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The Insulin-Only Bionic Pancreas Pivotal Trial: Testing the iLet in Adults and Children with Type 1 Diabetes (BG Run Testing of the iLet)

Adult_Parental_ICF Addendum Form (electronic)

Addendum #1

JCHR IRB Stamp Date 13MAY2021

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ADDENDUM TO THE CONSENT TO TAKE PART IN A RESEARCH STUDY

STUDY TITLE:
The Insulin-Only Bionic Pancreas Pivotal Trial: Testing the iLet in Adults and Children with Type 1 Diabetes

ADDENDUM FOR: Testing the iLet Using Inputted Blood Glucose Measurements – An additional optional testing procedure.

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

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). 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."

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.

NEW INFORMATION
You are currently taking part in the above-named research study. This form is called an Addendum to the consent form. The purpose of this form is to give you information about an additional optional testing procedures for the study. It is important that you understand the information in this form. You may ask questions at any time.

Since the time you signed the last consent form for this study, an additional testing procedure was added as an option to the Insulin-only Bionic Pancreas study. The purpose of the testing is to see how well the iLet works using blood glucose (BG) measurements from fingersticks rather than a continuous glucose monitor (CGM). This will be referred to as the BG-run testing. This optional testing 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) and Beta Bionics.

The BG-run testing will include approximately 230 participants at 16 clinical sites. The testing will last from about 48 to 60 hours.

You do not have to agree to this additional testing. If you decide to participate, your doctor(s) and clinic staff will perform this additional testing as described below.

BG-RUN TESTING OF THE iLET

To take part in this additional testing, you must be currently using the iLet. The additional testing period will start at the time of the final visit of the Insulin-only Bionic Pancreas study. This visit may be in person or may be virtual. If you take part in this additional testing, you will continue using the iLet until the end of the testing. Then we will discuss with you how to best restart your usual method for receiving insulin.

Participants who are less than 18 years old must be living with one or more parents/legal guardians who know about emergency procedures for hypoglycemia and hyperglycemia. If you are 18 years old or older and live alone, you must have someone with you during the two overnights of the study.

The additional testing will last for 48-60 hours. During this time, you will continue to use the iLet. You will use the same insulin you were using in the Insulin-only Bionic Pancreas study. At the first visit, you will be trained on the testing procedures. The visit may be conducted by video conference. The Dexcom G6 CGM sensor you are using will be removed. A new sensor will be inserted but you won't be able to see the glucose values. This is referred to as a 'blinded' sensor.

For about the next 48-60 hours, you will check your blood sugar level with a fingerstick at least every two hours during waking hours. You will need to do a fingerstick before and two hours after each meal plus before bedtime. Overnight, you will need to do a fingerstick at least once each night. You will need to enter the blood sugar values into the iLet. The iLet will alarm to request the blood sugar entry every two hours. However, during the overnight period, you can just turn off each alarm as long as you do one blood sugar measurement. You can do more fingersticks if you want to.

Day One will be the day that you started the BG-run testing. Phone or video contact will be made with you on Day Two to see how you are doing. Video or phone contacts will not be recorded.

On Day Three, phone or video contact will be made or you may have an in-person visit. At this visit, we will ask you to remove the iLet and blinded sensor and insert another Dexcom G6 sensor. You will be able to see the glucose values. We will discuss with you how to restart insulin for the next 2-4 days and you will have one more final visit. If the final visit is done by phone or video, we will provide you with information on returning the study devices.

You can choose to stop participating for any reason at any time.

ARE THERE RISKS TO THIS BG-RUN TESTING?

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

The same risks that were present in the Insulin-only Bionic Pancreas study will still be present during this period of additional testing. In particular, low blood sugars or high blood sugars are possible. If they occur, it could be dangerous to your health. We will give you instructions on what to do for a low blood sugar or high blood sugar.

For more information about risks and side effects, ask your study doctor.

- There may possibly be other side effects that are unknown at this time. If you are concerned about other, unknown side effects, please talk to your study doctor about this.

WHAT ARE THE POSSIBLE BENEFITS OF THIS BG-RUN TESTING?

If you agree to take part in this test, there may not be direct benefits to you. People who take part in this optional testing will add to new knowledge that may help other people with the same problem.

ARE THERE COSTS RELATED TO TAKING PART IN THIS BG-RUN TESTING?

There will be no costs to you for taking part in the additional testing.

IS THERE COMPENSATION FOR DOING THIS BG-RUN TESTING?

If you take part in the BG-run Testing, you will receive up to $120 for your participation. You will be paid $5.00 for each blood glucose measurement on the study blood glucose meter that is correctly entered into the iLet up to a maximum of 24 measurements during the testing period. The payment will be made either as a check or as a gift card at the end of each study visit or at the end of the study depending on your study doctor's office policy.

WHAT HAPPENS IF I EXPERIENCE AN INJURY RELATED TO THIS BG-RUN TESTING?

If you have an illness or injury that is related to this test/procedure, 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 Fiasp insulin or 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.

OTHER CONSIDERATIONS?

It is up to you to decide if you want to complete this additional testing. No one can make you continue. You may stop being in the study now or at any time. You will not be treated differently as a person if you decide to stop being in the study.

Everything in the consent form that you last signed is still valid, including the potential benefits, risks, and the use and disclosure of your health information.

If you would like the information in the previous consent form to be reviewed with you please let your study team know. They will review the form with you if you would like. You can also request another copy if you cannot find your original.

CONTACT INFORMATION FOR QUESTIONS OR PROBLEMS

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

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

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

ELECTRONIC ATTESTATION PAGES

Adult/Parental Attestation (For all participants)

I, _____ attest that I am authorized to provide consent as I am the following (select only one):
☐ Participant ☐ Natural or Adoptive Parent of participant; ☐ Legal Custodian of participant; or ☐ Legal Guardian of participant

By entering your password below, you/the participant agree to take part in this study. Your e-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

To electronically sign, click HERE. You will be asked to re-enter your password and click "sign"

Minor's Legally Authorized Representatives (LARs) Assent Attestation (For participants 7-17 years of age)

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

- you confirm that the study has been explained to the child in your presence in a language that the child could understand.
- you confirm that the child was told to ask questions and the questions were answered so the child could understand.
- you confirm that the child has expressly stated that he/she wants to be in the study at this time.

To electronically sign, click HERE. You will be asked to re-enter your password and click "sign"

Investigator's Attestation

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

To electronically sign, click HERE. You will be asked to re-enter your password and click "sign"