CONSENT TO TAKE PART IN A RESEARCH STUDY

STUDY TITLE: The Pediatric Artificial Pancreas (PEDAP) trial: A Randomized Controlled Comparison of the Control-IQ technology Versus Standard of Care in Young Children in Type 1 Diabetes

STUDY DOCTOR'S INFORMATION

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SUMMARY

In this form, when it says "you" it is referring to your child as the participant, 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 would be like a parent reviewing the information for their child to be in the study. In this case, "you" would mean "your child."

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 look at how well an investigational automated insulin delivery system ("study system") works in young children with type 1 diabetes. The study will find out how safe the system is compared to a regular insulin pump or daily injections of insulin along with an added glucose monitor.**

- **The study system is investigational for purposes of this study and is not approved by the Food and Drug Administration (FDA). For this reason, it is called experimental in this study.**

- **You will be asked to be in the study for about 6-7 months. The study includes several phases, described below. These phases will include fingersticks to draw blood. You and your child will also insert small sensors or catheters under your child's skin when using study devices.**
  - **If needed, you and your child will train on the study glucose monitor and practice using it for several weeks.**
  - **Then your child will start the main phase which is about 3 months. In this phase, your child will be randomly assigned (like flipping of a coin) into one of two groups. Your child's group will either use the study system or will keep using their current insulin pump or daily insulin injections. Both groups will use the study glucose monitor.**

- **The last phase is also about 3 months. For this phase, your child will switch to the study system if they were in the group that did not use the study system during the first phase.**
- **The study is designed so you can participate from home without visiting the clinic.**
- **You may have the option to be part of a focus group so we can learn more.**

- **The most likely risks to your child are pain, bruising, redness, and temporary discomfort from the fingerstick when blood is drawn or discomfort when a sensor or catheter is being inserted into the skin.**

- **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. The information gained from the study may help other children with type 1 diabetes in the future.**

- **If you do not want your child to participate, you may seek other options for your child which include standard treatment like continuing with your child's current diabetes management regimen or participation in other research studies.**

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

A "minor" is a person under the age of 18. A LAR for a minor is a natural or adoptive parent, a legal custodian, or a legal guardian.

WHAT IS INFORMED CONSENT?

You are being asked to take part in this research study because your child has type 1 diabetes and uses insulin. The goal of this study is to learn things that may help children with diabetes.

Your child's 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 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 allow your child to be in this study. If you decide not to be in this study, you and your child will not be treated differently as people just because you didn't want to be in this study. Also, your child's regular care will not be impacted.

WHO IS DOING THE STUDY?

This study is being done by your study team. It is being paid for by The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Tandem Diabetes Care is providing insulin pumps and related supplies. Dexcom is providing glucose monitoring supplies. Other companies may also provide study supplies.

The Jaeb Center for Health Research will use study 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 investigational automated insulin delivery system ("study system") for young children with type 1 diabetes can safely improve blood glucose (sometimes called blood sugar) control. The system uses continuous glucose monitoring (CGM), an insulin pump, and a software algorithm to automatically give insulin and control blood glucose. It is also sometimes called a "closed-loop" system.

The CGM sensor has a thin needle that is inserted just under the skin. It measures the glucose in the fluid under the skin and shows this information on the insulin pump every 5 minutes. The sensor needs to be changed about every 10 days. The insulin pump has a catheter that is inserted under the skin. It needs to be changed about every 3 days.

The study system is made by a company called Tandem Diabetes Care and is called t:slim X2 with Control-IQ. A similar version of the system has been tested in previous studies with adults and older children. These studies did not find increased risk for high or low blood glucose or other problems. The study system 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. Tandem Diabetes Care plans to use the results of this study to apply for FDA approval for the system to be used in younger children.

We expect up to 150 people will take part in this study for about 6-7 months at about 3 different clinical centers in the United States.

WHO CAN PARTICIPATE IN THIS STUDY?

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

- Have type 1 diabetes and have used insulin for at least 6 months
- 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 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
- Have a total daily insulin dose (TDD) of at least 5 U/day
- Weigh at least 20 pounds
- Be willing not to start any new glucose-lowering drugs during the study
- Live in the United States, with no plans to move outside the United States during the study period

Also, your child must not:

- Take any medicine but insulin to lower blood glucose

- Have certain medical conditions your study doctor will ask about, such as bleeding disorders, kidney disease, and glandular disease
- Have had more than 1 severe hypoglycemic event in the last 3 months involving a seizure or loss of consciousness
- Have had more than 1 diabetic ketoacidosis (DKA) event in the last 6 months, not counting any event when diabetes was first diagnosed
- Have used any oral or injectable steroid drugs within the last 8 weeks
- Have any skin allergy or intolerance to adhesives used with CGM or infusion set parts
- Have any plans to receive blood transfusions during the study
- Currently use any closed-loop system, or use an insulin pump that can't be used with the study CGM
- Participate in another drug or device study at the same time as this study
- Have any immediate family members who work for Tandem Diabetes Care or who are directly involved in running this study

Your study doctor and staff will review more health-related requirements with you. Your 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 6-7 months for your child to complete. The study is designed so you can do your study visits from home via videoconference (e.g. Zoom) without visiting the clinic if you and your 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 and your child agree to participate, you will provide your electronic signature to confirm your willingness to participate. Then we will ask you and your child some questions to make sure he/she qualifies, and it is safe for him/her to be in this study.

- Collection of information about you and your child: This 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. We will provide a scale to measure weight if you do not already have one at home.
- Your child's current personal doctor or provider may be someone who is not 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 study blood glucose meter and blood ketone meter to use during the study. Your child will need to perform blood glucose tests to calibrate the CGM (if it ever requires calibration) and respond to system alarms. Your child will need to perform a ketone test if your glucose level is higher than 300 mg/dL for more than 90 minutes, or greater than 400 mg/dL at any time. You will receive a cable, software, and computer, if necessary, so you can download data from the study ketone meter. We will give you and your child instructions on how to use and maintain your meters.

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

You will be asked to complete a set of questionnaires about your experience as a parent of a young child with type 1 diabetes.

The screening visit will last 1 to 2 hours.

CGM Run-In

If your child currently uses a CGM that is the same brand as the study CGM for at least 11 out of the last 14 days, your child will skip to the Main Phase of the study described below. Otherwise, your child will have a run-in period with the study CGM devices as described in this section.

Your child will wear the study CGM for 2 weeks

- Your study team will provide you with CGM supplies in person or have the supplies delivered to you.
- You and your child 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.
- Your child 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 and your child will have a follow-up visit after 2 weeks.
- Study staff will download the study CGM data to determine if your child 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 your child wore the CGM.
- Study staff may suggest changes to help you and your child improve your child's blood glucose control.

If your child's study doctor thinks it is necessary, your child may repeat this 2-week run-in once or twice. If your child was not using any CGM when you began the study, you must wear the CGM for a minimum of 4 weeks.

Main Phase

If your child skipped the CGM use phase above, the procedures described below could occur as part of the Screening visit. Otherwise, a separate visit will occur at least 2 weeks after the Screening visit.

If your child qualifies to start the main phase of the study, you and your child will again be asked if you have any questions about the study. We want to make sure that if you and your child continue, you

understand the study and feel that you and your child can follow the procedures needed in either study group.

You and 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.

At this visit, a computer program will be used to select whether or not your child will be given the Control-IQ closed-loop study system or use the study CGM with your child's current insulin pump or daily insulin injections. This is like flipping a coin to decide which group your child is assigned. The computer will assign the groups so that 2 out of every 3 participants are in the Control-IQ group, with the other 1 participant being in the Standard Care (SC) group. This is done completely randomly. Neither the study doctors nor you will not get to choose which group your child is in. Your child will continue the care in the assigned group for approximately 3 months.

You may use available software apps from the CGM manufacturer for mobile data access or remote monitoring during the study. You may not use any software not from the manufacturer.

SC Group

If assigned to this group, your child will continue to use his or her personal insulin pump or multiple daily injections of insulin along with the study CGM at home. If you are currently using a low blood glucose suspend (i.e. PLGS; LGS) feature on your child's insulin pump that works with the study CGM, you may continue to use that during the study. We will call you and your child after the first week to see how your child is doing with the study CGM. You and your child will have a visit after the second week so we can answer any questions you and your child may have and review your child's glucose data. Study staff may suggest changes to help you improve your child's blood glucose control. You will then continue to use the study CGM at home for a total of 13 weeks. You and your child will have a series of phone contacts and visits during this period as shown in the table below.

You and your child will be asked to upload data from the study CGM and ketone meter during the study. You and your child will do this before each scheduled clinic visit or phone call, and otherwise at least once every 4 weeks. You will be given all necessary equipment to do this.

Closed-Loop Group

If assigned to this group, you and your child will be trained to use the study system including the Tandem t:slim X2 with Control-IQ technology and Dexcom G6 CGM. Using the study system in closed-loop mode will automatically adjust your child's insulin delivery based on the CGM glucose readings. You and your child can always stop closed-loop mode at any time and take over control of your child's insulin pump. If your child was on multiple daily injections of insulin at the beginning of the study, your study doctor will decide what insulin pump settings your child will start with. These settings may be adjusted during the study.

Training may happen during one or more sessions. By the end of training, you and your child will be expected to perform certain tasks without help from study staff members. You and your child 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. If your child switched from insulin injections to the study system, you will have a phone call or videoconference after using the system for about 3 days. All participants will have a phone call with study staff after about 1 week to review your experience. Your child will continue to use the system for another week followed by a visit to review training and answer any questions you and your child have. Study staff may suggest changes to help you improve your blood glucose control. Then you will use the study system at home for about 11 more weeks. You will have a series of phone contacts and visits during this period as shown in the table below.

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:

- Your child has a fever above 101.5 degrees Fahrenheit
- Your child has a major illness
- Your child needs to use certain medications including epinephrine (e.g. for the emergency treatment of a severe allergic reaction or asthma attack) or oral or injectable steroids

You and your child will be asked to upload data from the study CGM, pump, and ketone meter during the study. You and your child should do this before each scheduled visit or phone call, and otherwise at least once every 4 weeks. You will be given all necessary equipment to do this.

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

Scheduled Visits After First Two Weeks (In-Clinic or Videoconference)
The schedule for additional visits is the same for everyone in the study. The main reason for these visits is to troubleshoot any problems and ask you and your child about any changes in your child's health.

Follow-up visits will occur at 6 weeks and 13 weeks.

<u>The following procedures will be performed in both groups at each visit, unless otherwise listed below:</u>

- Assessment of study device use
- Review of any problems or events that have occurred
- Download of study device data
- Fingerstick blood sample for HbA1c *(13 weeks)*
- Completion of Questionnaires (*13 weeks)*
- Height and Weight measurement will be repeated (*13 weeks)*

Scheduled Phone Calls
In addition to the 1-week phone call described above, study staff will call you and your child after about 10 weeks. The schedule for this call is the same for everyone in the study.

Phone Call Procedures

- Discussion of your child's use of the study devices
- Discussion of any changes in your child's health
- Review of available study device data to identify any safety issues

The Main Phase of the study will end at the 13-week visit.

Extension Study Phase

After the Main Phase of the study has ended, data will be collected for an additional 13 weeks. If you have been using the Control-IQ system, you will switch to an updated version of that system for the additional 13 weeks. If you have not been using the Control-IQ system, you will switch to using that same updated system for 13 weeks.

The updated system has some new features to improve its usability. You and your child will receive training on use of the system. As above, you and your child will be asked to upload data from either your child's study CGM, study pump, and ketone meter at least once every 4 weeks.

Scheduled Visits and Phone Calls During Extension Phase

You will have a phone call or videoconference after about 3 days to check how the updated system is working for you. You will have additional phone calls at 14 and 23 weeks and additional visits at 15 and 19 weeks.

Phone calls and visits will include:

- Assessment of study device use
- Review of any problems or events that have occurred
- Download of study device data

Final Visit (26-week Visit)

The final study visit will be about 26 weeks after the Screening visit. Procedures will be similar to those described for the Screening and follow-up visits. You and your child will be asked to return some study devices as instructed by study staff at this visit. If needed, your child will be switched back to the insulin pump he or she was using before entering the study. You and your child will complete another set of questionnaires with similar topics as before. There will be a final fingerstick for HbA1c tests. Height and weight measurements will also be repeated.

Focus Groups

Your child may be asked to take part in an online group with other participants during the study. The purpose of the group will be to hear about people's experiences with the device systems and how they affect the people who use them. Although we would like as many people as possible to be in a focus group, this will be optional. Your child can still be in the study even if you or your child does not want to be in a focus group.

The table below show what will happen at each phone call and visit:

	CGM Run-in	0	3d[1]	1w	2w	6w	10w	13w	13w + 3d	14w	15w	19w	23w	26w
		MAIN STUDY PHASE							EXTENSION PHASE					
Visit (V), Videoconference (VC), or Phone (P)	VC/V	VC/ V	VC/ P	P	VC/ V	VC/ V	P	VC/ V	VC/ P	P	VC /V	VC /V	P	VC/ V
Review if you can continue in the study	X	X												
Fingerstick for HbA1c		X						X						X
Device Data download(s)	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Review diabetes management and any new medical problems	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Questionnaires	X							X						X

[1] *Only for participants on daily insulin injections at enrollment assigned to the CLC group*

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 and your child to discuss these with your child's study doctor, your child's primary care provider, or another health care professional.

Study System Risks

There is a risk that parts of the closed-loop study system may not work properly. As a result, your child could receive less or more insulin than needed 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 child's actual glucose level.
- 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 your child may become thirsty, or have a higher level of glucose in his or her 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.

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 child's 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)

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)

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 will not reuse CGM receiver, transmitter, or sensor parts in more than one patient.

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, we will not reuse an insulin pump in more than one patient.

Risk of Re-using the Blood Glucose Meter or Ketone Meter

The FDA approved these meters for 'single-patient use'. 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 do not plan to reuse these meters.

Questionnaire Risks

The questions asked on the questionnaires will include questions about you and your child's 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 child's information confidential, but this is not a guarantee.

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

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 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. It is also possible that someone could recognize you from the focus group. 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.

The study doctor and staff will use your contact information to call, text or email you during the study. They may do this to send you things like appointment reminders. Study staff may also arrange videoconferences with you (e.g. Zoom) during the study. The videoconferences will not be recorded.

Study staff 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/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, this is unsecure and what you put in the text or email is not protected. You may receive calls, text messages, or emails once per week or more often.

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 treatment like continuing with your child's current diabetes management regimen, other research studies, or you may choose not to do anything. Your child's study doctor will discuss these choices 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 people. 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 you 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 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 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. 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 computer and scale

At the end of the study, or if you decide to withdraw your child from the study, you must return the investigational devices and computer, if one was borrowed for the study, to the study team listed on the front page. You may be permitted to keep the scale, blood ketone meter 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 $300 for participation. These payments will be paid as follows:

- Screening Visit: $50
- Randomization Visit: $50
- 2-week Visit: $50
- 6-week Visit: $50
- 13-week Visit: $50
- Extension Phase Completion: $50

Payment will made by check, 6-8 weeks after finishing the study. 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 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 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 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. You do not give up any legal rights, such as seeking compensation for injury, by electronically signing this form. If you feel you have been injured as a result of this study, you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover. Your study doctor, the study doctor's office, the Jaeb Center, and Tandem Diabetes Care 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.

You may also contact UVA Research Compliance Monitor PO Box 801011 Charlottesville, VA 22908 or at 434-924-8660.

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Mark DeBoer, M.D.
University of Virginia
Center for Diabetes Technology
560 Ray C Hunt Drive, Charlottesville, VA, 22923
Phone: (434) 924-9833

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 child's 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 child's 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 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

Purpose of Authorization
We have rules to protect information about your child. Federal and state laws also protect your child's information. By giving your electronic signature, you are giving your permission, called your "authorization," for the use and disclosure of information protected by the law.

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

Using and Sharing Your PHI
Your study doctor will collect information about your child. This information includes things learned from study procedures as well as your child's name, address, date of birth, and information from your child's medical records. These are examples of identifiable information and may be used to confirm you and your child's identity when you consent to participate in the study. After the consent process is complete, a code number without and identifiable information will replace your child's 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 child's study results with things like your date of birth, initials, and date of procedures:

- Your study doctor's office
- Your child's personal doctor's office, if different than your study doctor's office
- Jaeb Center for Health Research
- University of Virginia Center for Diabetes Technology
- 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 your child 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 child's 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 child's 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 child's 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 child's 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 child's 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 child's 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 your child 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 child's study PHI does not have a code number with it. Your permission for the use and sharing of your child's PHI lasts 50 years from the date that you provide your electronic signature or until the end of the study, whichever comes first.

The rest of your child's 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 child's name, address, telephone number, or social security number.

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 information that could identify your child. There may still be a chance that someone could identify your child, 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 your child.

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 will have communication with the study doctor's office by phone, text, or by video (like Zoom, 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 your child. 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.