Parents' or Guardians' Permission for Your Child to Be in a Research Study

Agreement of a Child to Be in a Research Study (Age 15 to 17 years of age)

In this form "you" means the child in the study and the parent or guardian.

- ✓ If you are the parent or guardian, you are being asked to give permission for your child to be in this study.
- ✓ If you are the child, you are being asked if you agree to be in this study.

In this form "we" means the researchers and staff involved in running this study at the University of Virginia.
In this form "you" means the person (your child) who is being asked to be in this study. As the parent or guardian, you are being asked to give permission for your child to be in this study.

Participant's Name_____ Medical Record # _____

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.
Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a copy of this form.

Who is funding this study?

This study is being funded by the Juvenile Diabetes Research Foundation (JDRF) and University of Virginia Strategic Investment Fund (SIF). All study devices (insulin pumps, continuous glucose monitors, infusion sets, and other supplies) and the cost of the camp will be paid with study funding. Camp Holiday Trail will manage the recreational activities of the study.

Key Information About This Research Study

Principal Investigator:	Chiara Fabris, PhD University of Virginia Center for Diabetes Technology (CDT) Box 400888, Charlottesville, VA 22903 Telephone: (434) 982-6483
Sponsor:	Juvenile Diabetes Research Foundation (JDRF) and University of Virginia Strategic Investment Fund

You are being asked to take part in a research study. You do not have to take part in this study.
You should only agree to take part in this study after reading this consent form and discussing it with the study team.

You may also discuss this with your family, friends, health care providers or others before you make a decision.

What problem is this study trying to solve?

The purpose of this study is to find out if a hybrid closed-loop control system with the study device software helps control diabetes better than standard hybrid closed-loop control system.

The Hybrid Closed Loop (HCL) pump is any insulin pump able to deliver variable (automated) basal insulin by using an algorithm and real-time continuous glucose monitor (CGM) sensor glucose trends. In particular, this study is trying to find out how this works during daytime and in the presence of higher-than-usual physical activity. Physical activity may increase your sensitivity to insulin – i.e., decrease the amount of insulin you need to lower your blood glucose levels – and is often challenging to handle, even with a closed-loop control system. Using a bolus calculator that knows about changes in your insulin sensitivity and modulates the amount of bolus insulin based on your insulin sensitivity may help with improving your glycemic control. In this study, we want to find out if using such a bolus calculator improves the performance of normal hybrid closed-loop control, during a diabetes camp.

This study will be done in two parts. The first part is the Pilot Study and up to 3 people will complete this study at UVA. The second part is the Main Study and up to 30 people will complete this study at UVA. Participants of the Pilot Study may also enroll in the Main Study.

You are being asked to take part in the Main study because you or your child are between the ages of 12 years old and less than 18 years old and your child have been diagnosed with type 1 diabetes mellitus.

Why would you want to take part in this study?

You might like to take part in this study because this study may improve your understanding of your diabetes. You may or may not be helped by being in this study, but the information gained by doing this study may help other people with type 1 diabetes mellitus at some future time.

Why would you NOT want to take part in this study?

You might not want to take part in this study because:

- You will need to stay at a camp. This camp may be held over 6 days / 5 nights or two long weekends (3 nights and 4 days).
- Your parents will not stay at the camp with you.
- You may sleep in a cabin with about 5-6 other study participants and camp counsellors.
- If tents are used, you will sleep in a tent by yourself
- You will need to use study equipment (study insulin pump, CGM) during the study.

NOTE: If you take part in this study, you must be willing to wear the study insulin pump and study CGM during the study. It may mean changing your fast acting insulin to Humalog or Novolog which are the only two insulins that are used in the insulin pumps. The study team will change insulin dosing and allow the algorithm (complex mathematical formula) to calculate your insulin dosages.

What will I have to do if I take part in this study?

Full details of all the procedures are found later in this form. If you take part in this study:

- You will be required to attend a screening visit either in person or by videoconference to see if you are eligible to participate in this study.
- You will participate in one study admission and about 4-5 calls/email/text/video visits.
- You will come to a local camp for the study admission.
- You will need to be fully vaccinated against 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 vaccination; participants who do not provide copy of their full COVID-19 vaccination record will not be able to participant in the study.
- You will need to have a COVID-19 PCR test (e.g., nasal swab, throat swab) 48-72 hours before the start of the study admission(s).
- You will not be able to participate if you have COVID-19 symptoms after taking the mandatory COVID-19 PCR test or during the study admission(s).
- You will need a negative COVID-19 PCR test if you have been in contact with someone who is known to be COVID-19 positive within the 7 days before the study admission.
- You will be trained on how to use the study CGM.
- You will have a finger stick blood sample to measure your hemoglobin a1c when you arrive for the study admission.
- You will have one parent or guardian come with you to any study appointments, and one parent will bring you to the study admission but will not be able to stay with you
- You will need to have access to internet and be willing to upload the data during study as needed
- You will be willing to stop using your personal CGM for the duration of study participation
- You will be willing to switch to Humalog or Novolog insulin if not used already
- You will be willing to eat at least 40 grams of carbohydrates per meal during the study admission.

What is the difference between being in this study and getting usual care?

If you take part in this study, the following things will be done differently than if you do not take part in this study.

- You will need to attend study visits and have access to internet and willingness to upload data during the study.
- You will use study devices and technology during the study.
- You will need to eat a minimum amount of carbohydrates during the meals that the study team will provide you during the study admission. These meals may be more food than what you eat normally eat.

What other treatments may I receive if I decide to not take part in this study?

The following alternative treatments are available to you if you decide not take part in this study:

- You may continue your diabetes care (using your personal insulin pump) as you normally do.

How long will this study take?

Your participation in this study will require 5-7 study visits over about 2 weeks. The length of each visit varies.

- Visit 1 is the screening visit to determine if you are eligible to participate in this study
- Visit 2 is a study equipment training visit
- Visit 3 is a pre-admission check-in visit that involves a phone call from a study team
- Visit 4 is the first camp admission
- *Visit 5 is a pre-admission check-in visit that involves a phone call from a study team**
- *Visit 6 is the second camp admission**
- Visit 7 is a follow-up phone call from a study team

**Note:* Visits 5 and 6 will occur only if the study admissions are held over two weekends.

What will happen if you are in the study?

Some of the study will be done by remote visits (i.e., a computer video connection/ videoconference) and some will be in person.

NOTE: All procedures/assessments and tests described in this consent are completed for research purposes only.

Visit 1: SCREENING (will last about 1-2 hours)

(Day 1 clinic and remotely)

If you agree to participate, you will sign this consent form before any study related procedures take place. The screening period is to make sure you are eligible, and it is safe for you to participate in the study. These include the following:

- A review of your medical and surgical history, allergies, and current medications.
- A physical examination and vital signs will be obtained (this includes height, weight, blood pressure, heart rate, temperature.
- A physical examination and vital signs (i.e. if available, height, weight, blood pressure, heart rate, temperature, and hemoglobin A1c). A physical history from your pediatrician or endocrinologist dated with the last 52 weeks may be substituted. If you are a female that already had your first menstrual period, we will obtain a urine pregnancy test. This pregnancy test must be negative for you to participate. Virginia law requires release of the test results to your parent/legal guardian if they request the results or request a copy of the medical record.
- You will be asked to complete a Demographic Data Survey (where you live, your education level, etc.) as required by the study.
- The study team will need to download up to 4 weeks of your personal insulin pump and/or CGM data.

RANDOMIZATION

If these tests show you are eligible, you will be randomly assigned (like the flip of a coin) to one of the two study groups. You have an equal chance of being assigned to Group 1 first or to Group 2 first. You will be assigned to the other group later in the study admission. Neither you nor your doctor can choose which group you are assigned. Neither you nor your doctor will know which group you will get until the study is done. But if your

doctor needs to know, the people doing this study can find out.

GROUP 1: Hybrid closed-loop control
GROUP 2: Hybrid closed-loop control with smart bolus calculator informed by insulin sensitivity

After randomization, you can immediately participate in visit 2.

Visit 2: Study Equipment Training (about 1-2 hours)
(Day 1 or 2)
Continuous Glucose Monitor (CGM) Training

- You will receive training on the use of the study CGM if you are not familiar with the equipment. The study team may have you watch the Dexcom training videos (https://www.dexcom.com/training-videos).
- You will stop using your personal CGM during this training session. You will begin wearing the study CGM.

If the CGM requires calibration, you will be asked to perform fingerstick blood glucose measurements with your home glucometer according to the Dexcom User Manual.

You will be provided the CGM supplies to use during the study.

Visit 3: Pre-Admission Check-In Visit (about 15 minutes)
(Day 3)
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

Visit 4: Camp Study Admission #1 (will last about 6 days/5 nights or 4 days/3 nights)
(Day 4-9 or Day 4-7)

- Your parents will drop you off at the camp and pick you up at the end of the study admission.
- The study team will ask you if you are experiencing COVID-19 symptoms (e.g., fever, shortness of breath, unexpected loss of taste or smell); if you have these symptoms, you will not be able to participate in study admission.
- If you begin to experience symptoms of COVID-19 (e.g., fever, shortness of breath, unexpected loss of taste or smell) during the study admission, you will be immediately isolated and discharged from the study. Before discharge, the use of a facial masks will be mandated. You will not engage in further camp activities prior to discharge. You will be tested for COVID-19 using an antigenic rapid test before you leave the camp. At discharge, you will be advised on appropriate isolation and testing to be completed.
- 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.
- You will be asked to maintain physical distance from other participants during the activities to reduce your risk of contracting COVID-19; in addition, you will have to wear a mask indoor and anytime you are asked to do so by the study staff.
- 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.
- A repeat urine pregnancy test will be performed if applicable. This pregnancy test must be negative for you to participate. Virginia law requires release of the test results to your parent/legal guardian if they request the results or request a copy of the medical record.
- You may give a small amount of blood. The blood may be taken from your finger to obtain a Hemoglobin A1c test.
- You will be provided meals at approximately 8 AM, 12:30 PM and 6 PM.
- You will be offered and provided snacks.
- The majority of the activities will take place outdoor. You will participate in structured supervised exercise (e.g., hiking, archery, arts & crafts, etc. – 3 hours in the morning and 3 hours in the afternoon). Study staff will be with you when you are engaging in camp activities.
- The activities and meals that you enjoy on day 2 and 3 of the study will be similar to study admission #2, day 10 and 11.
- You will be asked to notify staff of any alerts/alarms by the study device.
- You will interact with the other study participants and study staff.
- You will be continually monitored by study staff (i.e., physicians, nurses, technicians, and other study staff).

Study Admission Discharge
(Day 9)

On the last day of the camp, you will be discharged in the morning (10:00 – 1:00 pm) if CGM is between 80 and 250 mg/dL and ketones <0.6 mmol/L. Study equipment will be discontinued, and you will start using your personal equipment (personal insulin pump, personal insulin parameters, etc.) at this time. If you are returning for a second admission, you may be permitted to continue using the study CGM while at home. A study physician or another qualified study team member will discuss the transition back to personal equipment. You will be

asked to continue monitoring ketone levels for 24-48 hours after the study admission. Urine ketone supplies will be provided for this testing.

(*) Visit 5: Pre-Admission Check-In Visit (about 15 minutes)
(Day 8)
See visit 3 description.

(*) Visit 6: Camp Study Admission #2 (will last about 4 days/3 nights)
(Day 9-12)
See visit 4 description.

Below is an approximate schedule of events:

TIME	ACTIVITY
8:00 – 9:00 AM	Breakfast
9:00 – 12:00 PM	Camp activity
12:30 – 1:30 PM	Lunch
1:30 – 3:00 PM	Rest Hour
3:00 PM	Snack
3:15 – 5:15 PM	Camp activity
6:00 PM	Dinner
7:00 – 8:30 PM	Evening activity
8:30 PM	Snack
9:00 – 11:00 PM	Free time/bedtime

(*) Study Admission Discharge
(Day 12)
You will be discharged on the morning of Day 12 (10:00 – 1:00 pm) if CGM is between 80 and 250 mg/dL and ketones <0.6 mmol/L. The study equipment will be discontinued, and you will start using your personal equipment (personal insulin pump, CGM, personal insulin parameters, etc.) at this time. You will return the study devices and supplies (CGM, insulin pump,) to the study team. A study physician or another qualified study team member will discuss the transition back to personal equipment. You will be asked to continue monitoring ketone levels for 24-48 hours after the study admission. Urine ketone supplies will be provided for this testing.

You will be advised on isolation procedures and COVID-19 testing that should be completed if you have COVID-19 symptoms or was in close contact with someone with COVID-19 symptoms during this study admission.

Visit 7: Study Follow Up Visit
(Day 13)
There will be one follow-up phone call that will happen about 3-4 days after you stop using the study equipment to see how you are doing and to follow-up on any events that happened since stopping the study equipment.

You will be asked to follow up with the study team by phone within 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 also be asked to follow-up with the study teams if you develop symptoms of COVID 19 or test positive for COVID 19 within 7 days after discharge from the study admission.

Study Schedule

	Screening	CGM Training	Pre-Admission Check-in	Study Admission	Post-Admission Check-in
Location	Clinic/Remote	Clinic/Remote	Phone/Email	Camp Holiday Trails	Phone/Email/ Text/Video
Informed Consent	X				
Eligibility Assessment	X				
Medical History	X				
HbA1c (POC)				X (admission #1 only)	
Pregnancy test (if applicable)	X			X	
Physical Exam				X	
Vital Signs (height/weight)				X	
Randomization				X	
COVID-19 testing			X		
Wear Study CGM and Insulin Pump				X	
Review diabetes management and health related problems	X	X		X	X
Check In			X		X

What are your/and your parent/legal guardian's responsibilities in the study?

You and your parent/legal guardian have certain responsibilities to help ensure your safety.
These responsibilities are listed below:

- Your parent/legal guardian must bring you to each study visit.
- You and your parent/legal guardian must be completely truthful about your health history.
- Follow all instructions given.
- You or your parent/legal guardian should tell the study doctor or study staff about any changes in your health or the way you feel.
- Answer all of the study-related questions completely and accurately.
- Inform the study doctor or study staff as soon as possible if you have to take any new medications, including anything prescribed by a doctor or those that you can buy without a prescription (over the counter), including herbal supplements and vitamins. The study doctor will let you know if you can take these medications.

Blood Testing

The total amount of blood we will take will be less than a ½ teaspoon of blood. The blood we take will be tested to measure your hemoglobin A1c which is a blood test used to monitor how well you're managing your diabetes. When these tests are done any left-over sample will be thrown away or they will be de-identified. This means there is no information that could be used by anyone to determine who the sample came from.

If you want to know about the results before the study is done:

During the study, your study leader will let you know of any test results that may be important to your health. In addition, as the research moves forward, your study leader will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time, you can ask for more information about the study results.

What are the risks of being in this study?

Risks and side effects related to treating type 1 diabetes (with or without using study equipment):

Likely

- Risk of possible mild to moderate low blood sugar and possible symptoms of low blood sugar, such as sweating, trembling, difficulty thinking, dizziness, and feeling uncoordinated.
- Risk of possible mild to moderate high blood sugars and symptoms of high blood sugars such as thirst and frequent urination. You may have a higher level of sugar in your urine.
- Infusion set failures that may cause hyperglycemia and/or DKA.

Rare but serious

- Risk of severe temporary low blood sugar (hypoglycemia) that can lead to unconsciousness, hypoglycemic seizure, hospitalization or even death.

- Risk of prolonged high blood sugar leading to diabetic ketoacidosis (DKA), hospitalization, and coma. DKA can lead to renal failure (kidney failure), cardiac arrhythmia (irregular heartbeat), myocardial infarction (heart attack), rhabdomyolysis (muscle breakdown), and even death.

Risk of Changing Insulin Therapy:

Rare

- Mild allergic reaction including developing a rash after injection

Risks related to using a Continuous Glucose Monitoring Equipment:

Likely

- Failure or lack of sensitivity of the continuous glucose monitor sensor that requires replacement and or insertion of new sensor in your abdomen
- Discomfort from insertion of sensor into the skin

Less Likely

- Bruising less than ½ inch
- Bleeding less than ¼ teaspoon
- Sensitivity to adhesives with use of continuous glucose monitor resulting in skin irritation, redness, blistering, scarring, systemic allergic reaction (shock with breathing problems, heart failure)

Rare

- CGM sensor reads higher or lower than your actual glucose level
- CGM sensor stops working or cannot communicate with the system. If this occurs, the insulin pump will start delivering its preset basal rates within 30-60 minutes

Rare but serious

- Swelling or redness at insertion site
- Psychological reaction to viewing the continuous glucose monitor information or attending to continuous glucose monitor alarms or finger stick blood glucose values.
- Breakage of the continuous glucose monitor sensor under the skin with possible symptoms of skin irritation and inflammation. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Please call the study team or seek immediate medical assistance. Seek professional medical help if you have symptoms of infection or inflammation – redness, swelling or pain – at the insertion site.
- Bloodborne pathogen, such as Hepatitis B, if the shared CGM transmitter is not cleaned thoroughly with a diluted mixture of bleach or another appropriate cleaner after use per hospital approved cleaning procedure.

Risks and side effects related to the study system include:

Even though the study algorithm has been tested prior to this study, there is still a risk that parts of the system

may malfunction. As a result, you could receive less or more insulin than you need and be at risk for hyper- or hypoglycemia. The following are common cases of system malfunction:

- CGM sensor reads higher or lower than your actual blood glucose level
- CGM sensor stops working or cannot communicate with the system. If this occurs, the insulin pump will start delivering its preset basal rates within 30-60 minutes
- Infusion set failures

Risks associated with having your blood drawn:
Having blood drawn may cause:

- ✓ pain (common),
- ✓ a bruise (sometimes),
- ✓ fainting or passing out (not very often), and
- ✓ infection (rare).

If the people doing the study are exposed to your blood or body fluids in a way that could give them a disease, your blood may be tested. The tests might check for:

- ✓ hepatitis,
- ✓ HIV (Human Immunodeficiency Virus), or
- ✓ other infections.

You and the person exposed would be told the test results. However, your name would be kept private. If your test is positive for hepatitis or HIV or any other infection that may affect your clinical care, we will tell you the results and help you understand what the results mean for you.

Risk of injury while participating in camp activities:

A wide range of injuries may occur while you are at camp. Bruising, dislocations, sprains, and fractures are common.

Risk of Sharing the Insulin Pump, Continuous Glucose Monitor, Glucometers, and Ketone Meter:

Insulin pump, continuous glucose monitor, glucometers, and ketone meter as 'single use devices'. This means that they recommend that only one person use this device as there is a rare risk that a blood borne pathogen, such as Hepatitis B, may be spread if used with multiple patients. All devices will be cleaned will be cleaned thoroughly with a diluted mixture of bleach or another appropriate cleaner after use per approved cleaning procedure.

The CGM sensor will not be shared, and it will be discarded after use.

Risks of Videotaping/Audiotaping:

Photographs and videotapes will be used in presentations at conferences, potential study subjects, and potential research donors. Your picture can be blacked out in photographs that we maintain.

- The study team can keep a participant's identity anonymous.
- The study team will keep these photos and videotapes indefinitely.

- The study team is not able to restrict other participants from sharing photographs that include you (i.e. social media).

Risk of COVID-19:
The study team will follow Center for Disease Control (CDC) COVID-19 Guidelines that are in effect at the time of the camp for all aspects of the study to make this risk smaller.

If you begin to experience symptoms of COVID-19 (e.g., fever, shortness of breath, unexpected loss of taste or smell) during the study admission, you will be immediately isolated and discharged from the study. Before discharge, the use of a facial masks will be mandated. You will not engage in further camp activities prior to discharge. You will be tested for COVID using an antigenic rapid test before you leave the camp. At discharge, you will be advised on appropriate isolation and testing to be completed. You will also be asked to follow-up via phone with the study team 5-7 days after discharge. If you develop symptoms of COVID 19 or test positive for COVID 19 within 7 days after discharge, you will be asked to follow up via phone with the study team.

If a person in your group (other study participant or counselor) tests positive, universal masking for the group members will be mandated indoor and outdoor, with the exception of eating, drinking, showering, and sleeping; these activities will take place separately from other groups.

Hand sanitizers will be available during the entire study duration and study participants and staff will be encouraged to frequently sanitize their hands.

If the COVID-related situation changes before the camp admission, the study team will re-evaluate these guidelines in agreement with CDC recommendations. Increased restrictions may be necessary.

Loss of Privacy:
- The study team will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. All identifiable information about you will be replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data.
- We encourage you to discuss the risks with your study doctor or any other health care professional who may understand our process.
- The study admission will have other participants also in attendance.

Other Unexpected Risks:
You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Blood Donation:
If you participate in this study, it may affect your ability to donate blood. If you have any questions call the organization where you donate blood and talk to one of their nurses.

Risks for women:
Being in this study might hurt your unborn baby, so you will not be able to join or stay in the study if you become pregnant. If you have questions about birth control, please ask the study leader. If you are pregnant now, or get pregnant during the study, please tell us right away.

Other unexpected risks:
You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?
You will not benefit from being in this study. However, the information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?
You do not have to be in this study to be treated for your illness. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include:

- managing your illness as recommended by your endocrinologist.

If you are an employee of UVA, your job will not be affected if you decide not to participate in this study.
If you are a student at UVA, your grades will not be affected if you decide not to participate in this study.

Will being in this study cost you any money?
The following procedures/tests, which are being done for research purposes, will be provided at no cost to you or your health insurance: hemoglobin A1c test, pregnancy tests, COVID-19 test if performed at UVA, study equipment and their associated supplies (e.g. insulin pump, CGM supplies, ketone test, etc.). The study team will provide sleeping bag, sleeping pad, and a tent to use during the study admissions.

You will be responsible for the cost of your insulin that is used during the study. As previously noted, the use of the Dexcom Apps on a personal phone may result in data and text charges.

You and/or your insurance company must pay for any tests or care given beyond what is required in this study. This includes COVID-19 tests, if you decide to have those done in your community instead of at UVa. In addition, you and/or your health insurance may also have to pay for other drugs or treatments that are given to help you control any side effects. You will have to pay for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask your insurance company for an estimate of what these costs might be or if pre-approval is required.

The cost of the camp and all meals will be paid by the study.

You will be responsible for the cost of travel to come to any study visit and for any parking costs.

What if you are hurt in this study?
You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you

have been injured as a result of this study, you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

What happens if you leave the study early?

You can change your minds about being in the study any time. You can agree to be in the study now and change your minds later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your minds, the study can take you out of the study. Some of the reasons for doing so may include:

a. The study physician is concerned about your health
b. Your condition gets worse
c. The side effects of the treatment are too dangerous for you
d. New information shows the procedures will not work or is not safe for you
e. You do not follow your doctor's instructions
f. The study sponsor closes the study for safety, administrative or other reasons

If you decide to stop being in the study, we ask that you notify the research team so any scheduled admissions may be cancelled. The study insulin pump, study CGM and other supplies remain property of the CDT and will need to be returned.

Any data collected about you up until the time you leave the study must be kept in order to determine the results of the study.

How will your personal information be shared?

The UVA researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address, and date of birth
- Social Security number ONLY IF you are being paid to be in this study
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- Outside researchers from suppliers and potential funding agencies may observe the trial.
- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results

- People or groups that oversee the study to make sure it is done correctly
- The sponsor(s) of this study, and the people or groups it hires to help perform or review this research
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study
- Tax reporting offices (if you are paid for being in the study)
- People who evaluate study results, which can include sponsors and other companies that make the devices being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.
- Members of the Center for Diabetes Technology, researchers from outside of UVa and other non-medical staff will be present during the study to both observe and support the camp admission's recreational activities.
- Other participants will likely take photos of this event. Your face may be in these photos. Other participants may post these photos on social media without your permission.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

Information obtained from you during this study may be used in future research. Your information may be shared with other researchers inside or outside of the University of Virginia. They will not be sent with information that could identify you such as name, address, or phone number.

A description of this clinical trial will be available on http:// www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form or complete the "Leaving the Study Early" part of this form and return it to the researchers. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

A copy of this consent form will be put in your medical record. (This is not the same as the record of this research study.) This means that everyone who is allowed to see your medical records will be able to find out that you are in this study. This is done so your regular doctors will know what you receive as part of this study. If you have other health problems during the study, they will be able to treat you properly.

Would you like the study team to communicate with you by email or text message?

If you choose to communicate with the study team by unsecure email (email that is not encrypted) or text message to your personal phone, there is some risk that your health information could be read or accessed by someone else while the information is sent or saved by your email or phone provider.

Your personal email or phone provider may also share or release your information because they do not have to follow the privacy laws that UVA follows. Sometimes email and phone providers release information to marketing companies for use in direct advertising. If you choose to communicate by email or text messaging, UVA cannot control this potential loss of privacy, but we want to tell you about this possible risk.

You do not have to agree to communicate with the study team by email or text message to be in this study. If you agree to texting or emailing, the study team will collect your phone and /or email address from you that you would like them to use to contact you. Please note, if you agree to text messaging, charges may apply depending on your data/text plan with your phone provider.

Please contact the Principal Investigator listed earlier in this form to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:
Chiara Fabris, PhD
University of Virginia Center for Diabetes Technology (CDT)
Box 400888, Charlottesville, VA 22903 Telephone: (434) 982-6483

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908 /Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the UVA Study Tracking Number (at the bottom of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

You may also report a concern anonymously by calling the UVA Compliance Hotline phone number at 1-800-235-8700.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form, it means that you agree to join the study. You will receive a copy of this signed document.

Assent from Child (15-17 years of age)

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

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

Person Obtaining Assent of the Child (15-17 years of age)

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

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 (SIGNATURE)	PERSON OBTAINING ASSENT (PRINT)	DATE

Parental/ Guardian Permission

By signing below, you confirm you have the legal authority to sign for this child.

_____	_____	_____
PARENT/GUARDIAN (SIGNATURE)	PARENT/GUARDIAN (PRINT NAME)	DATE
_____	_____	_____
PARENT/GUARDIAN (SIGNATURE)	PARENT/GUARDIAN (PRINT NAME)	DATE

If you are unable to obtain parental permission from both parents/guardians, explain why not:

_____

Person Obtaining Parental/Guardian Permission

By signing below, you confirm that you have fully explained this study to the parent/guardian, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING PARENTAL/ GUARDIAN PERMISSION (SIGNATURE)	PERSON OBTAINING PARENTAL/GUARDIAN PERMISSION (PRINT NAME)	DATE

Notification of My Health Care Provider

Please indicate below whether you want us to notify your health care provider that you have agreed to take part in this study.

_____ Yes, I want the study doctor to notify my health care provider that I have agreed to take part in this study.

Health Care Provider Name: _____

Health Care Provider Address: _____

Study team will send a copy of the consent form to the health care provider.

_____ No, I do not want the study doctor to notify my health care provider that I have agreed to take part in this study, or I do not have a health care provider.

Leaving the Study Early

If you leave the study early the study leader will keep the data collected about you up until the time you leave the study to help determine the results of the study.

Check one option below:

____ I am withdrawing my consent from the intervention or treatment part of this study but agree to continue to have follow up information about me collected by the study team.
The follow up information will be collected by:

- Phone call one time
- Return of study equipment

____ I am withdrawing my consent for this study. No additional information may be collected about me including follow up information from my medical records.

Assent from Child (15-17 years of age) to be removed from the study early

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

Parental/ Guardian Permission

By signing below, you confirm you have the legal authority to sign for this child.

_____	_____	_____
PARENT/GUARDIAN (SIGNATURE)	PARENT/GUARDIAN (PRINT NAME)	DATE

Person Obtaining Consent

By signing below, you confirm that you have fully explained the implications of withdrawing from the study to the subject and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE