum Diabetes Research Institute or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, copy (using paper, digital, photographic or other methods), or remove your identifying information from Sansum Diabetes Research Institute.

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 Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Sansum Diabetes Research Institute.

If you cancel your permission for Sansum Diabetes Research Institute 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.

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

Sansum Diabetes Research Institute
ATTN: Kristin Castorino, DO
2219 Bath St.

Santa Barbara, CA 93105

Alternatively, you may cancel your permission by emailing the Principal Investigator at: kcastorino@sansum.org.

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 for Sansum Diabetes Research Institute to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

There is no expiration or end date related to the Sponsor's use of your health information received from Sansum Diabetes Research Institute as part of this study.

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

SANSUM DIABETES RESEARCH INSTITUTE

Approval Date: **June 30, 2022**
Not to be used after: **June 29, 2023**

Name and Clinic Number

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: _____

Study Participation

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

_____ / / _____ : _____ AM/PM
Printed Name Date Time

_____
Signature

Care Partner signature documents his/her permission to take part in this research. □ **NA**

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

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

SANSUM DIABETES RESEARCH INSTITUTE

Name and Clinic Number

HIPAA Authorization to Use and Disclose Protected Health Information

Approval Date: **June 30, 2022**
Not to be used after: **June 29, 2023**

Study Title: Supervised Safety and Feasibility Evaluation of the Zone-MPC Control Algorithm Integrated into the iAPS in Pregnant Patients with Type 1 Diabetes with Extension into Outpatient at Home

IRB#: 19-012342

Principal Investigator: Dr. Castorino and Colleagues

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 and 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.

Your baby's 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.

Your baby's health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

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

- Sansum Diabetes Research Institute research staff involved in this study.
- Researchers involved in this study at other institutions.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- 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.
- A group that oversees the data (study information) and safety of this research.

HIPAA Authorization to Use and Disclose Protected Health Information

Approval Date: June 30, 2022
Not to be used after: June 29, 2023

How your baby's information may be shared with others:

While taking part in this study, your baby will be assigned a code that is unique to your baby but does not include information that directly identifies your baby. This code will be used if your baby's study information is sent outside of Sansum Diabetes Research Institute. The groups or individuals who receive your baby's coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies your baby will not be used.

In addition, individuals involved in study oversight and not employed by Sansum Diabetes Research Institute may be allowed to review your baby's health information included in past, present, and future medical and/or research records. This review may be done on-site at Sansum Diabetes Research Institute or remotely (from an off-site location). These records contain information that directly identifies your baby. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your baby's identifying information from Sansum Diabetes Research Institute.

Is your baby's health information protected 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 baby's privacy; however, once your baby's 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 Rights and Permissions

Participation in this study is completely voluntary. Your baby has the right not to participate at all. Even if you decide to have your baby be a part of the study now, you may change your mind and stop your baby's participation at any time. You do not have to sign this form, but if you do not, your baby cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship or your baby's relationship with your baby's doctors or with Sansum Diabetes Research Institute.

If you cancel your permission for Sansum Diabetes Research Institute 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 for Sansum Diabetes Research Institute to use or share your baby's health information at any time by sending a letter to the address below:

HIPAA Authorization to Use and Disclose Protected Health Information

Approval Date: June 30, 2022
Not to be used after: June 29, 2023

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 Participant Advocate at: researchparticipantadvocate@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 for Sansum Diabetes Research Institute to use and share your baby's health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

There is no expiration or end date related to the Sponsor's use of your baby's health information received from Sansum Diabetes Research Institute as part of this study.

SANSUM DIABETES RESEARCH INSTITUTE

Name and Clinic Number

HIPAA Authorization to Use and Disclose Protected Health Information

Approval Date: **June 30, 2022**
Not to be used after: **June 29, 2023**

Signature of Parent(s)/Guardian for Child:

I give permission for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above.

_____
Printed Name of Child

	/ /	:	AM/PM
Printed Name of Parent or Guardian	Date	Time	

_____
Signature of Parent or Guardian