Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

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

Agreement of a Child to Be in a Research Study
(15 y.o. to < 18 y.o)

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 University of Virginia's Launchpad Fund and the University of Virginia's Strategic Investment Fund (SIV). The study insulin pump and its associated supplies (infusion sets, cartridges) will be provided by Tandem Diabetes Care, Inc. The study continuous glucose monitors (CGMs) and its supplies (sensors, transmitters) will be provided by Dexcom, Inc. The activity tracker (e.g. Fitbit), and hotel admission will be purchased with grant funding.

Key Information About This Research Study

Principal Investigator:	Dr. Mark DeBoer, MD, MSc University of Virginia Center for Diabetes Technology (CDT) Box 400888, Charlottesville, VA 22903 Telephone: 434-924-5956
Sponsor:	University of Virginia Launchpad Fund & 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 study team will be comparing two investigational Artificial Pancreas (AP) systems that the UVA Center for Diabetes Technology has developed. An artificial pancreas system delivers insulin automatically based on a blood glucose level that is provided from a continuous glucose monitor (CGM). One investigational AP system is called "*RocketAP*" which is designed to be able to identify when you have eaten and provide insulin for this meal. The second AP system is named USS Virginia, aka "*Control-IQ*." While both AP systems are similar, they contain different features that we will examine during this study. Specifically, the purpose of this study is to compare how both systems work when carbohydrate information at a dinner meal is entered into the insulin pump and when not entered into the insulin pump. This is called an "*announced*" meal and an "*unannounced"* meal.

High blood sugars may occur when carbohydrate amount has not been entered into the insulin pump (not announced) when using either of the two AP systems. There is also a chance that there could be low blood sugars if the AP systems deliver more insulin than is needed. We will be following you closely throughout the study to monitor for either of these possibilities and provide whatever treatment is needed.

You are being asked to take part in this study because you or your child are between the ages of 12-25 y.o. and has 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.

You must 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.

Why would you NOT want to take part in this study?
You might not want to take part in this study because:

- These studies may occur at a local hotel.
- The study requires two 64-hour (estimated time) hotel admissions with other participants; your parents will not stay at the hotel with you.
- You will need to use study equipment (study insulin pump, CGM, activity tracker) during the hotel admissions.
- You will need to complete a questionnaire about how you liked using the study equipment. It will take you less than 5 minutes to complete this questionnaire.

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:

- You will be required to attend a screening visit. It is the preference of the study team that this appointment if performed in person, but a video visit can be substituted.
- There will be 2 hotel admission and about 4 phone/email/text visits.
- You will have two COVID 19 test – one about 48-72 hours before the hotel admission and a second test at the start of the hotel admission.
- Any contact or in person visits will be done with standard COVID precautions.
- You will be trained on how to use the study devices; these are a CGM and an activity tracker. You will learn about the two different insulin pumps – one at each hotel admission.
- You may need to give a finger stick blood sample to measure your hemoglobin A1c.
- You will need to complete a questionnaire about how you liked using the study equipment. It will take you less than 5 minutes to complete this questionnaire.
- Only one parent or guardian may accompany you to any UVA facility, or to the hotel.

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.
- You will use study devices and technology during the study.
- You will need to eat a certain amount of carbohydrates during the dinner meals that the study team will provide you during the study admission. This meal may be more or less food than what you eat normally at dinner.

This is a research study about testing two Artificial Pancreas systems to assess how these systems respond when the user does not enter carbohydrate information from a meal. One of these systems is designed to notice when you have eaten and provide extra insulin for unannounced meals. This investigative system (RocketAP) has not been proven to be safe or helpful and has not been approved by the U.S. Food and Drug Administration (FDA). So far, the RocketAP has been not been used with study subjects. This system being studied in this trial has been tested in a computer only using insulin parameters that have been collected from thousands of people with type 1 diabetes. This is called computer simulation. The Control-IQ (USS Virginia) has been the foundation of our Artificial Pancreas research for more than a decade. It is not approved by the FDA; however, it has been tested on several hundred people and for more than 100,000 hours.

What other treatments may I receive if I decide to not take part in this study?
You may continue your diabetes care (personal insulin pump) as you normally do.

How long will this study take?

Your participation in this study will require 8 study visits over 28 days. Visit 1 is the screening visit to determine if you are eligible to participate in this study and will take about 1-2 hours. Visit 2 is a study equipment training visit and will take about 1-2 hours. Visit 3, 5, 6, and 8 are phone calls with you and the study team which will last about 15 minutes. Visit 4 and 7 are hotel admissions that will take about 64 hours each to complete.

Up to 30 people will enroll in this study at UVA.

All procedures discussed in this study are completed for research purposes only.

What will happen if you or your child are in the study?

Some of the study will be done by remote visit (for example a computer video connection) and some will be in-person. Please note that any in-person parts of the study will require standard

precautions against COVID-19, including wearing a mask, washing hands and maintaining social distancing of 6 feet when possible. Only one parent may accompany the adolescent.

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

(Day 1)

If you agree to take part in this study, you will sign this consent form before any study related procedures take place. Before you can start in the study, there will be a screening period. You will have tests and procedures during this time to make sure they are eligible, and it is safe for them to participate. These include the following:

- A review of your medical and surgical history, allergies, and current medications.
- A physical examination and vital signs (height, weight, blood pressure, heart rate, temperature). A physical history from your pediatrician or endocrinologist dated with the last 52 weeks may be substituted.
- You may give a small amount of blood. The blood may 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.
- 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 wear an activity tracker (i.e. 'Fitbit') on your wrist during the entire study to collect information about your activity and your heart rate. You may take it off before bathing.
- Demographic Data Survey (where you live, your education level, etc.)

If these tests show you are eligible, you will return to the clinic (within 60 days) to begin study procedures.

Visit 2: Study Equipment Training (will last 1-2 hours)

(Day 2)

This training is to introduce you to the CGM and activity tracker.

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 video (https://www.dexcom.com/training-videos). You will stop using your personal CGM during this training session. You will begin wearing the study CGM. You will download Dexcom Apps onto a phone to watch your CGM values and alerts in real-time. This App may be downloaded to a

phone provided to you by the study team, or you may use your personal phone. The use of the Dexcom App on a personal phone may result in data and text charges.

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.

Dexcom Share is a feature within the G6 app that allows for remote monitoring. Parents will be encouraged to watch your child's blood glucose values with the use of the Dexcom Share App for the duration of the study.

If currently using the Dexcom G6, the study team may download your CGM values that are up to 30 days before the start of the study.

Dexcom CGM Run-In Period
(Day 2-16)
If you are a no-G6 user, you will wear a study CGM at home for about 14 days.

If you are a G6 user, your personal CGM values may be used in place of this run-in period.

Activity Tracker
You will be supplied an activity tracker (e.g. Fitbit) to wear during the entire study. The tracker will record your activity level and heart rate.

You will be provided study contact information. You are welcome to call the study team with any questions or concerns that you may have at any time.

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

(Day 17)
You will be contacted by the study team approximately 48-72 hours prior to the hotel admission to:

- You will have a COVID 19 test within 72 hours of the admission. This test must be negative for you to participate in the study. This test must be a nasal swab PCR test. You may do this at UVa or a place of your choice in your community.
- Inquire about any changes to about your health (e.g. illness, changes in medications, etc…)

- Study team will verify that they have access to the CGM data collected during the 14 day at home use
- Verify that a new CGM sensor was placed approximately 24-72 hours prior to the admission for proper warm up
- Verify that the goal CGM reading is less than 200 mg/dL at time of arrival to the hotel
- Remind you to bring your insulin and the study supplies provided at the Study Equipment Training Session
- You will be reminded to bring quiet activities for yourself to enjoy during the hotel 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: Hotel Study Admission (will last up to 64 hours)

(Day 18-21)

- You will have a second COVID 19 test after arriving for the study. You will stay quarantined in your hotel room until this test comes back negative. This must be negative for you to continue in the study.
- 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.
- Your parents will drop you off at the hotel and pick you up at the end of the hotel admission.

Randomization

You will be randomly assigned (like the flip of a coin) to using the RocketAP system or the Control-IQ system during your first hotel admission. You will use the other system during your second hotel admission. You have an equal chance of being assigned to these groups. Neither you nor your study doctor can choose which group you are assigned. You and the study team will know which artificial pancreas system you are using during the admission.

Group 1: RocketAP

Group 2: Control-IQ

You will test each artificial pancreas system under two conditions during each hotel admission:

1. One dinner will have the meal "*announced*" meaning the number of carbohydrates in your dinner is entered into the insulin pump.

2. One dinner will have the meal "*unannounced*" meaning the number of carbohydrates in your dinner is not entered into the insulin pump.

At the Hotel Admission:

- You will come to a hotel for the hotel admission. This admission will last up to 64 hours**;** your parents will not stay at the hotel with you.
- The study team will confirm that you brought your insulin, insulin pump supplies, and regular medications to the hotel admission.
- The insulin pump's infusion set will be inserted on your abdomen.
- Your CGM value and your ketone value will be tested by the study team. The study physician may provide treatment if these values are too high or too low.
- You can participate in low-intensity activities like walking during the admission. You may also participate in group activities with the other study participants.
- You will be provided dinner between 6-7 pm.
- You will go to bed no later than 11 pm. Staff will wake you around 7-8 am. Breakfast will occur between 8-9 AM.
- At least two study team members (i.e. licensed medical physicians, nurses, technicians, etc…) will be present during the entire hotel admission.

Hotel Admission Study Timeline (*estimated*)

	Day 1	Day 2	Day 3	Day 4
7:00 – 8:00 am		Breakfast	Breakfast	Breakfast / Discharge
9:00 – 11:00 am		Group Activities	Group Activities	
10:00 am		Snack (Optional)	Snack (Optional)	
12:00 pm		Lunch	Lunch	
12:30 – 1:30 pm		Quiet activities	Quiet activities	
1:30 – 5:00 pm		Group Activities	Group Activities	
3:00 pm	Arrival			
3:00 – 5:00 pm	Check in			
5:00 – 6:00 pm	Quiet activities	Quiet activities	Quiet activities	
6:00 – 7:00 pm	Dinner	Dinner	Dinner	
7:00 – 7:00 am	Quiet activities	Quiet activities	Quiet activities	

**Group activities will not take place until all COVID test have been received and are confirmed to be negative.*

After the Hotel Admission:

- 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 hotel 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 24-48 hours after discharge from the hotel admission.

Questionnaire

- After the hotel admissions, you will be asked to fill out a questionnaire asking you how you liked the study equipment. This questionnaire will take about 5 minutes to complete.

Visit 5: Post-Admission Check In Visit (about 15 minutes)

(Day 22)
The study team will contact you about 24-48 hours after completing the Hotel Study Admission to ask you:

- How you are feeling
- If you have had any blood glucose values less than 60 mg/dL and more than 300 mg/dL
- Discuss insulin parameters

Visit 6: Pre-Admission Check In Visit (if more than 10 days since first admission)

(Day 23)
Same as Visit 3.

Visit 7: Hotel Study Admission (will last up to 64 hours)

(Day 24-27)
This visit will be the same as visit 4 except you will use the other study equipment. If you used the RocketAP system at your first hotel admission, you will use the Control-IQ system during this admission. If you used the Control-IQ system during your first hotel admission, you will use the RocketAP system at this hotel admission.

Additional precautions for COVID 19 are described in the section titled “Risk of COVID 19”.

Visit 8: Post-Admission Check In Visit (about 15 minutes)

(Day 28)
Same as Visit 5.
You will be asked to contact the study team if you have a Covid positive test within 14 days of discharge from the hotel.

Study Schedule

	Screening	Study Equipment Training	Pre-Admission Check-In	Study Admission #1	Post-Admission Check-In	Pre-Admission Check-In	Study Admission #2	Post-Admission Check-In
Location	**Clinic Remote**	**Clinic / Remote**	**Phone/ Email/Text**	**Hotel**	**Phone/ Email/Text**	**Phone/ Email/Text**	**Hotel**	**Phone/ Email/Text**
Visit	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Study Day	**1**	**2-16**	**17**	**18-21**	**22**	**23**	**24-27**	**28**
Informed Consent	X							
Eligibility Assessment	X							
Medical History	X							
HbA1c	X							
Pregnancy test (if applicable)	X	X		X			X	
Physical Exam	X							
Vital Signs (height/weight)	X							
Randomization				X				
CGM Run-In		14 days if needed						
COVID Testing			**X**	**X**				
New CGM Placement			X			X		
Study Dinner Sessions				Day 19 & 20			Day 25 & 26	
Survey / Questionnaires	X			Post			Post	
Review diabetes management and AEs			X	X	X	X	X	X

What are your responsibilities in the study?

You have certain responsibilities to help ensure your safety. These responsibilities are listed below:

- You and, if applicable, your parent/legal guardian need to attend each study visits as instructed by the study team. Parents will not stay for the hotel admissions.
- You must be completely truthful about your health history.

- Follow all instructions given.
- You 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.
- 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.

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

During the study, you are having an investigational procedure done. The purpose of the testing is NOT to diagnose any disease or abnormality you may have. Because the testing is investigational there is no way for the study leader to understand if the results are "normal" or "abnormal".

However, if any test results are concerning, the study leader will let you know. In addition, as the research moves forward, the study leader will keep you informed of any new findings about the research itself 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 may ask for more information about the study results.

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.

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

Insulin pump, continuous glucose monitor, 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.

Risk of COVID 19

If you are part of this study, you might have a higher chance of getting COVID 19. The study team has taken the actions below to make this risk smaller.

- You will have a COVID 19 test within 72 hours of the admission. This test must be negative for you to participate in the study.
- You will have a second COVID 19 test after arriving for the study. You will stay quarantined in your hotel room until this test comes back negative. This must be negative for you to continue in the study.
- Any participant or study staff member that might have been exposed to COVID within the 14 days before the study start day, or has symptoms of COVID within the 14 days before the study start day will not be allowed to participate or attend.
- You will have to agree to stay quarantined* for at least five days prior to the first COVID test and in between this test and arriving at the hotel.
- The study team will reserve a whole floor of the hotel 24 hours before your arrival. Only study staff and study participants will be allowed to be on this floor. (Hotel staff will only be allowed on the floor if there is an emergency).
- The hotel staff will clean these rooms before the study team arrives, and the study team will wipe down these rooms with disinfectant before you arrive.
- You and the study team will avoid the lobby of the hotel. Instead, you will use the back stairwell when no one else is in it.
- You will be assigned to a private hotel room. You may share a room with a sibling or housemate that you are currently living with.
- Food will be delivered to the floor by hotel staff. They will drop it off at the door of the elevator or stair well without coming onto the floor. Additional food will be dropped off by study staff that are not part of the group staying on the hotel floor. They will drop off the food like the hotel staff will.
- Study staff will have a COVID test within 72 hours of the admission. This test must be negative for them to attend the admission.
- Study staff will have a second COVID test after arriving for the study. This must be negative for them to continue working in the study.
- This study will have up to 20 participants, and 7 or more study staff (Research Coordinators, Doctors, Technicians, Nurses, etc).
- The study team will limit the amount of people that will be coming and going from the place of admission.
- There will be no group activities until all COVID tests taken when you arrive at the hotel come back negative.
- Group activities will require you and everyone else in the study to wear a mask and stay at least 6 feet apart at all times.

- Group activities will involve the following precautions:
    - Study personnel will be positioned within the group to supervise that participants remain separated by 6 feet at all times.
    - Use of masks will be required by study staff and participants at all times. Participants caught without a mask during any part of the activity will be escorted back to the hotel and will not be able to participate in activities.
    - We will always use the back stairwell (not elevator, not lobby) to exit hotel.
    - We will exit so that participants are always at least 6 feet apart from each other.
    - Walking will be the only form of transportation.
    - Preference for outdoor activities (e.g., walking, kicking soccer ball) will always be sought.
    - We will avoid areas where distancing is not possible.
    - Any indoor activities will be only be in a UVa facility that has been wiped down before use and has space so that there can be at least 6 feet between individuals at all times. Study staff will be there to make sure that you and other participants keep masks on and keep distanced. Entering the group activity space will be through the shortest path inside the building.
- All activities will follow state restrictions on numbers of people together.
- If you, other participants, or study staff develop symptoms of COVID during the study, then that person will no longer participate in the study, and they will get tested for COVID.

"Quarantine" means staying home with no close contact for more than 15 minutes, or contact only with an N95 or equivalent mask, with anyone who might have been exposed to COVID.

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 hotel 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 from Completing Questionnaires:
The questionnaires will not cause any physical or emotional risks. These documents are de-identified, meaning your name is not associated with your answers. Rather, the questionnaires are assigned a study subject number only.

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 may benefit from being in this study by having your blood glucose managed by an artificial pancreas system under supervision by the study team. It can also be beneficial as you may think more about your own diabetes control.

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 you be paid for being in this study?

You will be paid $300.00 by check for finishing this study. You should get your payment about 4 weeks after finishing the study. The compensation payment may be reported to the IRS as income.

- Hotel Admission #1: $150
- Hotel Admission #2: $150

If you do not finish the study, you will be paid for the study visits that you have completed. If the study leader says you cannot continue, you will be paid the full amount for the 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, study equipment and their associated supplies (e.g. insulin pump, CGM supplies, study phone (if provided), etc.…).

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 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 study team will pay for the cost of the hotel and the meals during the study admissions.

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 treatment 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 hotel 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.

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:
Mark DeBoer, MD, MSc
University of Virginia Center for Diabetes Technology (CDT)
Box 400888, Charlottesville, VA 22903
Telephone: 434-924-9833

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 IRB-HSR Number (at the top 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.

Consent from Adult Subject (18-25 y.o.)

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

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

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

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

Assent from Child (15-18 y.o.)

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 (less than 18 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 to Permit Your Child to Participate in this Study

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.

Adult/Parental/ Guardian Signature

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

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

Person Obtaining Signature

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 SIGNATURE (SIGNATURE)	PERSON OBTAINING SIGNATURE (PRINT)	DATE