CONSENT TO TAKE PART IN A RESEARCH STUDY

STUDY TITLE: The International Diabetes Closed Loop (iDCL) trial: A Randomized Crossover Comparison of Adaptive Model Predictive Control (MPC) Artificial Pancreas Versus Sensor Augmented Pump (SAP)/Predictive Low Glucose Suspend (PLGS) in the Outpatient Setting in Type 1 Diabetes (DCLP4)

STUDY DOCTOR'S INFORMATION

Name:
Contact Number:
Site Name:
Site Address:
Emergency (24-hour) Number:
Study Coordinator Name/Contact:

SUMMARY

In this form, when it says "you" it is referring to you as the participant if you are an adult, or to the person under your care that would be in the study if you are a legally authorized representative (LAR). Please see the next section called "Legally Authorized Representatives (LAR)" for more information about who can be a LAR.

This consent form will give you important information about this study. It will help you decide if you would like to take part in the study. You do not have to be in this study. You can stop the study at any time. You should read and discuss all the information in this consent form with the study doctor.

- **The study is being done to learn if an automated insulin delivery (AID) system can safely improve blood sugar control in people with type 1 diabetes. We will refer to this as the AID system.**
- **The study AID system includes an insulin pump, a continuous glucose monitor (CGM), and a computer program running on a cell phone. The CGM measures your sugar level. It sends this information to the cell phone. The computer program on the cell phone decides how much insulin should be given. Usually if your sugar level is going up, the insulin pump will increase the amount of insulin you get. If your sugar level is going down, it will decrease the amount of insulin you get.**
- **The AID system is not approved by the Food and Drug Administration (FDA). It can only be used in research studies. For this reason, it is called experimental in this study.**
- **You will be asked to be in the study for 6-7 months.**
    - **At first, testing will be done to see if you are qualified to be in the study. Depending on your experience with CGM, you may have a 2-4 week period of wearing the study CGM at home.**
    - **You will then start the main phase of the study, which is about 26 weeks. The main phase has two 13-week periods. During one period you will use the AID system. During the other period, you will use your own insulin pump and the study CGM.**

- **The most likely risks to you are pain, bruising, redness and temporary discomfort from blood draws, fingersticks, CGM sensor insertions, or infusion set insertions. Although unlikely, it is possible that the AID system could deliver too much or too little insulin. This could result in low blood sugar or high blood sugar. In rare cases, this could be serious.**
- **The possible benefit is better blood sugar control while you are in the study. You may not benefit from this study. The information gained from the study may help people with type 1 diabetes in the future.**
- **If you do not participate, you may choose to continue your current diabetes treatment.**

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

A LAR for an adult that lacks capacity to consent can be an attorney in fact, a court appointed guardian, a participant's spouse, a participant's adult child, or a participant's parent (in that order). This means that if the adult that lacks capacity to consent and has a court appointed guardian, then the spouse would not be permitted to serve as the LAR.

WHAT IS INFORMED CONSENT?

You are being asked to take part in this research study because you have type 1 diabetes. The goal of this study is to learn things that may help people with type 1 diabetes.

Your study doctor will be talking with you about this study and this form. You can take as much time as you need to think about whether or not you want to be in this study. You can also take a copy of this form with you to discuss with friends, family, or other doctors to help you decide. Please read this document carefully. Do not agree to be in this study unless all of your questions have been answered.

You do not have to be in this study. If you decide not to be in this study, you will not be treated differently as a person just because you didn't want to be in this study. Also, your regular care will not be impacted.

WHO IS DOING THE STUDY?

This study is being done by the diabetes staff at your clinic. It is being paid for by The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The Jaeb Center for Health Research will use the funding to organize the study. Your study doctor and clinic staff will use the funding to carry out this study. The name of the study doctor and the doctor's contact information is listed on the first page of this form. If one of the study doctors gets money or benefits from a company that makes the devices in this study, then they have to tell the Jaeb Center.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn whether an automated insulin delivery (AID) system can safely improve blood sugar control for people with type 1 diabetes. We will refer to this as "the AID system" or "the system". It is also sometimes called a "closed-loop" system or "artificial pancreas".

The study AID system includes an insulin pump, a continuous glucose monitor (CGM), and a computer program running on a cell phone. The CGM measures your sugar level. It sends this information to the cell phone. The computer program on the cell phone decides how much insulin should be given. Usually if your sugar level is going up, the insulin pump will increase the amount of insulin you get. And, if your sugar level is going down, it will decrease the amount of insulin you get.

WHO CAN PARTICIPATE IN THIS STUDY?

We expect about 35 people will take part in this study for 6-7 months at 5-7 different diabetes centers in the United States.

In general, to take part in this study, you must:

- Have type 1 diabetes
- Have used insulin for at least one year
- Have been using an insulin pump for at least 3 months
- Be familiar with the use of a carbohydrate ratio for meal boluses
- Be at least 18 years old
- Be willing to stop using any personal CGM once the study CGM is in use
- Be willing to switch to a different insulin type during the study if your study doctor says your type will not work with the study insulin pump

Also, you must not:

- Take Afrezza or any medicine except insulin or metformin to lower blood glucose, either now or during the study
- Have had two or more diabetic ketoacidosis (DKA) events in the last six months
- Have had two or more severe low blood sugar reactions in the last six months
- Participate in another drug or device study at the same time as this study
- Be pregnant or plan to become pregnant during the study if you are female

During part of the study, you will use your own insulin pump. If your insulin pump is part of a system that automatically delivers insulin, you must agree to not use this automated feature while you are using your personal pump. However, if your pump works with the study CGM to stop or decrease insulin if a low blood sugar is predicted, you will be able to use that feature.

Your study doctor and staff will review more health-related requirements with you.

WHAT WILL HAPPEN IN THIS STUDY?

The study will have an initial phase for training and to collect information. This will be followed by two 13-week periods. During one period, you will use the study AID system. The study AID system includes an insulin pump, a CGM, and a smartphone. During the other period, you will use your own personal insulin pump and use the study CGM.

The study insulin pump is made by a company called Tandem. It is called the Tandem t:AP pump. It has an infusion set that you will insert in your skin. You will need to change this 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. The sensor must be worn on the abdomen. The Dexcom G6 sensor will need to be replaced every 10 days, or sooner if it comes out or stops working.

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

The closed-loop app running on the study phone is made by researchers at Harvard University. Harvard personnel and others may benefit financially if the system becomes commercially available. If this information affects your willingness to participate in this study, please talk to your study team.

This study will take about 6-7 months for you to complete. The next sections list what will happen during the study.

Screening Visit

If you agree to participate, you will need to sign this consent form before any study-related procedures take place. Clinic staff will ask you questions and may do some tests to make sure you qualify and that it is safe for you to be in the study:

- Collection of information about you. This may include verifying contact information and confirming current medical conditions and current medications or supplements.
- Physical exam (height and weight, blood pressure and pulse)
- HbA1c test, if you have not done one in the last 3 months
- Additional blood tests if your study doctor has any concerns about medical conditions that might put you at risk in the study.
- A urine pregnancy test if you are a woman who can become pregnant. The pregnancy test must be negative for you to participate and will be repeated at some follow-up clinic visits during the study.
- Completion of questionnaires. Topics will include your feelings about managing your diabetes and using the study system and other diabetes technology.

We will give you a study blood glucose meter and blood ketone meter to use during the study. You will need to perform blood glucose tests to calibrate the CGM (if it requires calibration) and respond to system alarms. You will need to perform a ketone test if your glucose level is higher than 300 mg/dL for more than 2 hours, or greater than 400 mg/dL at any time. We will give you instructions on how to use and maintain your meters.

You will need to keep a glucagon emergency kit on hand at home, to treat severe hypoglycemia. Your study doctor will help you get a prescription for a kit if you don't already have one.

The screening visit will last approximately 1-2 hours.

CGM Start Up Phase

If you have used a Dexcom CGM for at least 11 out of the last 14 days, you can go directly to the Main Study Phase described below. Otherwise, you will first use the study CGM as described in this section. You will wear the study CGM for 2 weeks:

- You will be taught how to use the CGM including putting in a new sensor after 10 days. You will have to replace the sensor sooner if it comes out.
- You will use the CGM at home for 2 weeks. You should follow your normal routine during this time for meals, fingersticks, and insulin boluses.
- You will return for a follow-up clinic visit after 2 weeks.
- Study staff will download the study CGM data to determine if you wore it often enough to continue in the study—at least 11 out of 14 days. They will also check for any skin reaction in areas where you wore the CGM.
- Depending on the results, your study doctor may ask you to repeat this phase a second time before you move on to the Main Study Phase below.

Main Study Phase

If you skipped the CGM Start Up phase above, the procedures described below could occur on the same day as the Screening visit.

If you are eligible and want to start the main phase of the study, you will again be asked if you have any questions about the study. We want to make sure that if you continue, you understand the study. You need to feel that you could follow all of the study procedures.

We will draw blood for a laboratory HbA1c test. This blood will also be used for a C-Peptide test. This measures whether your body makes any of its own insulin. A urine pregnancy test will be performed if not already done within the past 6 days.

At this visit, a computer program will be used to decide whether you will be assigned to Group A or Group B described below. This is similar to flipping a coin.

- Group A participants use the study AID system for the first 13 weeks of the study and switch to their personal insulin pump and study CGM for the last 13 weeks.

- Group B participants use their personal insulin pump and study CGM for the first 13 weeks of the study and switch to the study AID system for the last 13 weeks.

You will have a 50/50 chance of being in either Group A or Group B. Neither you nor the study staff will have a choice in which group you will be placed.

You will receive all supplies needed for the study CGM, study blood glucose, study phone and study ketone meter. You will receive insulin infusion supplies for the 13 weeks that you use the study AID system.

Study AID System Training

You will be taught how to use the study system in all modes of operation. In closed-loop mode, the study system will automatically adjust your insulin delivery based on CGM readings. You can always stop closed-loop mode at any time and take over control of your insulin delivery.

You will have the option to switch your personal cell phone's SIM card to the study phone during the study. If you do this, you could avoid carrying two different phones during the study. Your study team will discuss this option with you to answer any questions you have. It will be your decision whether to switch your SIM card or not.

Training may happen during a single visit or two visits to the clinic. By the end of training, you will be expected to perform certain tasks without help from study staff members. You will be given a User Guide as a reference.

Study AID System 13-Week Home Use Period

You should use the study system in closed-loop mode whenever possible. In the following situations you should contact study staff to determine whether temporarily to stop closed-loop use:

- You have a fever above 101.5 degrees Fahrenheit
- You have a major illness
- You need to use certain medications including epinephrine (e.g. for the emergency treatment of a severe allergic reaction or asthma attack) or oral or injectable glucocorticoids.

When using the study phone:

- Do not upgrade the phone operating system or the study app will no longer allow closed-loop operation.
- Do not plug headphones into the study phone or alerts will be silenced.
- Do not put the phone on vibrate mode or alerts will be silenced.
- Do not use any software for CGM connectivity and monitoring (including the Dexcom Mobile App). This will interfere with CGM connectivity to the study phone.

Personal Pump 13-Week Home Use Period

If your personal pump has a closed-loop mode in addition to other modes, such as open-loop or Predictive Low-Glucose Suspend (PLGS), you must keep closed-loop mode turned off. You may use PLGS mode if it is compatible with the study CGM.

You may use available software apps from Dexcom for mobile data access or remote monitoring while using your personal insulin pump during the study. You may not use any software not available from Dexcom.

Guidelines for All Participants

You will be asked to upload data from the study CGM during the personal pump period of the study. You should do this before each scheduled clinic visit or phone call. You will be given all necessary equipment to do this. During the study system period, CGM and other study system data will upload automatically to the cloud.

You will be able to contact study staff at any time with a question, problem, or concern.

Scheduled Clinic Visits
During both 13-week periods, clinic visits will occur at 2 weeks, 6 weeks and 13 weeks.

The following procedures will be performed at each visit:
- Assessment of study device use
- Download of study device data
- Review of any problems or events that have occurred

In addition, the following will be done at the 13-week visit for each period:
- Urine pregnancy test if you are a woman who can become pregnant (first 13-Week visit only)
- Weight, height, and blood pressure
- Blood draw and fingerstick for HbA1c measurements
- Completion of study questionnaires

You will be asked to return some study devices as instructed by study staff at this visit. If needed, you will be switched back to the insulin pump you were using before entering the study.

Scheduled Phone Calls
Study staff will call you at 3 days, 4 weeks, and 9 weeks after the start of each 13-Week study period.

<u>Phone Call Procedures</u>
- Discussion of your use of the study devices
- Discussion of any changes in your health
- Review of available study device data to identify any safety issues

The table below shows what will happen at each visit:

Table 1. Schedule of Visits and Procedures

	Screening Visit	CGM Start Up Visit	Main Study Start	Days (d) or Weeks (w) from the Start of Each of Two 13-Week Study Periods						
				0d	3d	2w	4w	6w	9w	13w
Visit (V) or Phone Contact (C)	V	V	V	V	C	V	C	V	C	V
Informed Consent, medical history/physical exam, height, weight, blood pressure, pulse	X									
Pregnancy test	X			X						
Questionnaires	X									X
Review of CGM use	X	X								
Blood draw (HbA1c or C-peptide)			X							X
Study system training				X						
Review of any medical or device problems		X	X		X	X	X	X	X	X
Device data upload from home					X		X		X	
Device data download at clinic		X				X		X		X

WHAT ARE THE RISKS OF THIS STUDY?

If you choose to take part in this study, you need to know that there are some side effects or risks of being in this study.

Taking part in research often involves some risks of physical or psychological injury or discomfort. The most likely risks of this study are described below. These deserve careful thought. This study may include risks that are unknown at this time.

Risks related to your normal medical care are not listed in this form. We encourage you to discuss these with your study doctor, your primary care provider, or another health care professional.

AID Study System Risks

There is a risk that parts of the closed-loop study system may not work properly. As a result, you could receive less or more insulin than you need and be at risk for high or low blood glucose. The following are common ways the study system might not work correctly:

- CGM sensor reads higher or lower than your actual glucose level. This could result in the AID system delivering more or less insulin than it should. If this occurs, a low blood sugar or high blood sugar could occur. The consequences of a low or high blood sugar are described below.
- CGM sensor stops working or cannot communicate with the system. If this occurs, the insulin pump will start delivering its preset basal rates within approximately 20 minutes.

Risk of Low Blood Glucose

As with any person who uses insulin, there is always a risk of having a low blood glucose (hypoglycemia). Low blood glucose should not happen more often during the study than before the study. Symptoms of low blood glucose can include:

- Sweating
- Shaking
- Not feeling well
- Fainting
- Seizures (convulsions)

In very rare cases low blood glucose can lead to brain damage or death. Even if low blood glucose does occur, it almost always goes away quickly with treatment to raise the blood glucose.

Risk of High Blood Glucose

High blood glucose also should not happen more often during the study than before the study. High blood glucose usually does not cause many obvious symptoms, but you may become thirsty, or have a higher level of glucose in your urine. In severe cases of hyperglycemia, diabetic ketoacidosis (DKA) or coma may occur. DKA can lead to kidney failure, irregular heartbeat, heart attack, muscle breakdown, and even death.

Insulin Infusion Risks

Potential risks from using an insulin pump to deliver insulin under your skin include:

- Discomfort when the infusion set catheter is inserted into the skin (common)
- Itchiness, redness, bleeding and bruising at the insertion site (unlikely to rare)
- Tape allergies (rare)
- Infection at the site of sensor insertion (rare)
- Failure of the pump's infusion set. The infusion set may be clogged, kinked or have another problem that prevents the pump from delivering insulin. If this happens, a high blood sugar can occur and ketones can form. This can be serious as described above for the high blood sugar risk.

Blood Draw Risks

Possible risks from blood draws include:

- Pain (common)
- Bruising (common)
- Redness (common)
- Temporary discomfort from the needle stick (common)
- Clotting (unlikely)
- Excessive bleeding (unlikely)
- Lightheadedness (rare)

- Infection (rare)
- Fainting (rare)
- Swelling of tissue (rare)

Fingerstick Risks

About 2 drops (0.1 teaspoon) of blood will be removed by fingerstick to test blood glucose levels. It hurts when the lancet goes into your finger but not for long. In about 1 in 10 times, a small amount of bleeding under the skin will produce a bruise. A small scar may persist for several weeks. The risk of an infection is less than 1 in 1000. This should not be a significant contributor to risks in this study as fingersticks are part of the usual care for people with diabetes.

Continuous Glucose Monitoring Sensor Risks

Potential risks from using a CGM include:

- Discomfort when the sensor is inserted into the skin (common)
- Itchiness, redness, bleeding and bruising at the insertion site (unlikely to rare)
- Tape allergies (rare)
- Infection at the site of sensor insertion (rare)

Risk of Sharing the Continuous Glucose Monitor

The FDA approves a continuous glucose monitor as a 'single use device'. This means that they recommend that only one person use this device as there is a rare risk that a blood borne pathogen, such as Hepatitis B, may be spread if used with multiple patients. In the study, we may reuse CGM receivers after careful cleaning. The transmitters and sensors will not be reused.

Risk of Sharing the Insulin Pump

The FDA approves an insulin pump for 'single-patient use'. They suggest that only one person use this device as there is a rare risk that a blood borne pathogen, such as Hepatitis B, may be spread if used with multiple patients. In the study, the insulin pump may be reused after careful cleaning.

Questionnaire Risks

The questions asked on the questionnaires will include questions about your personal attitudes, and behaviors related to diabetes. It is possible you may find these questions to be upsetting. Similar questionnaires have been used in other studies, and this reaction is uncommon. You can refuse to answer any questions that make you feel uncomfortable. You can decide not to answer questions, take a break, or stop taking part in the study at any time. There are no physical risks present. Many precautions will be made to keep your information confidential, but this is not a guarantee.

Unknown Risks

It is always possible that anyone using a device for the first time may have an allergic reaction. Also, there may be additional risks from the device or the study procedures that are not known. If we find out that there are any new risks, you will be told about them. You will be able to decide if you want to continue in the study based on this new information.

Risks to Confidentiality

This study will be capturing some information about you that includes identifiable, personal information, like your date of birth. The study has procedures in place to protect that information. There is a chance that a loss of that protection could occur. This would be a loss of confidentiality. Please see the "How will my information be protected and kept confidential" section below for more information.

Unsecure Text or Email Messaging

The study doctor and staff may use your contact information to call, text or email you during the study. They may do this to send you things like appointment reminders. They are not allowed to send you identifiable health information by text or regular email because it is unsecure. This means that there is a risk that a message may be seen by someone that is not supposed to see it, like when an email gets hacked. Your email, phone number and your name will likely be in the text or email. If you think that the study doctor's office has texted or email information that they should not have please contact JCHR at 813-975-8690 and ask to speak to the IRB Administrator. If you text or send a regular email the study doctor's office is unsecure and what you put in the text or email is not protected.

Risks for Unborn Babies

The risks of the devices in this study on an unborn baby are unknown. For this reason, anyone who is pregnant cannot be in this study. Anyone who becomes pregnant during the study will have to stop being in the study**.** Urine pregnancy tests are done as part of this study for anyone that is considered to be able to get pregnant. For example, anyone that has started having menstrual periods, or is still having menstrual periods, will have pregnancy tests no matter how young or old they are. They will also be asked about how they plan to make sure that they do not become pregnant while in the study (like if they use birth control). The study doctors are required to do this even if someone thinks there is no possibility of pregnancy.

Please discuss the risks with your study doctor or any other health care provider.

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?

You may receive no direct benefit from being in this study. The possible benefits are a better understanding of your diabetes or a positive impact on your ability to manage your diabetes. People who take part in this research study will add to new knowledge that may help other people with type 1 diabetes.

ARE THERE OTHER OPTIONS THAN BEING IN THIS STUDY?

If you do not take part in this study, your options include standard treatment like continuing your current diabetes management regimen, other research studies, or you may choose not to do anything. Your study doctor will discuss these choices with you.

CAN I STOP BEING IN THE STUDY?

You can stop being in the study at any time. If you decide to stop being in this study, you will not be treated differently as a person. Also, your regular care will not be impacted. Please talk to your study doctor or staff so they know why you are stopping the study and can help you do so safely.

You can decide to stop getting text messages or email contacts at any time. You will need to tell your study doctor if you would like to stop receiving text messages or emails. You can still be in the study if you do not want to get text messages or emails anymore.

If we find out that there is any important new information about the study, you will be told about it. You will be able to decide if you want to continue in the study based on this new information.

The study may stop or the study doctor may decide to take you out of the study at any time. You do not have to give permission for the study to stop or for the study doctor to remove you from the study. You will be told if this happens.

Some reasons why you may be removed from the study include:

- The doctors feel that it is in your best interest
- If you do not follow the study instructions
- The doctors think that being in the study may cause you harm
- If you experience an injury related to the study
- If you need additional or different medication

If you withdraw, are removed from the study, or the study is stopped, you may continue to receive care like you normally would if you were not in this study. Also, you will no longer be able to use the device.

ARE THERE COSTS RELATED TO TAKING PART IN THE STUDY?

The costs of routine treatment, office visits, and tests that are part of your regular care will be billed to you or your insurance company like they normally would if you were not in a study. The study will pay for the following supplies at no cost to you.

- CGM system and CGM sensors
- Study insulin pump, infusion sets, and reservoirs/cartridges while using the study system
- Study smart phone
- Blood glucose meter, test strips, lancets
- Blood ketone meter, test strips, lancets

At the end of the study, or if you decide to withdraw from the study, you must return all system parts to the study team listed on the front page. Any additional tests and procedures will be billed to you or your insurance company like they normally would.

Please ask to speak to someone at your study doctor's office if you want more information about what you or your insurance will be expected to pay.

IS THERE PAYMENT FOR TAKING PART IN THIS STUDY?

If you take part in the study, you will receive up to $500 for your participation. These payments will be paid as follows:

- Screening Visit: $50
- CGM Start Up Visit/Randomization Visit: $50
- First 13-week period:
    - 2-week Visit: $50
    - 6-week Visit: $50
    - 13-week Visit: $100

- Second 13-week period:
    - 2-week Visit: $50
    - 6-week Visit: $50
    - 13-week Visit after return of all study related equipment: $100

If you withdraw from the study, you will still be paid for the visits that you have completed. You will not receive extra payments for visits that are required as part of your normal care or for visits that are for treating an illness or injury. The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form. The samples collected will not be used for whole genome sequencing or other genetic research.

Because payments made to you for participating in this study may be reported to the IRS as income, you may need to provide your social security number or a Form W-9 to your study doctor's office. These will not be shared outside of your doctor's office, other than as required by the IRS.

WHAT HAPPENS IF I HAVE AN ILLNESS OR INJURY FROM BEING IN THE STUDY?

If you have an illness or injury that is related to your participation in the study, then you can get care like you normally would. If you have an emergency, please seek emergency care as soon as possible. Please tell the emergency doctor that you are in a research study. Please also tell your study doctor about the emergency as soon as you can. The study does not plan to provide costs for care or other expenses relating to illnesses or injuries. Your study doctor, the study doctor's office, the Jaeb Center, and NIDDK are not planning to cover payment for lost wages, direct losses, or indirect losses.

CONTACT INFORMATION FOR QUESTIONS OR PROBLEMS

If you have questions about this study; a research illness or injury; or have concerns, suggestions or questions about the study, then contact your study doctor using the contact information on the first page of this form.

Contact the Jaeb Center for Health Research Institutional Review Board (IRB) Office at 813-975-8690 or irb@jaeb.org if you:

- Have questions about your rights as a research participant

- Wish to talk about your concerns or suggestions about the research
- Want additional information about the research, or
- Want to provide comments about the research.

HOW WILL MY INFORMATION BE PROTECTED AND KEPT CONFIDENTIAL?

As required by law, study-related records with identifying information will be kept confidential. Safety measures for the access, security, and privacy of your information have been put in place by law. Your date of birth and initials may be used in the study to help the researchers keep the right information together. This information will be protected as described below. Unless the law requires it, your name, address, social security number, telephone number, or any other directly identifying information will not be used to identify you.

Certificate of Confidentiality

NIDDK has given us a Certificate of Confidentiality for this study. This adds special protection for study information that identifies you and allows us, in some cases, to refuse to give out information that could identify you without your consent. This could be done when the information is requested by a federal, state, local court or public agency. If you need medical help, we may still share your identifiable information. As described in this form or in other cases, we may share identifiable information. For example, if the government inspects us, they may see your identifiable information. Your study doctor and research team will follow local laws and will tell the local or state authorities:

- if certain diseases are present;
- if they suspect neglect, abandonment, or abuse of you; and
- if your study doctor or research team learn that you plan to harm yourself or someone else

Purpose of Authorization

We have rules to protect information about you. Federal and state laws also protect your information. By signing this form you are giving your permission, called your "authorization," for the use and disclosure of information protected by the law.

You must sign this form, including the Protected Health Information Authorization statement included in the signature box at the end of this form if you want to be in the study. When you sign this form, you give permission for the use and sharing of your Protected Health Information (PHI) for the study. PHI is health information that identifies you. Your authorization is beneficial and important for the study. Without your authorization, you will not be able to be in this study.

Using and Sharing Your PHI

Your study doctor will collect information about you. This information includes things learned from study procedures as well as your name, address, date of birth, and information from your medical records. These are examples of identifiable information. A code number with your initials and date of birth will replace your name, address, telephone number, or social security number in the results given to the Jaeb Center for Health Research in Tampa, Florida.

The following people or companies involved in this study may see your study results with things like your date of birth, initials, and date of procedures:

- Your study doctor's office
- Jaeb Center for Health Research
- Sansum Diabetes Research Institute
- Harvard University
- Tandem Diabetes Care
- Dexcom, Inc.
- Advanced Research and Diagnostics Laboratory, University of Minnesota
- Researchers who are part of the study

The study doctor's office will not share study results that can identify you except as explained in this form or when required by law. The Jaeb Center and your study doctor's office will guard the privacy of your study PHI.

Who Can Receive and Use Your Study Information?
It is possible that people outside of this doctor's office and the Jaeb Center may need to see or receive your information from this study. Some examples include government agencies (such as the Food and Drug Administration), committees that monitor safety, other sites in the study, and companies that are providing either funding or supplies for the study, laboratories, and centers that may receive images. In most cases the information will have a code number with it instead of your name, address, telephone number, or social security number.

There are some situations where the information will not have a code number but may include your name, address, telephone number, or social security number (PHI). Once PHI is disclosed by your study doctor and the clinic staff, it may no longer be covered by the privacy laws. Everyone who needs to see your information will be told it is confidential, but we cannot guarantee full confidentiality once it leaves the doctor's office.

Can You Cancel Your Authorization?
You may cancel your permission for the collection of your study PHI at any time. You will need to contact your study doctors and give them a written notice of cancellation, or you may contact the JCHR IRB Office at 813-975-8690 or irb@jaeb.org. When you cancel your permission or when you withdraw from the study directly, you are no longer part of the study. No new information about you will be gathered for the study, except when there is a safety concern related to the study. If there is a safety concern, your entire medical record may need to be reviewed.

The Jaeb Center will receive all the information that was collected for the study up to the time that you cancel or withdraw from the study. The Jaeb Center will receive any new information about any safety concerns that may be related to the study.

When Will the Use and Sharing of Your PHI Stop?
Some of your study PHI does not have a code number with it. Your permission for the use and sharing of your PHI lasts 50 years from the date that you sign this form or until the end of the study, whichever comes first.

The rest of your study information that is not PHI does have a code number with it. When it is collected, it becomes part of a research report. Your permission for the use and sharing of this coded information will never end. This coded data does not have your name, address, telephone number, or social security number.

Other Considerations
The information collected in the study may be used in future studies or data analyses without additional permission from you. This may include research done by other researchers. Also, this may be done by Dexcom, with the CGM data to assess product performance or analyze glucose control in a large population. The use of your future study information may result in commercial profit. You will not be compensated for the future use of your study information other than what is described in this consent form. The information that may be shared will not contain any information that could identify you. There may still be a chance that someone could identify you, but this is not likely.

A copy of the information collected as part of the study will be made public in a dataset. This will be done after the study ends. This dataset will not contain any PHI. The study results will also be made public. These results will not have any information that could identify you. Study results without the identifiable information may be shared in medical journals and at scientific meetings. Your records will be confidential. No one will share your identity in a medical journal or at a scientific meeting.

Results from the study will not be sent to you.

You may also have communication with the study doctor's office by phone, text, or by video (like FaceTime or Skype). There is a chance that someone could see or hear the conversation like they could if you were speaking or texting with anyone.

Clinical Trial Reporting
A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by 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. A copy of one of the study consent form templates will also have to be posted on a federal Web site.

Adult Participant's Full Name (printed) _____

When the Participant Lacks Capacity to Consent Participation in the Study **N/A ☐**

I, _____ (print name of legally authorized representative ("LAR")) attest that I am authorized to provide consent and authorize the use and disclosure of the participant's protected health information on behalf of the participant named above as I am one of the following LARs (checkbox), and there is not a LAR that has higher authority (see following order):

☐ Attorney in Fact,
☐ Judicially Appointed Guardian,
☐ Participant's Spouse,
☐ Participant's Adult Child, then
☐ Participant's Parent

_____ _____
LAR Signature Date

I certify that the participant lacks capacity to consent and that the LAR named above is in fact the person authorized to consent on behalf of the participant.

_____ _____ _____
Investigator's Printed Name **Investigator's Signature** **Date**

Adult Study Participation

By signing below, you/the participant agree to take part in this study. Your signature means that:

- you have read this informed consent form
- you have been given the chance to discuss the study and to ask questions to your satisfaction
- you freely choose (or you freely choose to allow the participant) to participate and you/the participant can withdraw at any time
- you will receive a copy of this consent form
- you authorize the use and disclosure of your protected health information. This information is collected as part of participation in this study. You/the participant cannot be in this study if you do not provide this permission.

_____ _____
Participant's Signature Date

Investigator's Certification

I certify that to the best of my knowledge the participant or LAR(s) understand(s) the nature, demands, risks, and benefits involved in the participation of this study.

Investigator's Printed Name	Investigator's Signature	Date