# CONSENT TO TAKE PART IN A RESEARCH STUDY

**STUDY TITLE:** The International Diabetes Closed Loop (iDCL) trial: Clinical Acceptance of the Artificial Pancreas in Pediatrics. A Study of t:slim X2 with Control-IQ Technology

## 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 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 and how safe it is compared to a regular insulin pump 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.**

- **Your child will be asked to be in the study for about 6-9 months. The study includes several phases, described below. These phases will include needle sticks to draw blood. You and your child will also insert small sensors and catheters under your child's skin when using study devices.**

    - **If needed, you and your child will train on the study system devices and practice using them for several weeks.**
    - **Then your child will start the main phase which is about 6 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 use a regular insulin pump and glucose monitor.**

- **The last phase is 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.**
- **If your child used the study system during the first 4 months of the study, then your child will be asked to continue to use the study system for the next 3 months.**

- **The most likely risks to your child are pain, bruising, redness, and temporary discomfort from the needle stick 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?

Your child is 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 this condition.

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 your child 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 child's study doctor and team. It is being paid for by Tandem Diabetes Care. It is also supported by the National Institutes of Diabetes and Digestive and Kidney Diseases (NIDDK). The Jaeb Center for Health Research will use the funding from Tandem Diabetes Care 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 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 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 overall study system is made by a company called Tandem Diabetes Care and is called t:slim X2 with Control-IQ. The CGM and insulin pump part of the system are similar to devices that are currently available for people to purchase and use. The software algorithm runs on the pump and calculates how much insulin your child will automatically receive. This algorithm has been tested in previous studies using different CGMs, insulin pumps, and computer components. 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 to be able to sell the study system in the U.S.

We expect about 150 people will take part in this study for about 9 months at up to 4 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 one year
- Be familiar with the use of a carbohydrate ratio for meal boluses.
- Be between 6 and 13 years old
- Weight ≥25 kg (≥55 lbs) and ≤140 kg (≤308 lbs)

- Be willing to stop using any personal CGM once the study CGM is in use unless using any low glucose suspend system in which case, current and study CGMs may be both used
- Have a total daily insulin dose (TDD) of at least 10 U/day
- Be willing not to start any new glucose-lowering drugs during the study

Also, your child must not:

- Take any medicine but insulin or metformin to lower blood glucose, either now or during the study
- Participate in another study at the same time as this study
- Work for, or have any immediate family members work for Tandem Diabetes Care
- Be pregnant or plan to become pregnant during the study if you are female of child bearing age

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

## WHAT WILL HAPPEN IN THIS STUDY?

This study will take about 9 months for your child to complete. The next sections list what will happen during the study.

### *Screening Visit*

If you and your child agree to participate, you will sign this consent form and your child will sign an assent form. Then we will ask you and your child some questions and your child will have some tests done 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, the past and current medical conditions, surgical procedures, menstrual history (females), allergies, medications and supplements, family history, and whether or not your child has various symptoms. Your child also will also be asked about their pump settings and average daily insulin use over the past week.
- Physical exam (height and weight, blood pressure and pulse)
- Blood draw for:
    - Complete Metabolic Panel (CMP) to see how well your child's kidneys are working and to see the amount of certain salts and sugars in your child's blood
    - HbA1c test unless your child has had one within the past 2 weeks to start the study. Additional blood tests may be performed if the study doctor has any concerns about medical conditions that might put your child at risk in the study
- A urine pregnancy test if your child is a female who can become pregnant. The pregnancy test must be negative in order for your child to participate and will be repeated at some follow-up clinic visits during the study.

We will give your child 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 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 2 hours, or greater than 400 mg/dL at any time. 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.

The screening visit will last 1 to 2 hours.

CGM and Pump Run-In

If your child currently uses an insulin pump and has used 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

- 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 return for a follow-up clinic 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.
- If your child is on multiple daily insulin injections (MDI) at enrollment, they will receive a study pump to use. You and your child will be trained on the study pump at the same time as the study CGM training.
- Study staff may suggest changes to help your child improve your blood glucose control.
- 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.

***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.

We will draw blood for another HbA1c test. This blood will also be used for a C-Peptide test and a blood glucose test, which will be sent to a central laboratory for processing. This measures whether your child's body makes any of its own insulin. Everyone in the study will complete some questionnaires. Topics will include questions about your child's hypoglycemia awareness, low and high blood glucose, and your child's feelings about managing his or her diabetes.

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 study insulin pump (SAP or LGS if your child is on it at the time of the study start). This is like flipping a coin to decide which group your child is assigned. The computer will assign the groups so that 3 out of every 4 participants are in the Control-IQ group, with the other 1 participant being in the Standard of Care (SC) group. This is done completely randomly and the study doctors or you will not get to choose which group your child is in. This means that your child may be asked to switch pumps. This depends on which group your child is assigned to. Your child will continue the care in the assigned group for approximately 4 months.

You, as the parent, will also be asked to fill out a questionnaire on how you feel about your child using a closed-loop system to manage his or her diabetes.

You will receive diabetes education. The education will cover key parts of diabetes management.

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 use a regular insulin pump along with the study CGM at home. A pump will be provided if your child uses MDI. If you are currently using a low blood glucose suspend (i.e. PLGS; LGS) feature on your child's insulin pump, 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 come back to the clinic 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. Your child will then continue to use the study CGM and your child's personal insulin pump for about 16 weeks at home. You and your child will have a series of phone contacts and clinic visits during this period as shown in Table 1 on page 10.

You and your child will be asked to upload data from the study CGM 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 and your child 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. You and your child will be taught how to use the study system in all modes of operation similar to your child's personal

insulin pump. 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.

Training may happen during a single visit or two visits to the clinic. 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 printed User Guide as a reference. You and your child 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, for a 1-week period and then have a phone call with study staff to review your experience. Your child will continue to use the system for another week followed by a clinic 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 16 weeks. You will have a series of phone contacts and clinic visits during this period as shown in the table below.

Your child should use the study system in closed-loop mode whenever possible. Your child will be ask to use this mode as much as your child can. 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 glucocorticoids

You and your child will be asked to upload data from the study pump during the study. You and your child should do this before each scheduled clinic visit or phone call, and otherwise at least once every 4 weeks. You and your child 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 Clinic Visits***

The schedule for clinic 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 8 weeks and 16 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

- Blood draw for HbA1c *(16 week)*
- Completion of Questionnaires (*16 week)*
- Height and Weight measurement will be repeated (*8 week, 16 week)*

***Scheduled Phone Calls***
In addition to the 1-week phone call described above, study staff will call you and your child at 4 weeks, 6 weeks, 10 weeks, 12 weeks, and 14 weeks. The schedule for these calls 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 16-week visit. Participants of both groups will be asked to continue the study. If your child has been using the Control-IQ, your child will be asked to continue the study another 12 weeks. If your child has not been using the study system, you and your child have the option of switching to use the Control-IQ system for 12 weeks.

***Extension Study Phase***
At the 16-week visit, a 12-week Extension Phase will begin for all study participants. For this phase, your child will switch to the study system if he/she was in the SC group during the Main Phase. You and your child will receive training on the use of the insulin pump with Control-IQ.

As above, you and your child will be asked to upload data from either your child's study CGM or study pump at least once every 4 weeks.

***Scheduled Phone Calls during Extension Study***
You and your child will have two additional phone calls if your child has been already using the Control-IQ system. If you and your child are new to the system, you will have four additional phone calls and two clinic visits. You and your child should upload the study pump data before each call. The study team will:
- Discuss your child's use of the study devices
- Discuss any changes in your child's health
- Review of available study device data to identify any safety issues

***Final Visit (28-week Visit)***
The final study visit will be at least 28 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 blood draw for HbA1c tests. Height and weight measurements will also be repeated.

The table below shows what will happen at each visit:

| | 0 | 1w | 2w | 4w | 6w | 8w | 10w | 12w | 14w | 16w | 17w | 19w | 20w | 21w | 23w | 24w | 25w | 28w |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | MAIN STUDY PHASE | | | | | | | | | | EXTENSION STUDY PHASE | | | | | | | |
| **EXPERIMENTAL GROUP: Clinic Visit (V) or Phone Contact (P)** | V | P | V | P | P | V | P | P | P | V | | | P | | | P | | V |
| **SC GROUP: Clinic Visit (V) or Phone Contact (P)** | V | P | V | P | P | V | P | P | P | V | P | P | | P | V | | P | V |
| **Review if you can continue in the study** | X | | | | | | | | | | | | | | | | | |
| **Blood draw for: - HbA1c** | X | | | | | | | | | X | | | | | | | | X |
| **Blood draw for: - C-peptide test - CMP - Glucose** | X | | | | | | | | | | | | | | | | | |
| **Pregnancy test (females of child-bearing potential)** | X | | | | | X | | | | X | | | | | X | | | X |
| **Study device download** | 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 | X | X | X | X |
| **Questionnaires** | X | | | | | | | | | X | | | | | | | | X |

## WHAT ARE THE RISKS OF THIS STUDY?

If you choose to allow your child 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.

### 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.

### Blood Draw Risks

Anytime you have your blood drawn you may have these risks that are possible but unlikely, and usually mild.

- 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)

**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)

**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 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 receiver or transmitter parts after careful cleaning. The sensors will not be reused.

**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.

**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 you and your child's personal attitudes, and behaviors related to diabetes. It is possible you and your child may find these questions to be upsetting. Similar questionnaires have been used in other studies, and this reaction is uncommon. You and your child can refuse to answer any questions that make you feel uncomfortable. You and your child 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.

**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 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. Please see the "How will my information be protected and kept confidential" section below for more information.

**Risks for unborn babies:**
The risks of the device 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.

For minors, the results of a pregnancy test will only be told to the LAR if the minor has given permission by signing an Assent form. Minors will be told about the pregnancy tests in an Assent form. If you are not comfortable with any of the following, then you should not allow the minor to participate:

- The minor getting information about pregnancy
- The minor discussing pregnancy with you and the study doctor
- The minor having pregnancy tests
- The minor giving permission to share results of pregnancy tests

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 MY CHILD STOP BEING IN THE STUDY?**

You child can stop being in the study at any time. If your child decides 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 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.

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 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 study device 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

At the end of the study, or if you decide to withdraw your child from the study, you must return the devices to the study team listed on the front page. 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 $375 for participation. These payments will be paid as follows:

- Screening Visit: $25
- Run-in Visit/Randomization Visit: $50
- 2-week Visit: $50
- 8-week Visit: $50
- 16-week Visit: $100
- Extension Phase Completion: $100

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 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.

Because payments made to you for your child's participation 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 to the IRS.

**WHAT HAPPENS IF MY CHILD HAS 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. 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 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 child's 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 CHILD'S 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 child's 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 direct identifying information will not be used to identify your child.

### 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 child's 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 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 the Protected Health Information Authorization at the end of this form if you want your child to be in the study. When you sign the form, 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 child's 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. A code number with your child's initials and date of birth 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 child's date of birth, initials, and date of procedures:

- Your study doctor's office
- Jaeb Center for Health Research

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 child's study doctor's office will guard the privacy of your child's study PHI. Study results without the identifiable information may be shared in medical journals and at scientific meetings. Your child's records will be confidential. No one will share your child's identity in a medical journal or at a scientific meeting.

Results from the study ***will not*** be sent to you.

**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 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 child's 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.

**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.

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.

**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 child's 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 your child from the study directly, your child is 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 child's 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 your child 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 Child's 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 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 child's name, address, telephone number, or social security number.

**Minor's Full Name** (printed)**:** _____

**Minor's Legally Authorized Representatives (LARs) Permission**

I, _____ (print name of LAR) attest that I am one of the following individuals authorized to provide consent for the child named above as I am one of the following LARs (checkbox):
☐ Natural or Adoptive Parent; ☐ Legal Custodian; or ☐ Legal Guardian

By signing below, you agree to allow your child 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 satisfaction
- you authorize the use and sharing of your child's protected health information that is collected as part of the study
- you freely choose to allow your child to participate, you and your child can withdraw your child at any time, and you will receive a copy of this consent form

_____ _____
LAR 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**