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

Assent Form (electronic)

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ASSENT FORM

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 (RCT Period)

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. 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.

The study has several parts. First, we will do some testing to see if it is okay for you to be in the study. If yes, you will either use the bionic pancreas for 3 months or you will continue to manage your diabetes as you have been doing. The decision on whether or not you will use the bionic pancreas in this study is decided by a computer program. If you did not get to use the bionic pancreas during this study, you will be invited to participate in another study after this one so you can use the bionic pancreas if you want to.

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.

- Attend up to about 7 visits in 3-months. Some or all of the visits can be done in this clinic or by video call.
- Have your blood collected up to 8 times during the study
- Answer questions on paper or online
- Have phone calls with the study staff at least twice during the study. This is to check in and see if you are having any problems or have any questions.
- Use the study bionic pancreas or manage your diabetes as you normally do.
- If you are in the group using your own injections or insulin pump and do not currently use a Dexcom G6 CGM, you will wear a study CGM every day.
- When you are using the bionic pancreas, you will need to change the pump infusion set every 2-3 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.

Also, you might be asked to be in a focus group. In a focus group, people share their experiences with each other. We will be asking about diabetes and the tools used to manage diabetes in the study. The focus groups will be over the internet in what is called a virtual chat room. If you want to do this, please know that other people in the group will see you and hear you. We ask that everyone keep the focus groups private. We cannot promise that everyone will. You do not have to be in this part of the study if you don't want to. You can still be in the rest of the study.

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 the insulin infusion sets
- Pain or bruising from your fingerstick blood sugar checks or 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 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 please tell us that you **do not** want to be in the study. If you tell us that you want to be in the study, 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 start the study, 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 if you want to stay in the study we will get your electronic signature saying that you want to continue. If you do not want to stay in the study you do not have to.