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The Insulin-Only Bionic Pancreas Pivotal Trial: Screening Protocol

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 Pivotal Trial: Screening Protocol

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 collect information on what types of people may be interested in taking part in artificial pancreas studies. This information also will help us determine if you might be eligible for a future artificial pancreas study.**
- **This is a data collection study. There are no experimental study procedures.**
- **You will be asked to be in the study for about 1 day to 3 months, depending on whether or not you have been using a Dexcom G6 continuous glucose monitor (CGM) to manage your diabetes and when you completed questionnaires for the study. The study will involve collecting information about your medical history and medications you take. You will have a fingerstick or blood draw to test your hemoglobin A1c and fill out questionnaires about your feelings about diabetes. If you are a female, and able to have children, you may have a pregnancy test performed. If you have not been using a Dexcom G6 CGM, you will be asked to wear a sensor for about 14 days. You will not be able to see the blood glucose readings from the sensor while you are wearing it.**
- **Based on what we learn about you in this study, you may be asked to participate in a future Insulin-only Bionic Pancreas study. If you are eligible and interested in that study, we will discuss the study with you. You will be given a document similar to this which will describe that study.**
- **The most likely risks to you are pain, bruising, redness and temporary discomfort from blood draws, fingersticks, or Dexcom G6 sensor insertion.**
- **It is not likely that you will have direct benefit from participating in this study.**
- **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 and who may be willing to take part in studies with artificial pancreas systems in the future.

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 your study doctor's office. It is being paid for by The National Institutes of Diabetes and Digestive and Kidney Disease (NIDDK), Novo Nordisk, and Beta Bionics. 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 collect information on what types of people may be interested in using an artificial pancreas. The study also will help determine if you might be eligible for a future Insulin-only Bionic Pancreas study.

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 been using insulin for at least one year.
2. 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.
3. Be at least six years old.
4. Use a CGM to monitor your blood sugar. If you do not use a CGM, you must check your blood sugar at least three times a day on average.
5. Be willing to use a CGM if you do not use one already.

Also, you must not:

1. Be using a non-FDA approved closed-loop or hybrid closed-loop insulin delivery system.
2. Have a diagnosed hemoglobinopathy (a problem with your blood).
3. Currently be in another diabetes-related study that could affect the results of this study or your safety.
4. Have cystic fibrosis, pancreatitis, or another pancreatic disease, including pancreatic tumor or insulinoma, or history of complete pancreatectomy.
5. Have an allergy or severe reaction to adhesive or tape that must be used in the study.
6. Currently use or plan to use an oral diabetes drug known as an SGLT2 inhibitors or a sulfonylurea drug (use of GLP1, pramlintide or metformin is acceptable if you have been using a stable dose for at least 3 months).
7. Be pregnant.
8. Have advanced kidney disease.
    - If you are at least 18 years old and have not had this tested in the last 12 months, you will need to have a blood test done before you can be considered for the study
9. Have a condition the study doctor thinks would make it unsafe to be in the study.
10. Be unable to speak and read English.

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

WHAT WILL HAPPEN IN THIS STUDY?

We will be collecting information about you and your diabetes. We also will look at your ability to possibly be in a future Insulin-only Bionic Pancreas study.

If you decide to take part in this screening study, the following will happen:

Screening Visit

The screening visit will take about 2 hours and will take place at the study doctor's office. At this visit we will do some tests and procedures. 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.
- Do a physical exam, and measure your height, weight and blood pressure.
- Perform a pregnancy test if you are a female and able to have children.
- Do a fingerstick or blood draw for measurement of your hemoglobin A1c if you haven't had one in the past 2 weeks
- Ask you to complete questionnaires. This may be done on a separate day.
- If you do not already wear a Dexcom G6 CGM or if you do not use it regularly, you will be asked to:
    - Insert a "blinded" Dexcom G6 CGM sensor and give you the necessary instructions and supplies to collect data over the next two weeks. "Blinded" means that you will be wearing the sensor but will not be able to see the glucose values.
    - This may be done on a separate day.

Return Visit for Review of CGM Data
The review visit can be skipped if you already use a Dexcom G6 CGM and have at least 85% of CGM readings during the 14 days prior to the screening visit. If you do not meet that criteria, you will need a period of CGM use and will have a visit 14-21 days after screening to review the CGM data. If there has been less than 14 days of CGM data or less than 85% of CGM values during the 14 days of CGM wear, the CGM wear can be repeated with another visit to review the data.

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. Because this is a data collection study, we expect that the risks will be small.

The more common side effects that are known:

- Discomfort with the insertion or removal of the CGM sensor.
- The fingerstick or blood draw to measure your HbA1c may cause bruising, discomfort, bleeding, infection, or fainting. These are possible but unlikely, and usually mild.

The less common side effects that are known:

- Anytime you have your blood drawn you may have bruising, discomfort, bleeding, infection, or fainting. These risks are possible but unlikely, and usually mild.
- Rarely, a skin infection can occur at the site of the CGM insertion.
- Uncommonly, a skin rash or skin allergy can occur related to the tape used with the CGM sensor.
- Rarely, the Dexcom sensor may break and leave a small part under the skin. This may cause moderate redness, pain or swelling.

Unknown Risks
There may be additional risks from 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.

Risks for Unborn Babies

It is not expected that there would be risk to an unborn baby by being in this study, but it is possible. It is also possible that being pregnant can cause changes in blood sugar management. For this reason, anyone who is pregnant cannot be in this study. Anyone who becomes pregnant during the study will have to stop being in the study. Urine pregnancy tests are done as part of this study for anyone that is considered to be able to get pregnant. For example, anyone that has started having menstrual periods, or is still having menstrual periods, will have pregnancy tests no matter how young or old they are. They will also be asked about how they plan to make sure that they do not become pregnant while in the study (like if they use birth control). The study doctors are required to do this even if someone thinks there is no possibility of pregnancy.

For minors, the results of a pregnancy test will only be told to the LAR if the minor has given permission by signing an Assent form. Minors will be told about the pregnancy tests in 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

Study Questionnaires/Surveys

This study will involve asking you some questions about your general health and your diabetes. Some questions may make you uncomfortable. The questions being asked have been used in many studies before and in general the questions have not made people feel uncomfortable. To be considered for the study, you must answer all of the questions. If you do not want to answer all of the questions, then tell your study doctor that you do not want to stay in 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?

It is not likely that you will have any direct benefit. People who take part in this research study will add to new knowledge that may help other people with type 1 diabetes and help researchers decide what types of people may be likely to take part in future studies.

ARE THERE OTHER OPTIONS THAN BEING IN THIS STUDY?

Since this is a data collection study you can get care like you normally would.

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.

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
- If you do not follow the study instructions
- The doctors think that being in the study may cause you harm
- If you experience an injury
- 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.

ARE THERE COSTS RELATED TO TAKING PART IN THE STUDY?

This is a data collection study so it is not expected that there will be any costs related to being in this study.

IS THERE PAYMENT FOR TAKING PART IN THIS STUDY?

The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form. The samples collected will not be used for whole genome sequencing or other genetic research.

If you complete the study, you will receive $50 for your participation either as a check or as a gift card. The study is complete at the end of the CGM data collection.

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

This is a data collection study so we do not expect that you would have an illness or injury related to the study. If you do have an illness or injury, 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 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; an 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
- Beta Bionics
- Novo Nordisk
- 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. 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 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
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. 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.

You may 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.

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:

- 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 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
- 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

Person Obtaining Consent

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 or Designee's Printed Name

_____ _____
Investigator or Designee's Signature **Date**

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The Insulin-Only Bionic Pancreas Pivotal Trial: Screening Protocol

Assent Form

Document Date 16OCT2019
Version 1.0

JCHR IRB Stamp Date 1NOV2019

NCT04200313

ASSENT FORM

For Children 7 – 17 years old

STUDY: The Insulin-Only Bionic Pancreas Pivotal Trial: Screening Protocol

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 what types of people may be interested in using an artificial pancreas. The information from this study also might help us know if you are able to be in another study. We are asking you to be in the study because you have type 1 diabetes. 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:

- Have your blood drawn or have a fingerstick for HbA1c once during the study
- Answer questions on paper or online
- Wear a continuous glucose monitor (CGM) every day for 14 days.
    - If you already use a Dexcom G6 CGM, you may be able to skip this part.

You might experience some of these events:

- Redness, itching, pain or bruising from the CGM sensor.
- Pain or bruising from the fingerstick or from the blood draw

- When you are given the questions to answer, some of the questions might make you feel upset. If you do not want to answer all of the questions then you can tell the study doctor that you do not want to be in the study anymore. You can take a break from answering questions at any time.

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.

If you turn 18 years old while you are in this study, then we will keep getting information about you until your next visit to the study doctor's office. At that visit, you will be given the adult consent form to read and sign if you want to stay in the study. If you do not want to stay in the study you do not have to.

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

Person Obtaining Consent

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 or Designee's Printed Name

_____ _____
Investigator or Designee's Signature **Date**