

**HSR#210112: Hybrid Closed-Loop Control with Prandial Insulin Dosing Informed by Insulin Sensitivity in Adolescents with Type 1 Diabetes
(Main Study)**

ASSENT FORM TO BE IN A RESEARCH STUDY
(12 years old to 14 years of age)

Participant's Name _____ **Medical Record #** _____

Why would we like to speak with you?

We want to talk with you about being a part of something called a research study. A research study is when doctors collect information to learn more about a disease. Doctors who do research are also called researchers.

If you have any questions during our talk about this study, you can ask them. Don't worry about waiting until the person talking stops speaking to you. You can stop them at any time and ask your question.

Doctors at the University of Virginia are doing this research study to learn more about children living with type 1 diabetes mellitus. After we tell you about this research study, we will ask you if you'd like to be in this research study or not. If you decide to be in this research study, you will be asked to sign this paper and you can take a copy of it home with you.

It's okay to say 'NO' if you don't want to be in the study. It is also okay to be in the study now and leave it at any time. You should speak with your parent/guardian about your decision.

This research study is not about getting treatment. You will have treatment for your illness, whether or not you agree to be part of this research study.

The doctor in charge of this study is Dr. Chiara Fabris, PhD.

This screening appointment will take about 1-2 hours. The study admission is where we test the study equipment. These study admissions will be held at Camp Holiday Trails in Charlottesville VA. The camp will be last about 5 nights and 6 days or will be held over two weekends of 3 nights and 4 days (for example, a long weekend from Thursday to Sunday). Your parent will not stay with you at the camp.

If you agree to be in the research study, you will be asked to:

- Come to the camp as directed by the study team.
- Have only one parent or guardian accompany you to study visits at any UVA facility.
- Use the study equipment (study insulin pump, study CGM) during the camp.
- Provide proof of your COVID-19 vaccine.
- Perform a COVID-19 PCR test 48-72 hours before each study admission.

Why are we doing this research study?

We will be getting information from lots of boys and girls like you. There will be about 30 children who have

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type 1 diabetes at the camp.

The study team is trying to learn more about how to better manage your diabetes using an insulin pump. The study team will be testing a new system for giving you insulin automatically (sometimes referred to as an “artificial pancreas”). This new artificial pancreas system is made to be able to work better when you eat, using information on your insulin sensitivity.

What will happen to you if you are in the research study?

If you decide to participate in this study, this is what will happen:

- First, we will do screening to learn more about you to see if you can participate in the study
 - Your parents/guardians will be asked if you can take part in the study before the study starts.
 - For some parts of the study you will not need to come to clinic and those parts can be done by remote visit (for example a computer video connection) and some parts of the study will be in-person.
 - Only one parent may bring you to these study appointments.
 - The study team will give you the study supplies.
 - You will come to a local camp for the study admissions.
 - You will need to be fully vaccinated for COVID-19 and provide a copy of your vaccination record (the Center for Disease Control (CDC) defines people as fully vaccinated two weeks after receiving the second dose of the COVID-19 vaccine); participants who do not provide copy of their full COVID-19 vaccination record will not be able to participate in the study.

Screening:

- You and your parents/guardians will sign the consent form before or after you arrive at the screening appointment.
- You will be asked about the current medications you are taking. You will be asked what happens when you feel hypoglycemic (low blood sugar) or hyperglycemia (high blood sugar).
- You must be willing to switch to a different type of insulin, such as lispro (Humalog) or aspart (Novolog), if you are using glulisine (Apidra).
- The study doctor will do a physical exam including your vital signs (temperature, heart rate, blood pressure).
- If you are a female that already had your first menstrual period, we will obtain a urine pregnancy test. The results of the pregnancy test will be shared with you; however, it is required by Virginia law that the results be shown to your parents/legal guardian. The test must be negative for you to participate in the study.
- The study team will look at your insulin pump to review pump settings and average insulin delivery. The team may need to download this data from your insulin pump to a computer to look at the settings.
- The study team may also want to download your data from your personal CGM and insulin pump.

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- You will give a small amount of blood. The blood will be taken from your finger to obtain a Hemoglobin A1c test. This is the same test that you have done at your endocrinologist's office every 3 months.
- You will be trained how to use the study CGM.
- You will need to eat a minimum amount of carbohydrates during the meals that the study team will provide you during the study admission. This meal may be more food than what you eat normally at dinner.

Pre-Admission Requirements:

You will be contacted by the study team approximately 24-48 hours prior to each camp admission as a check-in visit to make sure that you have taken all the steps needed for you to come to the study admission:

- If you had a positive COVID test result in the 10 days prior to camp, you will not be allowed to attend the camp
- All participants and staff will take a COVID PCR test 48-72 hours before the camp admission; a negative result is needed to attend the camp
- If any COVID symptoms develop after taking this COVID PCR test, you will not be allowed to attend the camp
- If any contact with a COVID positive person happens in the 7 days prior to camp, you will not be allowed to attend the camp
- Verify that a new CGM sensor was placed approximately 24-48 hours prior to the admission for proper warm up
- Parents may optionally monitor CGM values using the Dexcom Share App during at home use of the CGM. A study phone may be provided if you do not have one to use. Your parents will not be able to monitor your CGM values at camp.
- Verify that the goal CGM reading is less than 200 mg/dL at time of arrival to the study admission
- Should any concerns regarding your health, pump information, or unforeseen issues arise, the admission may be cancelled at the discretion of the investigator

At the Study Admission:

- You will come to a local camp for the study admission. The camp will be last about 5 nights and 6 days or will be held over two weekends of 3 nights and 4 days.
- The study team will confirm that you brought your insulin, insulin pump supplies, and regular medications.
- You will begin using the study insulin pump. The study team will insert a new infusion set on your abdomen.
- You will have a finger stick blood sample to measure your hemoglobin a1c when you arrive for the study admission.
- You may be sleeping in cabins with other study participants and camp counselors.
- If tents are used in the study, you will sleep in a tent by yourself. The study team may need to enter your tent at night to monitor the study equipment and your glucose levels.

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- You will participate in group activities with the other study participants, but you will have to stay somewhat distant from them to protect you from the risk of COVID-19.
- You will have to wear a mask if you are indoor or anytime you are asked to do so by the study staff.
- If you experience COVID-19 symptoms during the admission, you will be discharged from the study. You will have a rapid COVID test before you leave the camp.
- You will wear a mask and socially distance for the remainder of the study if a participant or staff member from your group is discharged from the study with COVID-19 symptoms.
- Camp counselors will oversee your camp activities. Study staff will be with you during the entire admission.
- The camp will provide all meals and snacks.
- You will go to bed no later than 11 pm. Staff will wake you around 7-8 am.
- Study team members (i.e., licensed medical physicians, nurses, technicians, etc...) will be present at the camp during the entire study admission.

After the Study Admission:

- Study team will discontinue use of study pump and CGM and you will return to using your personal insulin pump.
- You and your parents will be asked to monitor your ketone levels for up to 24-48 hours after discharge from the study admission if ketones were present at time of discharge. Urine ketone strips may be provided to you if needed.
- The study team will contact you to see how you are feeling about 48-72 hours after discharge from the study admission.
- You will be asked to follow up with the study team by phone 5-7 after discharge if any of the following occurs:
 - You developed symptoms of COVID 19 during camp
 - You tested positive for COVID 19 during camp
 - You were part of the same pod as a person who developed symptoms of COVID 19 or tested positive for COVID 19 during camp
- You will be asked to follow up with the study team if you develop symptoms of COVID 19 or test positive for COVID 19 within 7 days after discharge from the study admission

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What things may bother or hurt you about being in this study?

Sometimes things happen to people in research studies that may hurt them or make them feel bad. These are called risks.

The most common risks are:

- Hypoglycemia (low blood sugar) which can make you feel confused, shaky, or sweaty. If your blood sugar goes extremely low, you may have a seizure, become unconscious or may need to get help at a hospital.
- Hyperglycemia (high blood sugar) which can make you feel thirsty, tired, or have a headache. If your blood sugar goes extremely high, you may pass out for a long time or may need to get help at a hospital.
- Blood sugar levels may drop quicker than normal because you are using more energy while participating in camp activities.
- A small amount of pain or bleeding when we put in the continuous glucose monitor's sensor in your stomach. You may have a bruise where the sensor is put into your stomach. An infection does not happen very often.
- You may hurt yourself while participating in camp activities.

If you are pregnant or think you might be pregnant, please tell us so we may talk about this with you. If you are female and of child-bearing potential, your urine sample will be tested to find out if you are pregnant. This test must be negative in order to continue study participation. The results of the pregnancy test will be provided to you. Also, Virginia law requires release of the test results to your parent(s)/legal guardian if they request the results or request a copy of your medical records. It is important that you contact the study doctor right away if you think you may be pregnant, if you have missed a period or it is late, or if you have a change in your usual menstrual cycle (heavier or lighter bleeding than usual or bleeding between periods).

Will this study help me?

People also may have good things happen to them because they are in research studies. These are called benefits. There are no direct benefits for you to participate in this study. However, you would be helping researchers learn more about type 1 diabetes.

Will you be paid for being in this study?

No. The study team is paying Camp Holiday Trials enrollment fee. Your parents will not pay this camp fee. If needed, the study team will provide a sleeping bag, a sleeping pad, and a tent to use during the study admissions.

Can you do something else instead?

Yes. Your doctor will tell you and your parents what other treatment(s) you may have instead.

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Do you have to be in this research study?

No. No one will be upset with you if you don't want to be in this research study. If you don't want to be in this research study, just tell us. If you want to be in the research study, tell us that. And remember, you can say yes now and change your mind later. It's up to you.

Please talk this over with your parents before you decide whether or not to be in the research study. Your parents have said that it is okay with them if you want to be in the research study. Even though your parents have said it is okay with them, you can still say 'No'.

What if you have questions?

You may ask questions at any time. You can ask now or later. You may talk to the doctor or someone else. Your parents/guardians have the information on who you or they may call after you go home.

What about your privacy?

The doctor will talk about you and the research study with your parent/guardian but will not talk about it with anyone else except the people working here. If the doctor needs to talk to anyone else about you, he/she will ask you and your parent/guardian if it is OK.

The following information must be released/reported to the appropriate authorities if at any time during the study there is concern that:

- child abuse or elder abuse has possibly occurred,
- you have a reportable communicable disease (i.e., certain sexually transmitted diseases or HIV)
- you disclose illegal criminal activities, illegal substance abuse or violence

Saying Yes or No to being in this research study

You can say yes or no. If you say yes, remember:

1. You can stop being in the study any time you want to
2. You can talk to the study doctor any time you have any questions
3. Besides your parents/guardian, your information will only be shared with the doctor and nurses in this study

If you sign this paper, it means that you have read this assent form, and you have talked with someone about it. It also means you have had all your questions for today answered and you want to be in the research study. If you don't want to be in the study, don't sign this paper.

Please ask as many questions as you need to make sure you understand the study before you sign this form. Being in the study is up to you, and no one will be upset if you don't sign this paper or if you change your mind later.

Consent from the parent/guardian MUST be obtained before approaching the child for their assent.

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Parent(s)/Guardian has signed Main informed consent ___ Yes ___ No

Name of Person Obtaining Consent of the Parent(s)/Legal Guardian _____

Signature of Person Obtaining Consent of the Parent(s)/Legal Guardian _____

Assent from Child (12-14 years of age)

CHILD
(SIGNATURE)

CHILD
(PRINT NAME)

DATE

Person Obtaining Assent of the Child (12-14 years of age)

By signing below, you confirm that the study has been explained to the child (less than 18 years of age), all questions have been answered and the child has voluntarily agreed to participate.

PERSON OBTAINING ASSENT OF
THE CHILD
(SIGNATURE)

PERSON OBTAINING ASSENT
OF THE CHILD
(PRINT NAME)

DATE