Consent to Participate in a Research Study
Clinical Acceptance of the Artificial Pancreas: The International Diabetes Closed Loop (iDCL) Trial - A Randomized Clinical Trial to Assess the Efficacy of Adjunctive Closed Loop Control Versus Sensor-Augmented Pump Therapy in the Management of Type 1 Diabetes

Today, you are being asked to take part in this **research** study because you have type 1 diabetes and use an insulin pump. The goal of this research is to get new knowledge that may help other people, but it is not the same as treatment of type 1 diabetes. We want to find what works best for treating you and others with this condition.

Your study team will be talking with you about this research and this document. Please take your time deciding whether you want to participate in this research and please carefully read this document. To take part in the study, you will need to carefully read and sign this document.

Before you decide to take part in this research study, we encourage you to speak with friends and family members about it. If you do not understand all the information, please ask your study doctor or nurse to explain. If you are taking part in another study, please tell us right away.

NON-PARTICIPATION STATEMENT

Participation in this study is voluntary and you must agree to take part. If you decide to stop participation in this research, that will happen immediately. No penalty or loss of medical care will result from your decision. While the study is occurring you may continue to receive medical care not related to this study.

WHO IS DOING THE STUDY

Your study team will carry out this study. Their names are listed on the Cover Page of this form. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), which is part of the federal government, is paying for this research. This funding 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

WHY ARE WE DOING THIS STUDY?

The purpose of this study is to see if the use of an automated insulin delivery system ("study system") can safely and successfully manage blood sugars. This type of system is also referred to as an artificial pancreas or a closed-loop system. The name of the study system is inControl. The system consists of (1) an insulin pump that delivers insulin, (2) a continuous glucose monitor or CGM that measures your sugar level, and (3) software that determines how much insulin will be given.

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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 every 5 minutes. The sensor needs to be changed about every 7 days. The insulin pump has a catheter that is inserted under the skin. It needs to be changed about every 3 days. This may be similar to the insulin pump infusion set you are already using.

The study system is experimental and can only be used for research. The U.S. Food and Drug Administration has approved its use in this research study.

We previously tested a version of this system in about 400 individuals. They used a similar version of the system in other studies for shorter periods of time at home. We did not find an increased risk for high or low blood sugars or other problems. We are now ready to further test the system at home with more people for a longer period.

HOW MANY PEOPLE ARE WE EXPECTING TAKE PART IN THIS STUDY?
We expect about 126 people will take part in this study at 7 different clinical centers in the United States and Europe.

WHO CAN PARTICIPATE IN THIS STUDY?
To take part in this study, you will need to:

1. Be at least 14 years old
2. Have type 1 diabetes and have used insulin for at least one year
3. Have used an insulin pump for at least the last 6 months
4. Have an HbA1c level <10.5% (a test of blood sugar control over the last 3 months)
5. Be willing to connect the study smartphone to the internet at least once per week either using your Wi-Fi or using a cell phone data plan provided to you
6. Not take any medicine but insulin to lower blood sugar either now or during the study

7. Not be employed by or have immediate family members employed by TypeZero Technologies, LLC.
8. Not have a boss or an immediate family member who is directly involved in the study.
9. Be willing not to participate in another study at the same time as this study
10. Be willing to follow the procedures that will be described in the next sections

There are some conditions that may prevent you from being part of the study. Your study doctor will check if you have these or not. Pregnant women cannot participate. If you are a woman who has the potential to get pregnant we will do a urine test to be sure you are not pregnant before you enter the study.

WHAT HAPPENS IF I AGREE TO TAKE PART IN THIS STUDY?

About half of the individuals in the study will use the closed-loop study system. The other individuals will use the CGM and insulin pump only, which we refer to as sensor-augmented pump (SAP).

This study will take about 12-17 weeks 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. You will have some tests done to make sure you qualify and that it is safe for you to be in the study.

These include the following:

- 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, social history (drinking, smoking, and drug habits), 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)
- 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 a ketone test if your glucose level is higher than 300 mg/dL for more than 1 hour, 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.

Initial CGM Use

If you have used a CGM that is the same as the study CGM for at least 21 out of the last 28 days, you will skip to the Main Phase of the study described below. Otherwise, you will use the study CGM as described here.

First, you will wear the study CGM for 2 weeks without being able to see the glucose values it records. This is called "blinded" CGM.

- You will be taught how to use the CGM including putting in a new sensor after 7 days (or sooner if the sensor 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. If you were using a personal CGM before entering the study, you may continue to use it.
- You will return for a follow-up clinic visit after 2 weeks.
- Study staff will download the "blinded" 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.
- Study staff may suggest changes to help you improve your blood sugar control.

If you are eligible to continue, study staff will change the CGM settings so you can see the CGM glucose values. You will wear the study CGM for 2 more weeks at home. This is called "unblinded" CGM.

- You will be trained how to use CGM information in your diabetes management.

- Study staff will download the "unblinded" study CGM data to determine if you wore if 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.
- Study staff may suggest changes to your insulin pump settings to help you improve your blood sugar control.

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 4 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. The 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 sugar, 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 your own insulin pump. Through a process similar to flipping a coin, you will be assigned to either the closed-loop group or the SAP group for the rest of the study. You will have a 50/50 chance of being in either 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.

<u>SAP Group</u>

If assigned to this group, you will use your personal insulin pump along with the study CGM at home. We will call you after the first week to see how you are doing with the CGM. 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 sugar control. You will then continue to use the study CGM and your personal pump for about 13 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 study devices at different times during the study. 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 pump on its own. You will also be trained to use the closed-loop study system to control the study pump. You will be taught how to use the study system in all modes of operation similar to your personal insulin pump. Using the study system in closed-loop mode will automatically adjust your insulin delivery based on the CGM glucose readings. You can always stop the study system at any time and take over control of your insulin pump.

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 printed User Guide as a reference. You will also wear a blinded CGM sensor as described above during your first two weeks of home use.

At-Home Study Procedures

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 sugar control. Then you will use the study system at home for about 13 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; details will be provided to you in a written guide

You will be provided with an Emergency Card with information regarding the study system to carry with you at all times while participating in the study in the event you need emergency medical care.

The study system will transfer CGM and pump data to a central database every few minutes when the study smartphone is connected to the internet. The system must be connected to the internet at least once per week.

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 5 weeks, 9 weeks, and 13 weeks.

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

- Assessment of study device use *(except 9-week visits)*
- Review of any problems or events that have occurred *(except 9-week visit)*
- Download of study device data
- Blood draw for HbA1c *(13-week visit)*
- Insertion of a blinded CGM device as described above *(9-week visit)*

Scheduled Phone Calls

In addition to the 1-week phone call described above, study staff will call you at 34 weeks. The schedule for these calls is the same for everyone in the study

<u>34-Week Phone Call Procedures</u>

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

Final Visit (13-week Visit)

The final study visit will be at least 13 weeks after the Screening visit. Procedures will be similar to those described for the Screening and follow-up visits. You will return some or all study devices as instructed by study staff. 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.

Table 1 below summarizes what will happen at each call and visit during the main study phase.

Table 1: Main Phase of Study

Week of Study:	0	1w	2w	3w	5w	9w	13w
Clinic Visit (V) or Phone Call (P)	**V**	**P**	**V**	**P**	**V**	**V**	**V**
Review if you can continue in the study	**X**						
Pregnancy Test	**X**						
Blinded CGM (2 weeks)						**X**	
Blood draw for HbA1c test	**X**						**X**
Blood draw for C-peptide test	**X**						
Study device download	**X**		**X**		**X**	**X**	**X**
Review diabetes management and any new medical problems	**X**	**X**	**X**	**X**	**X**		**X**
Study questionnaires	**X**						**X**

Additional Study Procedures

If you are a female and menstruating, you will be asked to keep a log of when your menses occur to see the impact it has on your blood sugars. You may choose not to participate in this part of the study if you prefer. If you participate, you will be given a paper log to record this information for the study team. This will help us to better understand blood sugar fluctuations and insulin requirements during menses and the impact of the closed-loop system. Your decision to participate, or to not participate, in these additional procedures will not affect your ability to be in this study.

ARE THERE RISKS IN THIS STUDY?

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

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

Risk of Low Blood Sugar

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

- sweating
- shaking
- not feeling well
- fainting
- seizures (convulsions)

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

Risk of High Blood Sugar

High blood sugar also should not happen more often during the study than before the study. High blood sugar usually does not cause many obvious symptoms, but you may become thirsty or have a higher level of sugar in your urine. In severe cases, 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 of blood will be removed by fingerstick to test blood sugar levels. It hurts when the needle 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.

Blood Draw Risk

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)

Total blood loss during this study is approximately 15 milliliters or about 3-4 teaspoons.

Insulin Pump Therapy Risks

The risks of using an insulin pump may include:

- Discomfort during insertion of the infusion set (common)
- Bruising at the site of infusion set insertion (common)
- Bleeding at the site of insertion (rare)
- Infection at the site of insertion (rare)
- Allergy to the infusion set or adhesive (rare)
- Insulin pump malfunction and mechanical problems (rare)
- Allergy to insulin (very rare)
- Changes to your skin (very rare)

Continuous Glucose Monitoring Sensor Risk

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)

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 sugars. The following are some 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 study system. If this occurs, the pump will start delivering your normal insulin rate within 30 minutes.

Risk of Reusing the Continuous Glucose Monitor

The FDA approved the 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 Reusing 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 Reusing the Insulin Pump

The FDA approved the 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.

Risks for Women

If you are pregnant now, or get pregnant during the study, please tell us. We do not know how the study may affect an unborn baby, so you will not be able to join or stay in the study. A urine pregnancy test will be done during the Screening visit and will be repeated during the study if you are a woman who can become pregnant. You and your partner must use an approved form of birth control during this study. Ask your doctor for more details about the proper birth control method for you.

Questionnaires

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

There may be additional risks associated with the study system that are not known at this time. If we become aware of any new risks, you will be told about them. You will be able to decide if you want to continue to take part in this study.

Loss of Privacy

Study staff will do their best to make sure that your private information is kept confidential, but participating in research may involve a loss of privacy and the potential for a breach of confidentiality. Information about you will be replaced with a code. A list linking the code and your information will be kept separate from the research data.

Information about your data uploaded from your study devices will be collected for the study and transmitted through a secure electronic system to the Jaeb Center for Health Research in Tampa, Florida. This center is coordinating the study. It reviews all of the study information that is collected. The Jaeb Center for Health Research will be reviewing the data, but will not have your personal information.

The blood glucose meter used in the study is made by a company called Ascensia. Data from the meter will be downloaded by study staff during clinic visits using software at the clinic. You should not try to use any other software to download data from the meter. This includes software from Ascensia called the CONTOUR DIABETES app. Your data may not remain confidential if you use this app or other software to download the data. Study staff will remind you about this during the study

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?

There may be a possible medical benefit to you if you decide to take part in the study, but it is not a guarantee. For instance, it is possible that your blood sugar control will improve during the study using the study system or using just your insulin pump with CGM. If you are just using the insulin pump, the blood sugar information from the CGM along with the instructions given for management changes will be useful for your diabetes control.

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

WHAT ALTERNATIVE PROCEDURES OR TREATMENT ARE AVAILABLE IF I DO NOT TAKE PART IN THIS STUDY?

If you do not take part in this study, you could continue using your current insulin pump. You could also talk with your doctor about other ways to take insulin. If you do not participate, your medical care will not be affected.

We encourage you to discuss these options with your study team, your general primary care physician, or another health care professional who has knowledge of type 1 diabetes.

WHAT IF I WANT TO WITHDRAW FROM THE STUDY, OR I AM ASKED TO WITHDRAW FROM THE STUDY?

You can stop participating in this study at any time. You may continue to receive medical care not related to this study. However, we encourage you to talk to a member of the study team so they know why you are stopping the study.

If there are any new findings during the study that may affect your participation, you will be told about them so you can decide if you want to continue.

No penalty or loss of medical care will result from your decision. You may continue to receive medical care not related to this study.

The study doctor may decide to stop your participation without your permission if he or she thinks that being in the study may cause you harm. Some possible reasons for this include:

- the study doctor decides that continued participation is not safe for you, especially if you have a severe low blood sugar or DKA
- you need treatment not allowed in the study
- failure to follow instructions
- the study is canceled

ARE THERE COSTS RELATED TO TAKING PART IN THE STUDY?

Testing that is specifically for this study will be paid for by the study. The costs of treatment, office visits, and tests that are part of your type 1 diabetes care will be your or your insurance company's responsibility. The study will pay for:

- CGM-pump system, system supplies, and smartphone (closed-loop group)
- CGM sensors (both treatment groups)
- Blood glucose meter, test strips, and control solution (both treatment groups)
- Blood ketone meter, test strips, and control solution (both treatment groups)

- Blinded CGM (both treatment groups)

At the end of the study, or if you decide to remove yourself from the study, you must return the study system parts to the study team listed on the Cover Page.

All other tests and procedures, including your own insulin, and other medical problems that would happen even if you were not in this study are your or your insurance company's responsibility.

IS THERE COMPENSATION FOR TAKING PART IN THIS STUDY?

If you take part in the study, you will be paid $50 for each completed office visit required for the study to cover travel and other visit-related expenses. You will not receive any compensation for extra visits your doctor believes are needed for your usual care.

WHAT HAPPENS IF I EXPERIENCE A RESEARCH RELATED INJURY?

Medical care is available if you have a research-related injury. If you have an emergency, you can get emergency care. If possible, you should tell the emergency care medical staff that you are in a research study. You should also tell your study team about the emergency as soon as possible.

The study will not provide costs for medical expenses or any other costs for research-related injuries. The costs of care are your or your insurance company's responsibility. Money for lost wages or direct or indirect losses is not available.

CONTACT INFORMATION FOR QUESTIONS OR PROBLEMS

If you have questions about this study, a research-related injury, have concerns, suggestions or questions about the study, contact your study team using the provided contact information on the Cover Page.

If you have unanswered questions about your rights as a research participant, wish to talk about your concerns or suggestions linked to the research study, want additional information about the research, or want to provide comments about the research, contact the Jaeb Center for Health Research Institutional Review Board (IRB) Office at 813-975-8690 or irb@jaeb.org

HOW WILL MY INFORMATION BE PROTECTED AND KEPT CONFIDENTIAL?

As required by law, study related records with identifying information will be kept confidential. Safeguards for authorized access, security, and privacy of your information have been put in

place by the Federal Privacy Regulations. 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.

A. Purpose of Authorization

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your information. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

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 disclosure 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 research study.

B. Use and Disclosure of the PHI

Your study doctor will collect information about you. This information includes things learned from procedures listed and described in this form as well as your name, address, date of birth, and information from your medical records. Your name, address, telephone number, and social security number 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 study coordinating center which is the Jaeb Center for Health Research in Tampa, Florida.

The study doctor's office will not disclose study results that have your identifiable information except as explained in Section C. or when required by law. The Jaeb Center and this doctor's office will guard the privacy of your study PHI.

Study results without the protected information may be shared in medical journals and at scientific meetings. Your records will be confidential. No one will disclose your identity in a medical journal or at a scientific meeting.

C. Authorized Recipients and Users

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 U.S. 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 federal Privacy Rule. Everyone who needs to see your information will be told it is confidential – but we cannot guarantee full confidentiality.

D. Other Considerations

The data collected in the study may be provided to other researchers to use; however, the data that are provided will not contain any information that could identify you.

When the results are made public, all of the study data collected may also be made public. However, there will be no identifying information included.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

E. Cancellation of HIPAA Authorization

You may cancel your permission for the use and disclosure of your study PHI at any time. You need to contact your study doctor and give him/her a notice of cancellation in writing. 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 an adverse (unfavorable) event that is related or potentially related to the study. If an adverse event happens, 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 of cancellation or withdrawal. The Jaeb Center will receive any new information about any adverse (unfavorable) event that is related or potentially related to the study.

F. 50 Year Expiration Date and Indefinite Expiration Date

Some of your study PHI does not have a code number with it. Your permission for the use and disclosure of this PHI lasts 50 years from the date of your signature or until the end of the study, whichever is sooner.

The rest of your study PHI does have a code number with it. When it is collected, it becomes a research report. Your permission for the use and disclosure of these coded data will never end. These coded data do not have your name, address, telephone number, or social security number. *The above supports the HIPAA Privacy Rule – 45 CFR 164.508*

STANFORD UNIVERSITY LOCAL REQUIRED LANGUAGE

Research–Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form

CA Bill of Rights

As a research participant, you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and

- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

Stanford University HIPAA Authorization

In order to participate in this study, you must also sign the Stanford University HIPAA Authorization Form.

With your permission, we may photograph or videotape your participation in this trial. Photographs and videotapes will be used in presentations at conferences, potential study subjects, and potential research donors. Your willingness to have photos taken is independent of your participation in this trial. Your photo or videotape will not be used without your consent. Your identity can remain anonymous.

I agree to be photographed/videotaped during this trial.

_____
Initials

I agree to be photographed/videotaped during this trial but would like to remain anonymous.

_____
Initials

I do **NOT CONSENT** to being photographed/videotaped during this trial.

_____
Initials

Consent to Participate in a Research Study
Clinical Acceptance of the Artificial Pancreas: The International Diabetes Closed Loop (iDCL) Trial - A Randomized Clinical Trial to Assess the Efficacy of Adjunctive Closed Loop Control Versus Sensor-Augmented Pump Therapy in the Management of Type 1 Diabetes

Your Full Name (printed) _____

Description of Representative's Authority to Act for the Subject

_____ **(**if applicable)

Protected Health Information Authorization

By signing, you authorize the use and disclosure of your protected health information. This information is collected as part of your participation in this study.

_____ _____
Signature Date

Study Enrollment

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

- ***you have read this informed consent form about the study named below;***
- ***you have been given the chance to discuss the study and to ask questions;***
- ***you have verbally summarized your understanding of the study to the person who is explaining it to you; and***
- ***you freely choose to participate.***

Name of Study: A Randomized Clinical Trial to Assess the Efficacy of Adjunctive Closed Loop Control Versus Sensor-Augmented Pump Therapy in the Management of Type 1 Diabetes

_____ _____
Signature Date

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

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

You will be given a signed copy of this document in case you want to read it again.