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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)

Assent Addendum Form (electronic)

Addendum #1

JCHR IRB Stamp Date 13MAY2021

NCT04200313

ASSENT FORM ADDENDUM

For Children 7 – 17 years old

STUDY:

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

FORM TO ADD ADDITIONAL TESTING CALLED BG-RUN TESTING OF THE ILET

Since you are in the Insulin-only Bionic Pancreas research study we want to ask you if you would do additional testing. We are doing the additional testing to see how well the iLet works using blood glucose (BG) measurements from fingersticks rather than a continuous glucose monitor (CGM).. You do not have to do this additional testing if you do not want. It is up to you. All you have to do is tell us. No one will be mad at you if you change your mind.

If you agree to do the additional testing, for 2-3 days you will be asked to stop using your current CGM and start using a blinded CGM. Blinded means you won't be able to see your glucose values. You will check your blood sugar level at least every two hours while you are awake. 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, or your parent/guardian, will need to enter every blood sugar value 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 check. You can do more fingersticks if you want to. At the end of the 2-3 days, we will ask you to remove the blinded CGM and use another CGM. You will be able to see the glucose values. After 2-4 days, you will have one more visit or phone call for the study.

We do not know if you will be helped by having the extra test. We may learn something that will help other people.

This additional testing 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 the additional testing, we will answer any questions about it that you may have. If you have other questions after you agree to do the additional testing, you can ask us and we will answer them or get an answer for you. You can stop being in this part of the study or the whole study at any time.

Everything that we told you about when you agreed to be in the main study is still true. You can ask to see that assent form again. You can ask any questions you have about that form too.