CONSENT TO TAKE PART IN A RESEARCH STUDY

STUDY TITLE: The Pediatric Artificial Pancreas Automated Initialization Trial (PEDAP-AI): A Pilot Study of AI Advisor-Driven Pump Initiation and Parameter Adaptation in Young Children with Type 1 Diabetes

STUDY DOCTOR'S INFORMATION

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

SUMMARY

This consent form will give you important information about this study. It will help you decide if you would like your child to take part in the study. Your child does not have to be in this study. You can stop your child's participation in 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 look at how well a "study system" works in young children with type 1 diabetes. The study system includes an insulin pump, a continuous glucose monitor (CGM), and a computer program. This computer program is also called an automated initialization (AI) program.**
- **The study will find out how safe the system is in helping manage your child's type 1 diabetes. The AI program will suggest pump settings for your child's study doctor to review.**
- **The study system is not approved by the Food and Drug Administration (FDA). For this reason, it is called investigational in this study.**
- **Your child will be asked to be in this research study for about 8 weeks. During this time, your child will use the study system (insulin pump, CGM, AI program). Please note that insulin and glucagon are not being paid for by the study.**
- **The study will involve a fingerstick to draw blood. You will also insert small sensors or catheters under your child's skin when using study devices.**
- **The most likely risks to your child are pain, bruising, redness and temporary discomfort from fingersticks, CGM sensor insertions, or infusion set insertions. Although unlikely, it is possible that the study pump 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 benefits are a better understanding of your child's diabetes or a positive impact on your ability to manage your child's diabetes. Your child may not benefit from this study, but that is what the study is trying to find out. The information gained from the study may help others with type 1 diabetes in the future.**

- **If you do not want your child to participate, you may seek other options which include standard treatments, like continuing with your child's current diabetes management regimen or participation in other research studies. Please talk to the study doctor about how these risks and benefits compare to the study risks and benefits.**

WHAT IS INFORMED CONSENT?

Informed consent is the process that tells you about what is involved in a research study. It tells you about the study, study procedures, and study treatments. It tells you about how study treatments are given and what side effects could happen. This process usually involves reading a form like this one, someone on the study team talking to you about the study, and getting answers to your questions and concerns. The goal is that you have all of the information you need so that you can decide if you want your child to participate in the study.

You can take as much time as you need to think about whether or not you want your child 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 enroll your child in this study. If you decide not to enroll your child in this study, you and your child will not be treated differently as a person just because you did not want them to be in this study. Also, your child's regular care will not be impacted.

WHO IS DOING THE STUDY?

This research study is being done by your child's study doctor and team. It is being paid for by The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The University of Virginia Center for Diabetes Technology (UVA) is creating the AI program that recommends pump settings to your study doctor. Tandem Diabetes Care is providing the study pump and related supplies. Dexcom is providing study glucose monitoring supplies. Other companies may also provide study supplies.

The Jaeb Center for Health Research (JCHR) will use the funding to organize the study. Your child's study doctor and clinic staff will use the funding to carry out this study. The name of the study doctor, the doctor's contact information, and the mailing address are 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 or AI program in this study, then they have to tell JCHR.

WHY IS THIS STUDY BEING DONE?

You are being asked to take part in this research study because your child has type 1 diabetes. The purpose of this study is to see how well the study system works in suggesting insulin delivery settings for young children with type 1 diabetes. The study will find out how safe the study system is in helping to manage your child's type 1 diabetes.

Study System
The study system includes an insulin pump, a CGM, and an AI program. The CGM measures your child's sugar level. It sends this information to the study pump. The AI program suggests pump settings for your child's study doctor to review during the study.

The study pump is made by a company called Tandem Diabetes Care. It is called t:slim X2 with Control-IQ technology. The insulin pump delivers insulin through an infusion set. The infusion set uses a flexible tubing connected to a small plastic flexible tube (cannula). The tube remains under your child's skin to deliver insulin. The infusion set needs to be replaced every three days. It also will need to be replaced if it stops working properly. The pump automatically adjusts insulin delivery up and down depending on your child's glucose levels. This pump is approved for use in children age 6 or older. It has been tested in previous studies with younger children. These studies did not find increased risk for high or low blood glucose or other problems.

The CGM sensor being used in this study is made by Dexcom, Inc. This sensor is called the Dexcom G6 or G7. It is approved by the FDA. It includes two parts: the sensor and the plastic transmitter. The sensor is placed under the skin. It measures the glucose in the fluid under the skin every five minutes. The transmitter snaps onto the sensor. The sensor must be worn on the abdomen. The sensor will need to be replaced every 10 days, or sooner if it comes out or stops working. During the study, you will be able to see your child's CGM glucose values on a smartphone and the study pump.

The AI program is made by UVA. The program recommends pump settings to the study doctor that affect how much insulin your child gets. The study doctor will have the ability to accept these suggestions or make changes before using them. The AI program does not control the pump directly. The pump settings it recommends must be entered into the pump with the help of your study doctor.

The study system (insulin pump, CGM, and AI program) is experimental and can only be used for research. The U.S. Food and Drug Administration (FDA) has approved its use in this research study.

WHO CAN PARTICIPATE IN THIS STUDY?

Up to 45 children will be in the study for about 8 weeks at 3 different clinical centers in the United States.

In general, to take part in this study, your child must:

- Have a clinical diagnosis of type 1 diabetes for at least 1 month
- Have a parent/LAR familiar with the use of a carbohydrate ratio for meal boluses
- Be at least 2 and less than 6 years old
- Be using a Dexcom CGM on at least 21 out of the last 28 days at the time child enrolls
- Have a parent/LAR knowledgeable about emergency procedures for severe hypoglycemia and able to contact emergency services and study staff
- Have a parent/LAR with access to a phone you provide that can run the Tandem t:connect Mobile App (typically Android 10 or above or iOS 15 or above)

- Have a parent/LAR willing to use the t:connect Mobile App and upload data at least once per day
- Have a parent/LAR willing to switch child to Humalog or Novolog, if not using already, and to use no other insulin besides these when using the study system
- Have a total daily insulin dose (TDD) of at least 5 U/day
- Be at least 20 pounds
- Have a parent/LAR willing not to start child on any new non-insulin glucose-lowering agent during the study
- Have a parent/LAR willing to participate in all training sessions as directed by study staff
- Live in the United States, with no plans to move outside the United States during the study period

Also, your child must not:

- Be taking any non-insulin glucose-lowering drug
- Have certain medical conditions your child's study doctor will ask you about, such as bleeding disorders, kidney disease, and glandular disease
- Have had more than 1 severe hypoglycemic event with seizure or loss of consciousness in the last 3 months
- Have had more than 1 diabetic ketoacidosis (DKA) event in the last 6 months
- Have used oral or injectable steroids within the last 8 weeks
- Have a known, ongoing adhesive intolerance
- Plan to receive blood transfusions or erythropoietin injections during the course of the study
- Have a condition, which in the opinion of the investigator would put the participant or study at risk
- Participate in another drug or device study at the same time as this study
- Have an immediate family member who is directly involved in the study or works for Tandem or Dexcom

Your child's study doctor and staff will review more health-related requirements with you. Your child's study doctor will also check to make sure you can read and write English well enough to use the system safely.

WHAT WILL HAPPEN IN THIS STUDY?

This study will take about 8 weeks to complete. The study is designed so that you can have study visits from home via videoconference with a secure method (e.g., Telehealth) without visiting the clinic if you and the study doctor prefer. So, the word "visit" below means either an in-clinic visit or a videoconference. The next sections list what will happen during the study.

Screening Visit

If you agree to have your child participate, you will provide your electronic signature to confirm your willingness to have your child participate.

- Collection of information about your child may include contact information, diabetes history, past and current medical conditions, surgical procedures, allergies, medications and supplements, family history, and whether or not your child has various symptoms. You will be asked for details about your child's insulin therapy and most recent HbA1c measurement.
- Measurement of your child's height and weight. A scale can be provided to measure your child's weight if you do not already have access to one.
- Your child's current personal doctor or provider may not be part of your study doctor's office. If so, the study doctor will contact your child's personal doctor's office to talk about your child's participation in the study and get some health information. To allow this, you will be asked to sign a release of information form that tells the personal doctor's office that it is okay to communicate health information with the study doctor's office. **The study doctor's office must be able to verify key health information from the personal doctor's office for your child's safety. If this cannot be done, then your child cannot be in the study.**

We will give you a blood glucose meter and blood ketone meter to use during the study. You will need to perform blood glucose tests to calibrate the study CGM (if it ever requires calibration) and respond to study pump alarms. You will need to perform ketone tests if your child's glucose level is higher than 300 mg/dL for more than 90 minutes, or greater than 400 mg/dL at any time. We will give you instructions on how to use and maintain your meters.

You will be asked to keep a glucagon emergency kit on hand at home. If your child needs a prescription for the glucagon emergency kit, you can ask your child's study doctor.

The screening visit will last 1 to 2 hours.

Main Phase

If your child qualifies 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 and feel that you and your child can follow the study procedures.

Closed-Loop Initiation Visit

Your child will use a kit to get a fingerstick blood sample to measure your child's HbA1c level. Study staff will give you the kit and help you use it. The kit can be used in the clinic or at home and is then sent to a central lab for analysis. If you use the kit at home, you must drop it in a mailbox (regular U.S. mail) within 24 hours of using it.

- Your child's study team will provide you with a study insulin pump and infusion supplies in person or have the material delivered to you. You will also get CGM supplies and blood ketone and blood glucose meters and supplies if you skipped the CGM start-up phase.
- You and your child will be taught how to use the pump. Training will include putting in a new infusion set after no more than 3 days. You will have to replace the set sooner if it comes out.

- Study staff will help you enter initial pump settings into the study pump. If your child was using a pump before the study, the study doctor may start with the same settings in the study pump. Otherwise, settings will first be recommended by the AI program. Then the recommended settings will be reviewed by your study doctor. The doctor can make changes if necessary before the settings are entered into the pump.
- During the study, you should not make any changes to pump settings that affect insulin delivery unless you discuss them first with study staff.
- Study staff will help you install the t:connect Mobile App on your phone and configure it to collect study data.

Training may happen during one or more sessions in the 10 days after the Screening visit. By the end of training, you will be expected to perform certain tasks without help from study staff members. You will need to upload your child's study device data at least once per day. You will be given a User Guide as a reference. You will be provided with study staff contact information that can help you should you need help.

Your child will use the study system at home, day and night.

3-Day Visit
Your child will have a visit after using the study pump for 3 days. We will review your child's experience. You will upload pump data from home using the t:connect Mobile App before this visit. Using the uploaded data, the AI program will make new suggestions for your child's study pump settings. The study doctor will review the settings and make changes as needed. Then the study team will help you enter the new settings into your pump.

Follow-up Visits at 1-Week, 2-Weeks, 4-Weeks, 6-Weeks, and 8-Weeks
Your child will continue to use the system for about 8 weeks total. At each visit, your child's experience with the study pump will be reviewed. You will upload device data from home. The AI program will make new suggestions for your child's study pump settings, and the study doctor will review and make changes as needed.

By the 2-Week visit, your child's study doctor will ask you which usual care insulin pump or insulin therapy you plan to use after the study. Your child's primary care doctor may be involved in this process.

At the 8-Week visit, your child must return all study devices (insulin pump, CGM, meters, and related supplies). After data are downloaded, your child may keep the glucose meter and ketone meter if desired. Your child will go back to using your desired usual care insulin pump or insulin therapy.

If needed, your child may have additional visits throughout the study.

3-Day Post-Study Contact
The study team will contact you 3 days after the 8-Week Visit. This contact can be done in person, by phone, or videoconference. The study team will confirm that your child successfully transitioned to their usual care insulin therapy.

The table below shows what will happen at each visit:

	Screening visit*	Closed-Loop Initiation visit**	3-day visit	1-week visit	2-week visit	4-week visit	6-week visit	8-week visit	3-day post-study contact
Informed Consent	X								
Eligibility Assessment	X								
Medical history/ height/weight	X								
Central lab HbA1c		X							
Study pump training		X							
Upload device data from home			X	X	X	X	X	X	
Review diabetes management, AEs, and medications		X	X	X	X	X	X	X	X
Manual pump parameter adjustment only if safety issue									X
AI-driven pump parameter initiation/adjustment ***		X	X	X	X	X	X		

**All screening visit procedures must be done within 28 days of consent.*
***All closed-loop initiation visit procedures must be done within 10 days of screening visit procedures.*
****Plus additional adjustments between visits if you and the study doctor feel they are necessary*

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.

These deserve careful thought. This study may include risks that are unknown at this time. Risks related to your child's normal medical care are not listed in this form. We encourage you to discuss these with your child's study doctor, your child's primary care provider, or another health care professional.

<u>The more common side effects that are known</u>

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 needed and be at risk for high or low blood glucose. The following are ways the study system might not work correctly:

- CGM sensor reads higher or lower than your actual glucose level
- The pump infusion set may be clogged, kinked or there may be another problem with the study system preventing insulin from being delivered
- 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.
- The AI program might suggest pump settings that cause too little or too much insulin to be delivered. Your study doctor will review all changes suggested by the AI program. If needed, the doctor can further adjust your settings manually at any time.

- If a high blood sugar occurs, symptoms may include blurry vision or increased urination, feeling thirsty, feeling very tired or having a headache. If blood sugar levels are high enough for an extended period of time, ketones can build up in the blood. Accumulation of ketones can result in nausea and vomiting.
- If a low blood sugar occurs, symptoms may include feeling anxious or nervous, sweating, rapid heart rate, confusion, unconsciousness or seizure.

Risks of the CGM

- Commonly, the insertion or removal of the CGM sensor could cause mild, temporary discomfort or a bruise. The CGM is usually accurate, but it is possible that the CGM could read higher or lower than your actual glucose level. If this occurs, you might take too much or too little insulin and might have a high or low blood sugar.

Insulin Infusion Risks

- Potential common risks from using an insulin pump to deliver insulin under your child's skin include discomfort when the infusion set catheter is inserted into the skin.

<u>Other less common side effects that are known</u>

Study System Risks

- In more severe cases, when there is an accumulation of ketones, diabetic ketoacidosis (DKA) or coma may occur. DKA can lead to kidney failure, irregular heartbeat, heart attack, muscle breakdown and even death.
- If prolonged severe hypoglycemia is not treated, it can cause brain damage (temporary or permanent). In extremely rare cases, death from a low blood sugar could occur.

Risks of the CGM

- Risks from using a CGM include itchiness, redness, bleeding at the insertion site (unlikely to rare), tape allergies (rare), infection at the site of sensor insertion (rare), and sensor breaking under skin (rare).
- Rarely, the tip of the CGM sensor could break off under the skin. If this occurs, it might need to be removed in the clinic.

Fingerstick Risks

- About 2 drops (0.1 teaspoon) of blood may be removed by fingerstick to test blood glucose levels or HbA1c. It hurts when the lancet goes into your child's finger but not for long. 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.

Insulin Infusion Risks

- Potential unlikely and rare risks from using an insulin pump to deliver insulin under your child's skin include itchiness, redness, bleeding and bruising at the insertion site (unlikely to rare), tape allergies (rare), infection at the site of sensor insertion (rare), and discomfort when insulin bolus is given (uncommon).
- If your child switches insulin that is different from their current insulin, there are some additional rare risks such as allergic reactions that might occur.

Other Risks

Some people may develop skin irritation or allergic reactions to the adhesives used to secure the CGM or insulin infusion sets. If these reactions occur, your study doctor will try different adhesives or taping approaches. A mild topical steroid cream or other medication may be required.

Unknown Risks

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 your child to continue in the study based on this new information.

Risks to Confidentiality

This study will be capturing some information about your child that includes identifiable, personal information, like your child's 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. If study supplies will be shipped to your home, there is a chance that someone might find out that you are in a research study or that your child has diabetes. If study supplies are shipped to you, the site will use the FedEx account that belongs to JCHR, the company coordinating the study. Therefore, JCHR may have access to your contact information, such as your name and address, through FedEx. Please see the "How will my information be protected and kept confidential?" section below for more information.

Data Entry/Uploads

The Tandem t:connect Mobile App will be used to upload your child's study pump data. This app should be configured by study staff not to have any personal information like email address or birthdate, but there is a chance that this information could be entered. Tandem has policies in place to protect you and your child's information. They use this information to provide the services of the app and for internal purposes, like training and making the app work better. For more information on their privacy policies, please visit their website or ask the study team for copies.

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 your child's private 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 and your child's name will likely be in the text or email. If you think that the study doctor's office has texted or emailed 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 to the study doctor's office, it is unsecure and what you put in the text or email is not protected. You may receive text messages before each visit.

Study staff may also arrange secure videoconferences with you (e.g., Telehealth) during the study. The videoconferences will not be recorded.

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

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?

The possible benefits are a better understanding of your child's diabetes or a positive impact on you and your child's ability to manage their diabetes. Your child also may not benefit from this study, but that is what the study is trying to find out. Children who take part in this research study will add to new knowledge that may help other children with type 1 diabetes.

ARE THERE OTHER OPTIONS THAN BEING IN THIS STUDY?

If your child does not take part in this study, your options include standard treatments like continuing with your child's current diabetes management plan, other research studies, or you may choose not to do anything. Your child's study doctor will discuss these choices and the risks and benefits of each with you.

CAN I STOP BEING IN THE STUDY?

You and your child can stop being in the study at any time. If you decide to stop being in this study, you and your child will not be treated differently as a person. Also, your child's 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.

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 your child to continue in the study based on this new information.

The study may stop or the study doctor may decide to take your child 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 your child from the study. You will be told if this happens.

Some reasons why your child may be removed from the study include:

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

If your child withdraws, is removed from the study, or the study is stopped, your child may continue to receive care like your child normally would if your child were not in this study, but your child will no longer be able to use the study system.

ARE THERE COSTS RELATED TO TAKING PART IN THE STUDY?

The study will pay for testing that is specifically for this study. The following study devices will be provided to you at no cost:

- CGM system and CGM sensors
- Study Insulin pump, infusion sets, and reservoirs/cartridges while using the closed-loop system
- Blood glucose meter, test strips, lancets, and control solution
- Blood ketone meter, test strips, lancets, and control solution
- If necessary, a scale

The costs of routine treatment, office visits, and tests that are part of your child's regular care will be billed to you or your child's insurance company like they normally would if your child were not in a study. **You will also be responsible for the costs of the insulins and glucagon you will need in the study like you normally would. The study will not be paying for these medicines.**

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.

At the end of the study, or if you decide to withdraw your child from the study, you must return the study supplies, as requested. You may be permitted to keep the scale (if supplied), blood ketone meter (once all data is removed) and blood glucose meter. Any additional tests and procedures will be billed to you or your child's insurance company like they normally would.

IS THERE PAYMENT FOR TAKING PART IN THIS STUDY?

If your child takes part in the study, you will receive up to $350 for participation, regardless of whether the visits are conducted in clinic or virtually. These payments will be paid by gift card, debit card, or check from the study doctor's office as follows:

- Screening Visit: $50
- Closed-Loop Initiation Visit: $50
- 1-week Visit: $50
- 2-week Visit: $50
- 4-week Visit: $50
- 6-week Visit: $50
- 8-week Visit: $50

Please discuss with your study doctor's office about when and how these payments will be made.

If you withdraw your child from the study, you will still be paid for the visits that your child has completed. You will not receive payment for the 3-day post-study contact. You will not receive extra

payments for visits that are required as part of your child's normal care or for visits that are for treating an illness or injury.

The use of your child's samples may result in commercial profit. You will not be compensated for the use of your child's samples other than what is described in this consent form. The samples collected will only be used for HbA1c and 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 your child has an illness or injury that is related to your child's participation in the study, then you can get care for your child like you normally would. If you have an emergency, please seek emergency care as soon as possible. Please tell the emergency doctor that your child is in a research study. Please also tell your study doctor about the emergency as soon as you can. Care will be billed to you or your insurance like it normally would. 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, Tandem Diabetes Care, Dexcom, and UVA 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, comments or suggestions about the research. You can also contact the IRB if you want more information about your rights, injury reimbursement, or the future use of your information or samples.

HOW WILL MY INFORMATION BE PROTECTED AND KEPT CONFIDENTIAL?

This section tells you about the use and/or disclosure (sharing) of your personal Protected Health Information (PHI) if you decide to participate in this study. Your health information that may be used or disclosed is described below. This is like the information that is usually found in your medical records that will be collected for the study. Only the health information about you that is needed for this research study will be used or disclosed. This information will be kept confidential and private as required by law. The specific types of information that will be released and used for this research are:

- Hospital discharge summaries
- Medical history / treatments
- Laboratory / diagnostic tests
- Operative report (about an operation)

- Biological specimen(s) and/or slide(s)
- Diabetes records

You are being asked to not only be in this study, but also to give your permission for your child's PHI to be released from your doctors, clinics, and hospitals to the researchers doing this study. This is called giving your Authorization. The PHI is necessary for the study to be done, so you do have to give your Authorization in order for your child to be in the study. If you do not want to give Authorization, then your child will not be able to be in the study.

Your Authorization for PHI lasts 50 years from the date that you sign this form or until the end of the study, whichever comes first. You may cancel your Authorization at any time. **You will need to contact your study doctor's office in writing, or you may contact the JCHR IRB Office at 813-975-8690 or irb@jaeb.org.** When you fully cancel your Authorization, your child is no longer part of the study. No new PHI will be shared for the study, except if there is a safety concern. If there is a safety concern, your child's entire medical record may need to be reviewed. The researchers will receive all the information that was collected for the study up to the time that you canceled your Authorization or are no longer in the study. Any information that has been received will remain in the study database after you withdraw.

The researchers will use a code that may have your child's initials or date of birth to keep your child's study information (study results) together at the Jaeb Center for Health Research in Tampa, Florida. Your Authorization for the use and sharing of the coded study results will never end. Also, the following people or companies involved in this study may see your child's study results with things like your child's date of birth, initials, and date of procedures:

- your child's treating healthcare providers and their staff,
- associated healthcare institutions and hospitals where your child receives care
- Jaeb Center for Health Research
- University of Virginia Center for Diabetes Technology (UVA)
- Tandem Diabetes Care
- Dexcom, Inc.
- Advanced Research and Diagnostics Laboratory, University of Minnesota
- Researchers who are part of the study

Sometimes people not directly working on the study need to see your child's PHI. For example, the Food and Drug Administration (FDA), other federal agencies, and committees that monitor safety may inspect health and study records. In most cases, the information will be coded instead of having your child's PHI, but not always. For example, if your child participates in this study, then this form could be reviewed and it would have your child's name on it. Once PHI is shared, it may no longer be covered by the privacy laws.

You have the right to see your child's records. During the study, you may not be able to see or get copies of everything. For example, if you are not supposed to know which study group your child is in, then we wouldn't want to tell you before the study ends. The study doctor will be able to tell you if you will have to wait to get some information. When the study is over, you have the right to see your child's full records.

Certificate of Confidentiality
NIDDK has given us a Certificate of Confidentiality for this study. This adds special protection for study information that identifies your child and allows us, in some cases, to refuse to give out information that could identify your child without your consent. This could be done when the information is requested by a federal, state, local court or public agency. If your child needs medical help, we may still share your child's 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 child's identifiable information. Your child's 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 your child; and
- if your study doctor or research team learn that your child plans to harm him/herself or someone else

Clinical Trial Reporting
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. A copy of one of the study consent form templates will also have to be posted on a federal Web site.

Other Considerations
The information collected in the study may be used in future studies without additional permission from you. This may include research done by other researchers. The information that may be shared will not contain any PHI that could identify your child. There may still be a chance that someone could identify your child, but this is not likely. The study results will also be made public. These results will not have any PHI either. Study results without PHI may be shared in medical journals and at scientific meetings.

A limited dataset that contains some PHI may be provided to certain researchers. This PHI will not include things like your child's name, address, identifying pictures, or medical record numbers. Any researcher would need to sign an agreement to protect your child's PHI before getting this dataset as required by law.

Results from the study will not be sent to you.

Social Media
We would like to ask you not to share any of the specific details of this study publicly, like in social media posts. This is one way we can help protect confidentiality. This is also important because the products being used in this study are not available outside of this study. You do have the right to discuss the study with others to help you decide if you want your child to be in the study or stay in the study at any time.

eConsent

If you agree for your child to be in the study at this time, you will be asked to electronically sign with your unique username and password, called eConsent. You will be able to save or print copies of this form. You can also ask the study doctor's office for a paper copy at any time at no cost. The Jaeb Center will have your eConsent information, like your name. This information will be kept separate from your study results. It will be kept confidential and private.