JCHR
JAEB CENTER FOR HEALTH RESEARCH

EXPEDITED
IRB APPROVED
31 AUG 2018

CONSENT FOR YOUR CHILD TO TAKE PART IN A RESEARCH STUDY

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

STUDY DOCTOR'S INFORMATION

Name: [***fillable field***]
Contact Number: [***fillable field***]
Site Name: [***fillable field***]
Site Address: [***fillable field***]
Emergency (24-hour) Number: [***fillable field***]
Study Coordinator Name/Contact: **[*fillable field*]**

SUMMARY

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

- **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.**

- **We are asking that your child be in the study for about 10 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 it. Otherwise, your child will randomly be assigned either to keep using the study system or to use a regular insulin pump and glucose monitor. 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 that you and your child may experience 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. 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)

Where we say "you" in this form, we mean a natural or adoptive parent, a legal custodian, or a legal guardian (collectively known as a "Legally Authorized Representative" or "LAR" for short). Where we say "your child" in this form, we mean the child under your direct care as the LAR.

WHAT IS INFORMED CONSENT?

We are asking you to allow your child 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 type 1 diabetes. We want to find what works best for treating your child and other 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 review with your child, your friends, family, or other doctors to help you decide. Please read this document carefully. Do not allow your child to be in this study unless all of your questions, and your child's questions have been answered.

You do not have to allow your child to be in this study. If you decide that you do not want your child to be in this study, you and your child will not be treated differently. Also, you and your child's regular care will not be impacted.

WHO IS DOING THE STUDY?

This study is being done by your child's study team. It is being paid for by The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The funding will be used by your child's doctor's office and other clinical centers to conduct the research study and by the Jaeb Center for Health Research to coordinate the 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 get money or benefits from a company that makes the devices in this study, then they have to tell the Jaeb Center. The Jaeb Center has a policy to make sure that study doctors cannot work on this study if they get money or benefits that would influence how they do the study.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn whether an investigational automated insulin delivery system ("study system") for individuals 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. 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 get FDA approval to sell the study system in the U.S.

We expect about 168 people will take part in this study for about 10 months at 7 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 at least 14 years old
- Be willing to stop using any personal CGM once the study CGM is in use
- Be willing to use an insulin pump during the study with no automatic insulin adjustment based on glucose level. This means:
    - If your child currently uses an insulin pump, you may not be able to use features like low-glucose suspend or closed-loop control, even if you replace or upgrade your pump during the study. Low-glucose suspend refers to a pump decreasing or stopping insulin delivery if a low blood sugar is predicted or occurs. Closed-loop control refers to a system that automatically increases or decreases insulin delivery to try to keep the blood sugar as close to normal as possible.

  - If the study gives your child an insulin pump to use, you may not be able to use features like low-glucose suspend or closed-loop control.
- 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 or TypeZero Technologies, LLC
- Be pregnant or plan to become pregnant during the study if you are female

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 10 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 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)
- HbA1c test unless your child has had one within the past 2 weeks
- Additional blood tests 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 MDI at enrollment they receive a study pump to use and you and your child will be trained on the study pump concurrently with the study CGM
- Study staff may suggest changes to help your child improve your blood glucose control.

If your child is on multiple daily injections of insulin (MDI):

- If your child was using a CGM before the study started, your child will receive a study insulin pump to use during these 2 weeks. You and your child will be trained on the study pump along with the study CGM.

Study staff may suggest changes to help you and your child improve your child's blood glucose control.

- Otherwise, you child will continue with MDI and the study CGM for 2 weeks. Then you and your child will have a clinic visit to check how the CGM is working. Then your child will receive a study insulin pump and use it with the CGM for another 2 weeks as described above.

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. This measures whether your child's body makes any of its own insulin. Everyone in the study will complete some questionnaires. Topics will include a personality assessment, 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 closed-loop study system or use the study CGM with your child's regular insulin pump (SAP). Through a process similar to flipping a coin, your child will be assigned to either the closed-loop group or the SAP group for the first 6 months of the study. Your child will have a two thirds chance of being in the closed-loop group. Neither you, your child, nor the study staff will have a choice in which group your child will be placed.

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.

SAP Group

If assigned to this group, your child will use a regular insulin pump (with no automated insulin control based on blood glucose level) along with the study CGM at home. A pump will be provided if necessary. We will call you and your child after the first week to see how your child is doing with the 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. You will then continue to use the study CGM and your personal pump for about 26 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 below.

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.

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 26 weeks. You will have a series of phone contacts and clinic 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 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 6 weeks, 13 weeks, and 26 weeks.

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

- Assessment of study device use
- Review of any problems or events that have occurred
- Download of study device data
- Blood draw for HbA1c *(13-week, 26 week)*
- Completion of Questionnaires (*13-week, 26 week)*
- Height and Weight measurement will be repeated (*13-week, 26 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, 9 weeks, 17 weeks and 20 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

Extension Study Phase

At the 26-week visit, a 13 week Extension Phase will begin.

For this phase, your child will switch to the study system if they were in the SAP group during the Main Phase. If your child was in the closed-loop group during the Main Phase, a computer program will be used to select whether your child will keep using the closed-loop system or your child will switch to use the study CGM with a regular insulin pump with no automated insulin delivery (SAP). Your child will have a 50/50 chance of staying in the closed-loop group. Neither you, your child nor the study staff will have a choice in which group your child will be placed. You and your child will receive training as follows:

- SAP group switching to closed-loop: will be trained on the closed loop system
- Closed-loop group remaining on closed-loop: will receive refresher training on the closed-loop system
- Closed-loop group switching to SAP: will receive refresher training on the differences between the closed-loop system and SAP with a regular insulin pump

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

If you switched from SAP to closed-loop for the Extension Phase, you and your child will have two additional phone calls. You and your child should upload the study pump data before each call. These calls will occur 1 week and 2 weeks into the phase and will involve the following:

- 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

Final Visit (39-week Visit)
The final study visit will be at least 39 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:

Table 1: Main Phase and Extension Phase of Study

	0	1w	2w	4w	6w	9w	13w	17w	21w	26w	27w	28w	39w
Clinic Visit (V) or Phone Contact (P)	V	P	V	P	V	P	V	P	P	V	P*	P*	V
Review if you can continue in the study	X												
Blood draw for HbA1c	X						X			X			X
Blood draw for C-peptide test	X												
Pregnancy test (females of child-bearing potential)	X						X			X			
Study device download	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
Questionnaires	X						X			X			X

*Only performed for the participants in the Extension Phase who either switched from SAP to CLC, or vice-versa.

WHAT ARE THE RISKS OF THIS STUDY?

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

Risks related to your 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

- Possible risks from blood draws include:
- Pain (common)
- Bruising (common)
- Redness (common)
- Temporary discomfort from the needle stick (common)
- Clotting (unlikely)
- Excessive bleeding (unlikely)
- Lightheadedness (rare)
- Infection (rare)
- Fainting (rare)

- Swelling of tissue (rare)

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 for your child, 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. Please see the "How will my child's information be protected and kept confidential" section below for more information.

Risks for women:
The risks of the devices in this study on an unborn baby are unknown. For this reason, if your child is female, she cannot take part in the study if she is pregnant. The study doctor will perform pregnancy tests if your child has had a menstrual period. The study doctors are required to do this even if you think there is no possibility that your child is pregnant or could get pregnant during the study. The results of your child's pregnancy test will only be told to you if your child gives permission by signing the Assent form. Your child will be told about the pregnancy tests in the Assent form. If you are not comfortable with any of the following, then you should not allow your child to participate:

- your child getting information about pregnancy
- your child discussing pregnancy with you and the study doctor
- your child having pregnancy tests
- how the study doctor will get your child's permission

Please discuss the risks with your child and your child's study doctor or any other health care provider.

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?
You and your child may receive no direct benefit from being in this study. 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 you do not want your child to take part in this study, other options for your child 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 and your child.

CAN MY CHILD STOP BEING IN THE STUDY?

You or your child can stop participation in this study at any time. If you or your child decide to stop being in this study, you and your child will not be treated differently. Also, you and your child's regular care will not be impacted. Please talk to your child's study doctor or staff so they know why you and your child are stopping the study and can help your child 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 and your child 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 the best interest of your child
- 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 your child does not follow the study instructions

If your child 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.

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 study will pay for the following supplies at no cost to your child:

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

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 your child has 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 the study doctor about the emergency as soon as you can. The study will not provide costs for care or other expenses relating to illnesses or injuries. Your child's study doctor, the doctor's office, the Jaeb Center, and NIDDK are not offering 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 the 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.

IS THERE PAYMENT FOR TAKING PART IN THIS STUDY?

If you allow your child take part in the study, you will receive up to $475 for participation. These payments will be paid as follows:

- Screening Visit: $25
- Run-in Visit/Randomization Visit: $50
- 2-week Visit: $50
- 6-week Visit: $50
- 13-week Visit: $100
- 26-week Visit: $100
- 39-week Visit after return of all study related equipment: $100

If you withdraw your child from the study, or if your child withdraws, 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.

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. 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

The 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. The 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 the 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 sharing 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 Child's 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 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 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 or your child. Study staff will provide an update once the study results are available through http://www.ClinicalTrials.gov.

Who Can Receive and Use Your Child's 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 sponsor the study. 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). If so, people outside this doctor's office who assist in your child's care may see your child's study PHI. They may not be covered by the law. 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. The study results will also be made public. These results will not have any information that could identify your child.

Clinical Trial Reporting
A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by law. This website will not include information that can identify your child. At most, the website will include a summary of the results. You can search this website at any time.

Can You Cancel Your Authorization?
You may cancel your permission for the use and sharing 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. When you cancel your permission or when you withdraw your child from the study directly, your child will no longer be a 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 child's study information 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.

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

Legally Authorized Representatives (LARs) Permission

I, _____ (print name of legally authorized representative ("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 the LAR(s) named above are in fact the person(s) authorized to consent for the child. I also certify that to the best of my knowledge the participant or LAR understands the nature, demands, risks, and benefits involved in the participation of this study.

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

ASSENT FORM

For Children 14 – 17 years old

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

A research study is like a science project at school and it is a way to learn new things. We are doing a study to find out more about whether an investigational system that automatically controls an insulin pump can safely and successfully manage blood sugars. We call this a "closed-loop" system, or "artificial pancreas" or "study system." The system runs on an insulin pump and uses a continuous glucose monitor (CGM) that measures your sugar level every 5 minutes. The CGM uses a needle inserted just under the skin. The study system has been approved by FDA for this study and is experimental and can only be used for research.

First, there will be a few weeks of training on study devices if needed. Then two thirds of the people in this study will begin using the study system for 6 months, and the others will use a regular insulin pump (no closed-loop) along with CGM. It is a random choice, like flipping a coin. No one knows which group you will be in ahead of time.

After 6 months, everyone who did not get to use the study system will switch to it for 3 months. Those who were already using the study system will get another random assignment. Half will keep using the study system for another 3 months and half will switch to a regular pump along with CGM for 3 months.

We are asking you to be in the study because you have type 1 diabetes and use insulin. You do not have to be in this study if you do not want. It is up to you. You can even say okay now and you can change your mind later. All you have to do is tell us. No one will be mad at you if you change your mind.

This study will take about 10 months to complete. If you agree to be in this study, you will be asked to do:

- Clinic visits: You will come to this clinic for a visit up to about 8 times.
- Telephone/Email: We will contact you or your parent/guardian by telephone or email you to see how you are doing.
- Finger sticks and blood draws: these will be done several times during the study so we can test some of your blood.
- Questionnaires: you will be asked to answer questions on paper or online.
- Blood sugar checks: You must check your blood sugar as instructed by study doctors.
- Continuous glucose monitoring (CGM): You will use a CGM sensor every day and must change it every 10 days.
- Insulin Pump: you will use either a study insulin pump or a regular insulin pump with no closed-loop depending on which group and study period you are in.
- Medical records: We will look at your past doctor visits and use information about your care.

ASSENT FORM

For Children 14 – 17 years old

You may experience some of these events:

- High or low blood sugar levels
- Redness, itching, discomfort or bruising from the glucose sensors or from the insulin infusion sets
- Pain or bruising from your fingerstick blood sugar checks and other blood tests
- Embarrassment about questions asked on the questionnaires

If you are female and you are pregnant right now, you cannot be in this study. If you become pregnant, you will not be able to stay in the study. If you think you could be pregnant, please tell the study team that you do not want to be in this study. The study team is not allowed to tell your parents. You may be asked to have pregnancy tests for this study. If you are asked, then you have to have these tests in order to be in the study. The study doctor will talk to you and your parents about the results. If you do not want to have the tests, or you do not want the study doctor to talk to you and your parents about the test results, then you do not have to be in the study. If you are not okay with being in this study, then do not sign this form. If you sign this form, then you are saying that it is okay to do the pregnancy tests and to talk to you and your parents about the test results. You do not have to be in the study if you don't want to.

We do not know if you will be helped by being in this study. We may learn something that will help other children with type 1 diabetes.

This study was explained to your parents and they said that you could be in it. You can talk about this with them before you decide. Before you say yes to be in this study, we will answer any questions about the study that you may have. If you have other questions after you sign this form, you can ask us and we will answer them or get an answer for you. You can stop being in the study at any time.

Child's Name (print)**:** _____

Child's Permission

Signing below means:

- You have read this form and that you choose to be in this study
- If you are a female, signing this form means that you are okay with having pregnancy tests and with the study doctor talking to you and your parents about the test results

If you don't want to be in this study you do not have to sign. Being in this study is up to you, and no one will be mad at you if you don't sign, or even if you change your mind later. If you want to be in this study, please sign your name. You will get a copy of this form in case you want to read it again.

_____ _____

Sign Your Name Date

ASSENT FORM

For Children 14 – 17 years old

Parental/LAR Permission

Where we say "parent" in this form, we mean a natural or adoptive parent, a legal custodian, or a legal guardian (collectively known as "Legally Authorized Representatives" or "LARs" for short)

I, _____ as an LAR of the child named above, confirm that the study has been explained to the child in my presence in a language that the child could understand. The child was told to ask questions and the questions were answered so the child could understand.

_____ _____

Sign Your Name Date

Investigator's Certification

I certify that to the best of my knowledge the child understands the nature, demands, risks, and benefits involved in the participation of this study.

_____ _____ _____

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

CONSENT TO TAKE PART IN A RESEARCH STUDY

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

STUDY DOCTOR'S INFORMATION

Name: [***fillable field***]
Contact Number: [***fillable field***]
Site Name: [***fillable field***]
Site Address: [***fillable field***]
Emergency (24-hour) Number: [***fillable field***]
Study Coordinator Name/Contact: **[*fillable field*]**

SUMMARY

This consent form will give you important information about this study. It will help you decide if 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.**

- **You will be asked to be in the study for about 10 months. The study includes several phases, described below. These phases will include needle sticks to draw blood. You will also insert small sensors and catheters under your skin when using study devices.**
  - **If needed, you will train on the study system devices and practice using them for several weeks.**
  - **Then you will start the main phase, which is about 6 months. In this phase you will be randomly assigned (like flipping a coin) into one of two groups. Your 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 you will switch to the study system if you were in the group that didn't use it. Otherwise, you will be randomly assigned either to keep using the study system or to use a regular insulin pump and glucose monitor.**

- **The most likely risks to you 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 you may experience are a better understanding of your diabetes or a positive impact on your ability to manage your diabetes. You also may**

not benefit from this study. The information gained from the study may help people with type 1 diabetes in the future.

- **If you do not participate, you may choose to continue your current diabetes management regimen or to participate in other research studies.**

WHAT IS INFORMED CONSENT?

You are being asked to take part in this research study because you have type 1 diabetes and use insulin. The goal of this study is to learn things that may help people with type 1 diabetes. We want to find what works best for treating people like you with this condtion.

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

You do not have to be in this study. If you decide not to be in this study, you will not be treated differently. Also, your 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 some other study supplies. Other companies may also provide study supplies. The funding and supplies will be used by your doctor's office and other clinical centers to conduct the research study and by the Jaeb Center for Health Research to coordinate the 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 get money or benefits from a company that makes the devices in this study, then they have to tell the Jaeb Center. The Jaeb Center has a policy to make sure that study doctors cannot work on this study if they get money or benefits that would influence how they do the study.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn whether an investigational automated insulin delivery system ("study system") for individuals 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 you 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 get FDA approval to sell the study system in the U.S.

We expect about 168 people will take part in this study for about 10 months at 7 different clinical centers in the United States.

WHO CAN PARTICIPATE IN THIS STUDY?

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

- Have type 1 diabetes and have used insulin for at least one year
- 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
- Be familiar with the use of a carbohydrate ratio for meal boluses
- Be at least 14 years old
- Be willing to stop using any personal CGM once the study CGM is in use
- Be willing to use an insulin pump during the study with no automatic insulin adjustment based on glucose level. This means:
    - If you currently use an insulin pump, you may not be able to use features like low-glucose suspend or closed-loop control, even if you replace or upgrade your pump during the study. Low-glucose suspend refers to a pump decreasing or stopping insulin delivery if a low blood sugar is predicted or occurs. Closed-loop control refers to a system that automatically increases or decreases insulin delivery to try to keep the blood sugar as close to normal as possible.
    - If the study gives you an insulin pump to use, you may not be able to use features like low-glucose suspend or closed-loop control.
- 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, you must not:

- Take any medicine but insulin or metformin to lower blood glucose, either now or during the study
- Participate in another drug or device study at the same time as this study
- Work for, or have any immediate family members work for Tandem Diabetes Care or TypeZero Technologies, LLC
- Have any immediate family member who is directly involved in the study
- Be pregnant or plan to become pregnant during the study if you are female

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

WHAT WILL HAPPEN IN THIS STUDY?
This study will take about 10 months for you to complete. The next sections list what will happen during the study.

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

- Collection of information about you: This may include contact information, diabetes history, the past and current medical conditions, surgical procedures, menstrual history (females), allergies, medications and supplements, family history, education and income background, and whether or not you have various symptoms. You also will also be asked about your pump settings and average daily insulin use over the past week.
- Physical exam (height and weight, blood pressure and pulse)
- HbA1c test unless you have had one within the past 2 weeks
- Additional blood tests if your study doctor has any concerns about medical conditions that might put you at risk in the study
- A urine pregnancy test if you are a woman who can become pregnant. The pregnancy test must be negative for you to participate and will be repeated at some follow-up clinic visits during the study.

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

You will be asked to keep a glucagon emergency kit on hand at home. If you 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 you currently use an insulin pump and have used a CGM that is the same brand as the study CGM for at least 11 out of the last 14 days, you will skip to the Main Phase of the study described below. Otherwise, you will have a run-in period with study devices as described in this section.

You will wear the study CGM for 2 weeks:

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

If you are on multiple daily injections of insulin (MDI):

- If you were using CGM before the study started, you will receive a study insulin pump to use during these 2 weeks. You will be trained on the study pump along with the study CGM. Study staff may suggest changes to help you improve your blood glucose control.
- Otherwise, you will continue with MDI and the study CGM for 2 weeks. Then you will have a clinic visit to check how the CGM is working. Then you will receive a study insulin pump and use it with the CGM for another 2 weeks as described above.

If your study doctor thinks it is necessary, you may repeat this 2-week run in once or twice.

Main Phase

If you 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 you qualify 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 could 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. This measures whether your body makes any of its own insulin. Everyone in the study will complete some questionnaires. Topics will include a personality assessment, hypoglycemia awareness, low and high blood glucose, and your feelings about managing your diabetes.

At this visit, a computer program will be used to select whether or not you will be given the closed-loop study system or use the study CGM with a regular insulin pump (SAP). Through a process similar to flipping a coin, you will be assigned to either the closed-loop group or the SAP

group for the first 6 months of the study. You will have a two thirds chance of being in the closed-loop group. Neither you nor the study staff will have a choice in which group you will be placed.

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.

SAP Group

If assigned to this group, you will use a regular insulin pump (with no automated insulin control based on blood glucose level) along with the study CGM at home. A pump will be provided to you if necessary. We will call you after the first week to see how you are doing with the CGM and pump. You will come back to the clinic after your second week so we can answer any questions you may have and review your glucose data. Study staff may suggest changes to help you improve your blood glucose control. You will then continue to use the study CGM and your personal pump for about 26 weeks at home. You will have a series of phone contacts and clinic visits during this period as shown in Table 1 below.

You will be asked to upload data from the study CGM during the study. You should 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 will be trained to use the study system. System parts include the Tandem t:slim X2 insulin pump with Control-IQ technology and the study CGM system. You will be taught how to use the study system in all modes of operation. Using the study system in closed-loop mode will automatically adjust your insulin delivery based on the CGM glucose readings. You can always stop closed-loop mode at any time and take over control of your insulin delivery.

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

You 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. You will continue to use the system for another week followed by a clinic visit to review your training and answer any questions you 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 26 weeks. You will have a series of phone contacts and clinic 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:

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

You will be asked to upload data from the study pump during the study. You should 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.

You 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 about any changes in your health.

Follow-up visits will occur at 6 weeks, 13 weeks, and 26 weeks.

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

- Assessment of study device use
- Review of any problems or events that have occurred
- Download of study device data
- Blood draw for HbA1c *(13-week, 26 week)*
- Completion of Questionnaires (*13-week, 26 week)*
- Weight measurement will be repeated, in addition to height for participants <21 years old (*13-week, 26 week)*

Scheduled Phone Calls

In addition to the 1-week phone call described above, study staff will call you at 4 weeks, 9 weeks, 17 weeks and 20 weeks. The schedule for these calls is the same for everyone in the study.

Phone Call Procedures

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

The Main Phase of the study will end at the 26-week visit.

Extension Study Phase

At the 26-week visit, a 13-week Extension Phase will begin.

For this phase, you will switch to the study system if you were in the SAP group during the Main Phase. If you were in the closed-loop group during the Main Phase, a computer program will be used to select whether you will keep using the closed-loop system or you will switch to use the study CGM with a regular insulin pump with no automated insulin delivery (SAP). You will have a 50/50 chance of staying in the closed-loop group. Neither you nor the study staff will have a choice in which group you will be placed. You will receive training as follows:

- SAP group switching to closed-loop: will be trained on the closed-loop system
- Closed-loop group remaining on closed-loop: will receive refresher training on the closed-loop system
- Closed-loop group switching to SAP: will receive refresher training on the differences between the closed-loop system and SAP with a regular insulin pump

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

Scheduled Phone Calls during Extension Study

If you switch from SAP to closed-loop for the Extension Phase or if you switch to SAP, you will have two additional phone calls. You should upload study pump data before each call. These calls will occur 1 week and 2 weeks into the phase and will involve the following:

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

Final Visit (39-week Visit)

The final study visit will be at least 39 weeks after the Screening visit. Procedures will be similar to those described for the Screening and follow-up visits. You will be asked to return some study devices as instructed by study staff at this visit. If needed, you will be switched back to the insulin pump you were using before entering the study. You will complete another set of questionnaires with similar topics as before. There will be a final blood draw for HbA1c tests. You will have weight and (if you are under 21 years old) height measurements taken again.

The table below shows what will happen at each visit:

Table 1: Main Phase and Extension Phase of Study

	0	1w	2w	4w	6w	9w	13w	17w	21w	26w	27w	28w	39w
Clinic Visit (V) or Phone Contact (P)	V	P	V	P	V	P	V	P	P	V	P*	P*	V
Review if you can continue in the study	X												
Blood draw for HbA1c	X						X			X			X
Blood draw for C-peptide test	X												
Pregnancy test (females of child-bearing potential)	X						X			X			
Study device download	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
Questionnaires	X						X			X			X

** For participants who switched to the closed-loop system or switched to SAP*

WHAT ARE THE RISKS OF THIS STUDY?

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

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

Risk of Low Blood Glucose

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

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

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

Risk of High Blood Glucose

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

Fingerstick Risks

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

Blood Draw Risks

Possible risks from blood draws include:

- Pain (common)
- Bruising (common)
- Redness (common)
- Temporary discomfort from the needle stick (common)
- Clotting (unlikely)
- Excessive bleeding (unlikely)
- Lightheadedness (rare)
- Infection (rare)
- Fainting (rare)
- Swelling of tissue (rare)

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, you could receive less or more insulin than you need and be at risk for high or low blood glucose. The following are common ways the study system might not work correctly:

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

Unknown risks:

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

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

Risks for women:
The risks of the devices in this study on an unborn baby are unknown. For this reason, women who are pregnant cannot be in this study. Women who become pregnant during the study will have to stop being in the study. Urine pregnancy tests are done as part of this study. You will also be asked about how you plan to make sure that you do not become pregnant while in the study (like if you use birth control).

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

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?

You may receive no direct benefit from being in this study. People who take part in this research study will add to new knowledge that may help other people with type 1 diabetes.

ARE THERE OTHER OPTIONS THAN BEING IN THIS STUDY?

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

CAN I STOP BEING IN THE STUDY?

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

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.

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

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

- The doctors feel that it is in your best interest
- The doctors think that being in the study may cause you harm

- If you experience an injury related to the study
- If you need additional or different medication
- If you do not follow the study instructions

If you are removed from the study or the study is stopped, you may continue to receive care like you normally would if you were not in this study.

ARE THERE COSTS RELATED TO TAKING PART IN THE STUDY?

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

- CGM system and CGM sensors
- Study Insulin pump, infusion sets, and reservoirs/cartridges while using the 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 from the study, you must return all system parts to the study team listed on the front page. Any additional tests and procedures will be billed to you or your insurance company like they normally would.

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

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

IS THERE PAYMENT FOR TAKING PART IN THIS STUDY?

If you take part in the study, you will receive up to $475 for your participation. These payments will be paid as follows:

- Screening Visit: $25
- Run-in Visit/Randomization Visit: $50
- 2-week Visit: $50
- 6-week Visit: $50
- 13-week Visit: $100
- 26-week Visit: $100
- 39-week Visit after return of all study related equipment: $100

If you withdraw from the study, you will still be paid for the visits that you have completed. You will not receive extra payments for visits that are required as part of your normal care or for visits that are for treating an illness or injury.

The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form.

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. Unless the law requires it, your name, address, social security number, telephone number, or any other direct identifying information will not be used to identify you.

Certificate of Confidentiality

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

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

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

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

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

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

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. Study staff will provide an update once the study results are available through http://www.ClinicalTrials.gov.

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

There are some situations where the information will not have a code number but may include your name, address, telephone number, or social security number (PHI). If so, people outside this doctor's office who assist in your care may see your study PHI. They may not be covered by the law. Everyone who needs to see your information will be told it is confidential, but we cannot guarantee full confidentiality once it leaves the 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 you. There may still be a chance that someone could identify you, but this is not likely. The study results will also be made public. These results will not have any information that could identify you.

Clinical Trial Reporting
A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. A copy of one of the study consent form templates will also have to be posted on a federal website.

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

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

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

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

Participant's Full Name (printed) _____

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

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

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

_____ _____
LAR Signature Date

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

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

Study Participation

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

- you have read this informed consent form
- you have been given the chance to discuss the study and to ask questions to your satisfaction
- you freely choose (or you freely choose to allow the participant) to participate, you/the participant can withdraw at any time, and you will receive a copy of this consent form

_____ _____
Participant or LAR Signature Date

Protected Health Information Authorization

By signing, you authorize the use and disclosure of your/the participant's protected health information. This information is collected as part of participation in this study. You/the participant cannot be in this study if you do not provide this permission.

_____ _____

Participant or LAR Signature Date

Investigator's Certification

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

_____ _____ _____

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