JCHR
JAEB CENTER FOR HEALTH RESEARCH

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IRB APPROVED
AUG 14, 2017

Assent to Participate in a Research Study
Clinical Acceptance of the Artificial Pancreas: The International Diabetes Closed Loop (iDCL) Trial - A Randomized Clinical Trial to Assess the Efficacy of Adjunctive Closed Loop Control Versus Sensor-Augmented Pump Therapy in the Management of Type 1 Diabetes

ASSENT FORM

For Children 14 – 17 years old

Participant's Name: _____

We want to tell you about a research study we are doing. A research study is like a science project at school and it is a way to learn about something. You are being asked to join the study because you have type 1 diabetes and use an insulin pump.

The purpose of this study is to learn whether a system that automatically controls an insulin pump can safely and successfully manage blood sugars. We call this a "closed-loop" system or "artificial pancreas" or "study system." The system runs on a smartphone and uses a continuous glucose monitor (CGM) that measures your sugar level every 5 minutes. The CGM uses a needle inserted just under the skin. The study system has been approved by FDA for this study and is experimental and can only be used for research.

Half of the people in this study will use the study system, and the other half will use their regular insulin pump along with CGM. It is a random choice, like flipping a coin. No one knows which group you will be in ahead of time.

This study will take at least 3 months to complete. If you agree to join, you will be asked to do:

- Clinic visits and Telephone Calls: you will come to this clinic for a visit at least 5 times and we will call you or your parent/guardian by telephone at least 2 times to see how you are doing.
- Finger sticks and blood draws: these will be done several times during the study so we can test some of your blood.
- Questionnaires: you will be asked to answer questions on paper or online.
- Blood sugar checks: you will need to check your blood sugar as instructed by study doctors.
- CGM: you will use the CGM sensor every day and must change it every 7 days.
- Medical records: we will look at your past doctor visits and use information about your care.
- Menstrual diary log: if you are a female and menstruating, you may be asked to keep a log of when your menses occur so study doctors can learn how menses impact blood sugar levels and insulin needs.

You might experience some of these things:

- High or low blood glucose levels
- Redness, itching, discomfort or bruising from the glucose sensors or the insulin infusion sets
- Pain or bruising from your fingerstick glucose checks and other blood tests
- Embarrassment about questions asked on the questionnaires

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 do not have to join this study if you do not want. It is up to you. You can say okay now, and you can change your mind later. All you must do is tell us. No one will be mad at you if you change your mind.

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 here	Today's Date
_____	_____
Investigator's Printed Name	Date
_____	_____
Investigator's Signature	Date

Assent Statement *(to be signed by parent or legal guardian)*

By signing, you agree that this study has been explained to your child in your presence in language that your child can understand and he or she has been encouraged to ask questions about the study now and at any time in the future.

_____	_____
Signature	Date
_____	_____
Signature	Date

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