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The Insulin-Only Bionic Pancreas Test Run

Adult_LAR Informed Consent Form

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NCT04200313

CONSENT TO TAKE PART IN A RESEARCH STUDY

STUDY TITLE: The Insulin-Only Bionic Pancreas Test Run

STUDY DOCTOR'S INFORMATION
Name:
Contact Number:
Site Name:
Site Address:
Emergency (24-hour) Number:
Study Coordinator Name/Contact:

SUMMARY

In this form, when it says "you" it is referring to you as the participant if you are an adult, or to the person under your care that would be in the study if you are a legally authorized representative (LAR). Please see the next section called "Legally Authorized Representatives (LAR)" for more information about who can be a LAR. This would be like a parent reviewing the information for their child to be in the study. In this case, "you" would mean "your child."

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

- **The study is being done to learn if an automated insulin delivery system (the iLet Bionic Pancreas system [BP]) can safely improve blood sugar control in people with type 1 diabetes.**
- **The BP includes an insulin pump, a continuous glucose monitor (CGM), and a computer program. The CGM measures your sugar level. It sends this information to the insulin pump. A computer program on the insulin pump decides how much insulin should be given. Usually if your sugar level is going up, the insulin pump will increase the amount of insulin you get. And, if your sugar level is going down, it will decrease the amount of insulin you get.**
- **The BP system is not approved by the Food and Drug Administration (FDA). It can only be used in research studies. For this reason, it is called experimental in this study. The insulins used in this study are FDA approved.**
- **You will be asked to be in the study for about 1 week.**
- **The most likely risks to you are pain, bruising, redness and temporary discomfort from blood draws, fingersticks, or CGM sensor insertions, or infusion set insertions. Although unlikely, it is possible that the system could deliver too much or too little insulin. This could result in low blood sugar or high blood sugar. In rare cases, this could be serious.**
- **The possible benefit is better blood sugar control while you are in the study. You may not benefit from this study. The information gained in this study may help people with type 1 diabetes in the future.**
- **If you do not participate, you may choose to continue your current diabetes treatment.**

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

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

WHAT IS INFORMED CONSENT?

You are being asked to take part in this research study because you have type 1 diabetes. The goal of this study is to learn things that may help people with type 1 diabetes.

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 as a person just because you didn't want to be in this study. Also, your regular care will not be impacted.

WHO IS DOING THE STUDY?

This study is being done by the diabetes staff at your clinic. It is being paid for by The National Institutes of Diabetes and Digestive and Kidney Disease (NIDDK) and Beta Bionics. Novo Nordisk and Eli Lilly will be providing some of the insulin for the study. The Jaeb Center for Health Research will use the funding to organize the study. Your study doctor and clinic staff will use the funding to carry out this study. The name of the study doctor and the doctor's contact information is listed on the first page of this form. If one of the study doctors gets money or benefits from a company that makes the devices in this study, then they have to tell the Jaeb Center.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn whether an automated insulin delivery system (the iLet Bionic Pancreas [BP]) can safely improve blood sugar control for individuals with type 1 diabetes. The system uses a CGM, an insulin pump, and a software program to automatically give insulin and control blood sugar. It is also sometimes called a "closed-loop" system or "artificial pancreas". The study will include about 35-40 people who will use this system at multiple centers in the US.

WHO CAN PARTICIPATE IN THIS STUDY?

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

1. Have had type 1 diabetes for at least one year and be using insulin for at least one year.
2. Be at least six years old.
3. Use either an insulin pump or multiple daily injections (MDI), with or without CGM for at least three months consistently before you collect CGM data for the study
4. Avoid starting any new non-insulin diabetes medications during the study period.

5. If you are not yet 18 years old, you must live with at least one parent/legal guardian who knows the emergency response for severe low blood sugars.
6. For females who may become pregnant, and are sexually active. you must agree to use birth control.

Also, you must not:

1. Plan to make a major change to your usual diabetes care within the next 3 months
   - Examples of this would include changing from MDI therapy to an insulin pump, starting or stopping use of a CGM, or changing to an insulin pump that automatically stops insulin delivery if your blood sugar is too low.
2. Be using a non-FDA approved closed-loop or hybrid closed-loop insulin delivery system.
3. Be using Apidra insulin and be unwilling to switch during the study.
4. Currently be in another diabetes-related clinical trial.
5. Have any of the following medical conditions:
   - cystic fibrosis, pancreatitis, or another pancreatic disease, including pancreatic tumor or insulinoma, or history of complete pancreatectomy
   - advanced kidney disease
     - If you are at least 18 years old and have not had this tested in the last 2 years, you will need to have a blood test done before you can be considered for the study
   - hemoglobinopathy
6. Have electrically powered implants that might be susceptible to RF interference.
7. Have an allergy or severe reaction to adhesive or tape that must be used in the study.
8. Currently be using or plan to use an oral diabetes drug known as an SGLT2 inhibitors or a sulfonylurea drug.
9. If you are using a GLP1 drug, pramlintide, or metformin, you must be on a stable dose for 3 months before enrolling in the study. If you are using a GLP1 drug or pramlintide, you must be willing to stop using these while you are using the iLet BP System.
10. Be pregnant or breast feeding.
11. Have a condition the study doctor thinks would make it unsafe to be in the study.
12. Work for or have immediate family members who work for Beta Bionics or the study team.
13. Be unable to speak and read English.
    - For pediatric participants, both caregivers and participants must be able to speak and read English

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

WHAT WILL HAPPEN IN THIS STUDY?

The purpose of this study is to test a new device, the iLet Bionic Pancreas (BP), for controlling blood sugar levels. A bionic pancreas also can be referred to as an artificial pancreas, closed loop system, or automated insulin delivery system. The BP consists of (1) a continuous glucose monitor (CGM) that measures the glucose in the fluid under the skin, (2) a pump that delivers insulin, and (3) a computer program that determines how much insulin will be given.

In addition to the iLet insulin pump itself, the entire iLet BP system includes a glass insulin cartridge, an infusion set and pieces to help fill the cartridge with insulin. The infusion set for this study is called the iLet infusion set. It uses a flexible tubing connected to a small plastic flexible tube (cannula). The tube remains under your skin to deliver insulin. This tubing uses a special adapter to connect to the iLet BP reservoir of insulin. The infusion set, tubing and cartridge need to be replaced every two to three days. It also will need to be replaced if it stops working.

The CGM sensor being used in this study is made by Dexcom, Inc. This sensor is called the Dexcom G6. It includes two parts: the sensor and the plastic transmitter. The Dexcom G6 sensor is placed under the skin. It measures the glucose in the fluid under the skin every five minutes. The transmitter snaps onto the sensor. It relays the sugar level values to the iLet. The software on the iLet uses the sugar level values from the sensor to decide how much insulin to deliver. The sensor must be worn on the abdomen. If you are not yet 18 years old, the sensor may also be worn on the upper buttocks. The Dexcom G6 sensor will need to be replaced every 10 days, or sooner if it comes out or stops working. The Dexcom G6 uses a web program called Clarity to get the glucose readings. The study team will help you set up an account in Clarity. To set up the account you will need to provide an email address and your date of birth. Dexcom will have access to your CGM data and the information used to create the account including your email address. This information will be stored in a secure database. If you are not comfortable using your personal information a different email address and birthdate can be created for you to use.

The use of the BP system with the Dexcom G6 CGM and infusion set are not approved by the US Food and Drug Administration (FDA). The BP system can only be used in research studies.

You will use the BP system with either insulin lispro (Humalog) or insulin aspart (Novolog). This should be the insulin you currently are using. Humalog and Novolog are approved by the FDA to treat diabetes, but not for use in the iLet BP system.

If you decide to take part in this study, you may be able to complete some or all of the study visits by video conference and you will do the following:

Screening Visit
The screening visit will take about two hours. If you took part in a separate screening protocol, you may be able to skip all or part of this testing.

At this visit we will do some tests and procedures to see if you qualify to be in the study. The study doctor will review the results of these tests and procedures. If you don't qualify, the study doctor will tell you why. During this visit we will:

- Ask you some questions about your personal and family medical history, medications and any other personal history that is important to your health and being in the study.
- If you are female and able to become pregnant, we will perform a urine pregnancy test to see if you are pregnant. If you are pregnant or breast feeding you cannot be in the study.
    - *If the visit is done by video conference, a pregnancy test will be given to you to take at home. This will be the same process for all visits that are done by video conference during the study.*

- Measure your height and weight.
  - *If the visit is done by video conference and you do not have a scale at home to measure your weight, one will be given to you. You will use the same scale for all visits during the study when weight is measured.*
- Collect blood for measurement of your hemoglobin A1c.
  - *If the visit is done by video conference a report of your most recent result will be acceptable*.
- Have you complete questionnaires.
- If you are using a Dexcom G6 CGM, we will download the information to see how much data you have collected over the last 14 days.
  - If you do not have at least 85% of readings during the last 14 days, we will ask you to wear your Dexcom CGM daily to obtain this amount.
- If you do not use a Dexcom G6, we will insert a Dexcom G6 CGM sensor and give you the necessary CGM supplies to collect data over the next two weeks. If you currently use a Dexcom G5, you will be able to see the blood sugar values while wearing the sensor. If you do not use a Dexcom G5, you will not be able to see the blood sugar values of this sensor.
- Have you answer questions about how you feel when you have low blood sugar.

Study Start Visit
This visit will occur at the beginning of the study and will take up to two to three hours. If you do not need to collect CGM data for 14 days, this visit can be on the same day as the Screening visit. During this visit we will:

- Train you how to use the study blood glucose meter and ketone meter.
- Train you how to use the BP system, including replacing the insulin cartridge, understanding the information on the BP display, and using the features of the device.
  - Representatives of the company that make the BP system may be present to help train you how to use the system.
- Train you how to use the Dexcom G6 CGM system (or review with you if you are already using this CGM). Ask you to insert the Dexcom G6 CGM sensor if you do not already have one inserted.
- Ask you to fill the insulin reservoir, prime the tubing and prepare the iLet BP for use. We will have you place the insulin infusion set.
- Ask you to stop your usual diabetes treatment and start the BP system.
- Give you the BP and necessary supplies, CGM and supplies, and glucose and ketone testing supplies you will need.

If the visit is on a different day than the Screening visit, we will also do the following:

- Ask you some questions about any changes to your medical history since your last visit to confirm you are still eligible to participate.
- Review the study procedures and answer any questions you might have.
- If you are female and able to become pregnant, we will perform a urine pregnancy test to see if you are pregnant. If you are pregnant or breast feeding you cannot be in the study.
- Measure your height and weight.

Phone Call Check In
Study staff will contact you by phone 1-2 days after the study start visit. They will ask you about any issues you have had and answer any questions at this time. You can contact study staff at any time during the study if you have any questions. You do not need to wait until this phone call or a clinic visit.

Home Procedures
You will be asked to do the following:

- Calibrate the Dexcom G6 CGM if it is inaccurate.
  - You should use the study blood glucose meter for all calibrations and checking your blood sugar when you think the CGM might not be accurate.
- Depending on how aware you are of your symptoms of hypoglycemia (based on your answers to some questions), you may be asked to check your blood sugar between 2 and 3am on the first 2-3 nights after you start using the BP system.
- When using the study blood glucose meter, you should only test using your fingers.
- Carry fast-acting carbohydrates at all times in case of a low blood sugar.
- Do not change your weight in the BP or the settings in the BP or CGM without contacting study staff first.
- Change your insulin infusion set and reservoir every two to three days, or whenever the insulin level gets low.
- Charge the iLet BP once a day, or whenever the battery level gets low.
- Remove the iLet BP for all water related activities
- Limit the amount of time you are disconnected from the BP.
- Tell a study staff member if you become ill during the study. You will continue to see your own regular doctors for any illness or medical advice not related to study procedures.
  - If you are admitted to the hospital for any reason, you will be asked to contact your study staff as soon as possible and stop using the iLet while you are in the hospital.
- Treating low blood sugars:
  - Study staff will recommend you set a hypoglycemia alarm for 70 mg/dl. The Dexcom CGM will alarm at 55 mg/dl and the iLet BP will alarm at 50 mg/dl.
  - If you hear any of these alarms or feel symptoms of a low blood sugar level, you should check your blood sugar using the study meter. You may take carbohydrates to treat a low blood sugar level at any time as you choose.
  - You can contact study staff at any time if you have questions about the study procedures or your blood sugar level.
- Treating high blood sugars:
  - Study staff will recommend you set a hyperglycemia alarm for 250 mg/dl.
  - If you hear any high blood sugar alarms or feel symptoms of a high blood sugar level, you should check your blood sugar using the study meter.
  - If your blood sugar is high, you should check the insulin infusion site, tubing, and the iLet BP to make sure they are working. If you have any suspicion of insulin site failure, the set should be replaced. You should continue to monitor your blood sugar until it returns to normal.
  - If your blood sugar is above 300 mg/dL for more than 90 minutes, you should check your blood ketone level using the study meter. If your ketones are 0.6 mmol/l or higher, you

should replace your infusion set and call the study team. You should continue to monitor your blood sugar and blood ketones until they return to normal. You will be given an instruction sheet that will have these details of what to do.

- You can contact study staff at any time if you have questions about the study procedures or your blood sugar level.

Study Stop Visit
This visit will be 4-7 days after your study start visit. Study staff will review the visit schedule with you. This visit will take about an hour.

At this visit we will:

- Ask you about any problems that have occurred while using the BP system.
- Measure your height and weight.
- Download all study devices.

You will go back to your pre-study diabetes routine. The study doctor will decide on the insulin dosing you will use and if you use an insulin pump, will help change the settings in your pump as needed.

The table below shows what will happen at each visit:

Schedule of Study Visits[c] and Procedures During Main Study

	Screening	Study Start (0d)	1-2d (phone call)	4-7d Study Stop
Informed Consent	X			
Eligibility assessment	X	X[a]		
HbA1c-point of care/local lab	X			
Urine pregnancy test[b]	X	X[a]		
Height/weight	X	X[a]		X
Questionnaires	X			
Data download	X			X
Medical history updates		X[a]	X	X

[a] This will not be done if you are starting the same day as the Screening Visit
[b] For females with child-bearing potential
[c] Visits may be in-clinic or virtual

WHAT ARE THE RISKS OF THIS STUDY?

If you choose to take part in this study, you need to know that there are some side effects or risks of being in this study.

The more common side effects that are known:

- Discomfort with the insertion or removal of the infusion set or CGM sensor.
- The fingerstick or blood draw to measure your HbA1c may cause bruising, discomfort, bleeding, infection or fainting. These risks are possible but unlikely and usually mild.
- Reaction at the site where the insulin is injected into your body can include bruising, bleeding, pain or discomfort redness, swelling or itching. These problems usually go away after a few days. You can reduce the risk by changing the place where you put the infusion set on.
- Allergic reactions to the insulin used in this study may occur in other parts of your body. Signs may include rash, redness, hives itching or wheezing at the infusion site. A more serious reaction may lead to swelling of your throat and face, or breathing problems, fast heart rate, pale and cold skin, feeling dizzy or weak. If you have signs of a serious allergic reaction you must stop taking the insulin immediately and get emergency help right away.

The less common side effects that are known:

- About 1 out of 10 people will get a mild bruise from fingerstick blood sugar checks or the blood draws. A small scar may persist for several weeks. The risk of local infection from fingersticks or blood draws. is less than 1 in 1000.
- Skin infections at the site of the infusion set or CGM insertion (low risk)
- Skin rash or allergy related to the tape used with the infusion sets or CGM sensor
- Rarely, the Dexcom sensor may break and leave a small part under the skin. This may cause moderate redness, pain or swelling.
- Skin changes where you inject your insulin may occur. The fatty layer under your skin may shrink ("lipo-atrophy) or get thicker (lipo-hypertrophy). This risk of these changes is 1 in 100. You can reduce the risk by changing the place where you put the infusion set on.
- If your glucose level decreases very quickly, this may cause changes to your vision or cause feelings of "pins and needles" in your hands, arms, feet, or legs for a short time.
- If you change the type of insulin you use, you may have swelling around your ankles or other joints for a short time.

BP System Risks

There is a risk that parts of the bionic pancreas system may not work properly. As a result, you could receive less or more insulin than needed and be at risk for high or low blood sugars. Common reasons for the BP system not working correctly are:

- CGM sensor reads higher or lower than your actual blood sugar
- Batteries run out faster than usual
- The infusion set may be clogged, kinked or there may be another problem with the BP preventing insulin from being delivered

If a high blood sugar occurs, symptoms may include blurry vision or increased urination, feeling thirsty, feeling very tired or having a headache. If blood glucose levels are high enough for an extended period of time, ketones can build up in the blood. Accumulation of ketones can result in nausea and vomiting. In more severe cases, diabetic ketoacidosis (DKA) or coma may occur. DKA can lead to kidney failure, irregular heartbeat, heart attack, muscle breakdown and even death.

If a low blood sugar occurs, symptoms may include feeling anxious or nervous, sweating, rapid heart rate, confusion, unconsciousness or seizure. In extremely rare cases, death from a low blood sugar could occur.

Risks for Unborn Babies

High or low blood sugars can be harmful to an unborn baby or to an infant who is breastfeeding. The risks of the BP system used in this study on an unborn baby are unknown. Anyone who is pregnant or breastfeeding cannot be in this study. Urine pregnancy tests are done as part of this study for anyone that is considered to be able to get pregnant. For example, anyone who has started having menstrual periods, or is still having menstrual periods, will have pregnancy tests no matter how young or old they are. The study doctors are required to do this even if someone thinks there is no possibility of pregnancy.

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

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

Unknown Risks

There may be additional risks from using the BP system 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.

The study doctor and staff may use your contact information to call, text or email you during the study. They may do this to send you things like appointment reminders. They are not allowed to send you identifiable health information by text or regular email because it is unsecure. This means that there is a risk that a message may be seen by someone that is not supposed to see it, like when an email gets hacked. Your email, phone number and your/your child's name will likely be in the text or email. If you think that the study doctor's office has texted or email information that they should not have please contact JCHR at 813-975-8690 and ask to speak to the IRB Administrator. If you text or send a regular email the study doctor's office is unsecure and what you put in the text or email is not protected.

Study Questionnaires/Surveys

This study will involve asking you some questions about your diabetes and your overall health. You also will be asked questions about how you feel about things like diabetes and your life. The risk of these questions is that you might feel upset or uncomfortable. It is important that all questions are answered,

but if you don't want to, then you can withdraw from the study. You can decide to take a break or stop taking part in the study at any time.

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

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?

The possible benefit is improved blood sugar control but that is what the study is trying to find out. 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 usual diabetes therapy, 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 as a person. 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 is any important new information about the study, you will be told about it. 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 study doctors feel that it is in your best interest
- If you do not follow the study instructions
- The study 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 withdraw, 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. Also, you will no longer be able to use the BP system and you must return the BP system and all related supplies to the study staff.

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 BP system, blood glucose meter and supplies and ketone meter and supplies will be provided to you at no cost. If you use insulin pens you will be given Humalog (lispro) or Novolog (aspart) vials. Visits and procedures that are required solely for study purposes will not be billed to you or your insurance. At the end of the study, or if you decide to withdraw from the study, you must return the BP system and all related supplies to the study staff. Any additional tests and procedures will be billed to you or your insurance company like they normally would.

Please ask to speak to someone at your study doctor's office if you want more information about what you or your insurance will be expected to pay

IS THERE PAYMENT FOR TAKING PART IN THIS STUDY?

If you take part in the study, you will receive up to $100 for your participation. The payment will be paid as follows: $50 for screening and $50 for the study end visit. The payment will be made either as a check or as a gift card at the end of each visit or at the end of the study depending on your study team's policy.

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.

Because payments made to you for participating in this study may be reported to the IRS as income, you may need to provide your social security number or a Form W-9 to your study doctor's office. These will not be shared outside of your study doctor's office, other than as required by the IRS.

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

If 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 does plan to provide costs for care or other expenses relating to illnesses or injuries **directly resulting from a manufacturing defect** in the iLet device. Otherwise, the study does not plan to provide costs for care or other expenses relating to illnesses or injuries. Your study doctor, the study doctor's office, the Jaeb Center, NIDDK, Novo Nordisk and Beta Bionics are not planning to cover payment for lost wages, direct losses, or indirect losses.

CONTACT INFORMATION FOR QUESTIONS OR PROBLEMS

If you have questions about this study; a research illness or injury; or have concerns, suggestions or questions about the study, then contact your study doctor using the contact information on the first page of this form.

Contact the Jaeb Center for Health Research Institutional Review Board (IRB) Office at 813-975-8690 or irb@jaeb.org if you:

- Have questions about your rights as a research participant
- Wish to talk about your concerns or suggestions about the research
- Want additional information about the research, or
- Want to provide comments about the research.

HOW WILL MY INFORMATION BE PROTECTED AND KEPT CONFIDENTIAL?

As required by law, study-related records with identifying information will be kept confidential. Safety measures for the access, security, and privacy of your information have been put in place by law. Your date of birth and initials may be used in the study to help the researchers keep the right information together. This information will be protected as described below. Unless the law requires it, your name, address, social security number, telephone number, or any other directly identifying information will not be used to identify you.

Certificate of Confidentiality

NIDDK has given us a Certificate of Confidentiality for this study. This adds special protection for study information that identifies 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. Your 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 your 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 this form, including the Protected Health Information Authorization statement included in the signature box at the end of this form if you want to be in the study. When you sign this 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 with your initials and date of

birth 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 following people or companies involved in this study may see your study results with things like your date of birth, initials, and date of procedures:

- Your study doctor's office
- Jaeb Center for Health Research
- Novo Nordisk
- Beta Bionics
- NIDDK
- Researchers who are part of the study

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.

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 are providing either funding or supplies for the study, laboratories, and centers that may receive images. Dexcom, Inc. will have access to CGM data and the information used to create your Dexcom Clarity account. 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). Once PHI is disclosed by your study doctor and the clinic staff, it may no longer be covered by the privacy laws. Everyone who needs to see your information will be told it is confidential, but we cannot guarantee full confidentiality once it leaves the study doctor's office.

Can You Cancel Your Authorization?
You may cancel your permission for the collection of your study PHI at any time. You will need to contact your study doctors and give them a written notice of cancellation, or you may contact the JCHR IRB Office at 813-975-8690 or irb@jaeb.org. When you cancel your permission or when you withdraw from the study directly, you are no longer part of the study. No new information about 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 that is not PHI does have a code number with it. When it is collected, it becomes part of a research report. Your permission for the use and sharing of this coded information will never end. This coded data does not have your name, address, telephone number, or social security number.

Other Considerations
A copy of the information collected as part of the study will be made public in a dataset. This will be done after the study ends. This dataset will not contain any PHI. The study results will also be made public. These results will not have any information that could identify you.

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

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.

Contact from the Jaeb Center
Separately from your research data, the Jaeb Center for Health Research in Tampa, Florida will be provided with information on how to contact you for the questionnaires described earlier.

You may also have communication with the study doctor's office by phone, text, or by video (like FaceTime or Skype). There is a chance that someone could see or hear the conversation like they could if you were speaking or texting with anyone.

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

When the participant is a minor, check "N/A" here and skip this page **N/A ☐**

Adult Participant's Full Name (printed) _____

Adult 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 and you/the participant can withdraw at any time you will receive a copy of this consent form
- you authorize the use and disclosure of your 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's Signature Date

When the Participant is Not a Minor, check "N/A" and skip this page N/A ☐

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

Minor's Legally Authorized Representatives (LARs) Permission

I, _____ (print name of LAR) attest that I am one of the following individuals authorized to provide consent for the child named above as I am one of the following LARs (checkbox):

☐ Natural or Adoptive Parent; ☐ Legal Custodian; or ☐ Legal Guardian

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

1. you have read this informed consent form
2. you have been given the chance to discuss the study and to ask questions to your satisfaction 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
3. you authorize the use and disclosure of your child's protected health information. This information is collected as part of participation in this study. Your child cannot be in this study if you do not provide this permission.

_____ _____

LAR Signature Date

Investigator's Certification

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

_____ _____ _____

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

Jaeb Center for Health Research
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The Insulin-Only Bionic Pancreas Test Run

Assent Form

Document Date 11AUG2020
Version 3.1

JCHR IRB Stamp Date 12AUG2020

NCT04200313

ASSENT FORM

For Children 7 – 17 years old

STUDY: The Insulin-Only Bionic Pancreas Test Run

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 a system, called a bionic pancreas can safely manage blood sugars. The bionic pancreas includes an insulin pump, a continuous glucose monitor (CGM), and a computer program. The CGM measures your sugar level. It sends this information to the insulin pump. A computer program on the insulin pump decides how much insulin should be given. Usually if your sugar level is going up, the insulin pump will increase the amount of insulin you get. And, if your sugar level is going down, it will decrease the amount of insulin you get.

The bionic pancreas is not approved by the government, but doctors can still use it if they think it will help people. We are asking you to be in the study because you have type 1 diabetes. We will be finding out if the bionic pancreas works the way it is supposed to work. 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. You can still get help with your type 1 diabetes if you are not in the study.

If you agree to be in this study, you will be asked to do the things listed below. If you were part of another screening study, you may be able to skip some of these things.

- Complete a few study visits. These visits can either be done in this clinic or by video call.
- Have your blood drawn or have a fingerstick for HbA1c once during the study.
- Answer questions on paper or online.
- Wear your Dexcom G6 continuous glucose monitor (CGM) every day for 14 days.
- Talk with the clinic at least once during the study. This is to check in and see if you are having any problems or have any questions.
- When you are using the bionic pancreas, you will need to change the pump infusion set every 2-3 days for up to 7 days. You will need to wear the CGM sensor every day and put in a new sensor every 10 days. You may be asked to check your blood sugar during the first 2-3 nights after you start using the bionic pancreas. We will give you a lot of instructions to follow when you are using the bionic pancreas.

You might experience some of these events:

- High or low blood sugar levels. The bionic pancreas might not keep your blood sugar in range.
- Redness, itching, pain or bruising from the glucose sensors or from the insulin infusion sets
- Pain or bruising from your fingerstick blood sugar checks or from the blood draw
- When you are given the questions to answer, some of the questions might make you feel upset. You can take a break from answering questions at any time, or if you do not want to answer all of the questions, you can tell the study doctor that you do not want to be in the study anymore.

If you are female and you are pregnant right now, you cannot be in this 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

Parental/LAR Attestation

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, _____ (print name of LAR) attest that I am one of the following individuals authorized to provide consent for the child named above as I am one of the following LARs (checkbox):

☐ Natural or Adoptive Parent; ☐ Legal Custodian; or ☐ Legal Guardian

I am signing below to 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**