# 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.

**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 National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The study insulin pump and its associated supplies (infusion sets, cartridges), the study continuous glucose monitor (CGM) and its supplies (sensors, transmitters), activity tracker, and the hotel/rented house (from here on "hotel" will be used for both hotel or a rented house) admission will be purchased with grant funding.

**Note:** You will need to provide your own glucometer, insulin, and blood glucose strips.

## Key Information About This Research Study

| | |
|---|---|
| **Principal Investigator:** | Dr. Sue Brown, MD<br>University of Virginia Center for Diabetes Technology (CDT)<br>Box 400888, Charlottesville, VA 22903<br>Telephone: 434-982-0602 |
| **Sponsor:** | National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) |

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 assess a system developed by the UVA Center for Diabetes Technology. The UVA Model Predictive Control Artificial Pancreas (RocketAP) system recognizes that a person's blood sugar rises, likely due to a meal being eaten and the system then delivers a quick priming dose of insulin to stop the blood sugar level from rising too high. This part of the Rocket AP system is called the **bolus priming system**. This study will test using the Rocket AP system when the bolus priming system is turned on during the day compared to when there is no bolus priming system turned on during the day. An artificial pancreas system delivers insulin automatically based on a blood glucose level that is provided from a continuous glucose monitor (CGM). The RocketAP system is a combination of an insulin pump, a CGM, and the RocketAP software.

High blood sugars may occur when carbohydrate amount has not been entered into the insulin pump when using

the investigational AP system. There is also a chance that there could be low blood sugars if the AP systems deliver more insulin than is needed such as if the systems were to deliver insulin for a meal when a meal was not actually eaten. This study requires one 96-hour hotel admission. We will be following you closely throughout the hotel admission to monitor for either of these possibilities and provide whatever treatment is needed.

The UVA Model Predictive Control Artificial Pancreas (RocketAP system) 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, it has been tested on 35 human 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.

**Conflict of Interest**
When a person or an organization has a financial or other interest large enough to seem as if it could affect their judgment, it is called a conflict of interest.

As the owner of the patent of UVA Model Predictive Control Artificial Pancreas (RocketAP system) the University of Virginia may make money if this study has good results.

You are being asked to take part in this study because you are between the ages of 18-65 years old and 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 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:

- This study is using the RocketAP system that is not approved by the FDA.
- The study requires approximately 96-hour hotel admission with other study participants.
- You will need to use study equipment (study insulin pump, study CGM, study activity tracker) during the hotel admission.
- You will be asked to complete a survey.
- You may not use tobacco or alcohol during the hotel study.
- If you take part in this study, you must be willing to wear the Rocket AP system during the course of your study participation. It may mean changing your fast acting insulin to Humalog or Novolog which are the only 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.
- You may not use tobacco or alcohol during the hotel study.

**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

is performed in person, but a video visit can be substituted.
- You will have breakfast, lunch, and dinner each day of the hotel admission at times determined by the study team.
- You will have dinner that has a high carbohydrate and high fat content such as pizza.
- You will have a breakfast that is a fast-acting carbohydrate such as orange juice or apple juice.
- You will follow Center for Disease Control (CDC) and local COVID-19 guidelines in effect at the time of the study.
- You will be trained on general use of the Rocket AP system, and the study activity tracker.
- You will participate in low- and high-intensity exercise during the hotel admission.
- You will need to give a finger stick blood sample to measure your Hemoglobin A1c.

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

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

**How many people will take part in this study?**
Up to 6 people will sign consent for the Pilot Study. Up to 30 people will sign consent for the Main Study.

# How long will this study take?
Your participation in this study will require 5 study visits over 8 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 hour.
- Visit 3 and 5 are phone calls with you and the study team which will last about 15 minutes.
- Visit 4 is a hotel admission that will take up to 96 hours to complete.

# 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) 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 Visit (will last about 1-2 hours)
**(Day 1/ Clinical Research Unit (CRU) Visit)**

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 you are eligible, and it is safe for you 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 endocrinologist or another physician dated within the last 9 months may be substituted.
- 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. A Hemoglobin A1c value that was obtained within the last two weeks may be substituted for this test.
- You will have an electrocardiogram to evaluate the electrical activity of your heart.
- A pregnancy test for all females of childbearing potential that must be negative to participate in this study. This will either be a urine or blood pregnancy test.
- You will be asked to complete Demographic Data Survey (gender, race, ethnicity, where you live, your education level, household income, health insurance status, monthly insulin costs) as required by the study. You will complete electronically this survey with the use of your personal tablet/phone, or phone provided by the study if required onto a secure study website.
- Up to 6 months of historical data from your personal insulin pump, glucometer, or continuous glucose monitor may be downloaded or recorded. Data will be obtained from your personal insulin pump and CGM. This data may be obtained through the commercial applications (e.g. t:connect and Dexcom G6).

If these tests show you are eligible, you will return to the clinic (within 30 days) to begin study procedures. Visit 1 and Visit 2 may be completed on the same day. The pregnancy test will not be repeated if visit 1 and visit 2 are the same day.

## Visit 2: Study Equipment Training (about 1 hour)

**(Day 2/Remote or CRU Visit)**

This training is to introduce you to the CGM and activity tracker. This training may be completed via video conferencing, with supplies sent to you in advance of the call.

### Continuous Glucose Monitor (CGM) Training

You will receive training on the use of the study CGM if you are not familiar with the CGM. The study team may have you watch the Dexcom training video (https://www.dexcom.com/training-videos).

You will stop using your personal CGM when they start the study sensor.

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

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

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.

Dexcom Share is a feature within the G6 app that allows for remote monitoring. You can continue to share your blood glucose values with your family or friends with the use of the Dexcom Share App when you are not at the hotel. The Share app will not function on study equipment during the hotel admission.

**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 at Hotel (about 15 minutes)

**(Day 3/Telephone call)**

You will be contacted by the study team approximately 48-72 hours prior to the hotel admission by phone to verify the following:

- You will have a COVID-19 test within the first 24 hours of the hotel admission or up to 72 hours before the hotel admission. This test must be negative for you to participate in the study. This test must be a FDA authorized test. You may do this at UVA or a place of your choice in your community.
- Inquire about any changes to your health (e.g. illness, changes in medications)
- Verify that a study CGM sensor was placed approximately 24-72 hours prior to the study admission for proper warm up.
- Remind you that the CGM reading should be less than 200 mg/dL at the start of the study at 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 96 hours)

**(Day 4-8/Hotel)**

### Randomization

You will be randomly assigned (like the flip of a coin) to determine the order of the system approach during your hotel admission. There are two approaches to be used for different 24-hour periods during the study (one that uses a bolus priming system to give additional insulin and one that does not use a bolus priming system).You will not be entering carbohydrate information into the pump once the study system is started. You and the study team will know which artificial pancreas system approach you are using during the admission.

*Hotel Admission Arrival (Day 0):*

- You will come to a hotel for the hotel admission. This admission will last up to approximately 96 hours**.**
- The study team will confirm that you brought your insulin, insulin pump supplies, and regular medications to the hotel admission.
- A repeat urine pregnancy test will be performed, if applicable, before starting the study research pump. This pregnancy test must be negative for you to participate.
- You will change your CGM sensor if your current sensor was inserted more than 24-72hours before your arrival.
- The study team will provide dinner.

*Hotel Admission:*

- Your home insulin pump will be discontinued, and the study research insulin pump will be set and inserted on your abdomen.
- You may be asked to use a Tandem infusion set. This infusion set will be replaced with a new infusion set in two days.
- 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. This treatment may include asking you to drink fluids, walk, etc. to reduce your ketones prior to the start of the study.
- You will have breakfast, lunch, and dinner.
- You will eat meals at the times designated by the study team.
- You will eat the same breakfast, lunch, and dinner for two of the days of the hotel admission.
- Carbohydrates consumed at breakfast on one day will be a fast-acting carbohydrate such as orange juice or apple juice.
- You will eat one dinner with high carbohydrate and high fat such as a pizza.
- You will continue to use the activity tracker throughout the study admission.
- You will participate in a high-intensity exercise activity (e.g. exercise bike, treadmill, etc.) during the study. This exercise is meant to raise your heart rate.
- 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 go to bed no later than 11 pm.
- 
- You will eat meals at the times designated by the study team.
- At least two study team members (e.g. technicians, nurse, physician, nurse practitioner, physician assistant, ) will be present during the entire hotel admission.
- Any adjustments to your current insulin parameters during the hotel study admission will be done with the assistance of the study physician or physician's assistant.

*Hotel Discharge:*

- Your CGM value will need to be stable and between 80-300 mg/dL with ketone levels less than or equal to 0.6 mmol/L.
- You will return the study equipment (e.g., study insulin pump, study CGM, study activity tracker).
- You will return to using your personal insulin pump.
- You will be asked to monitor your ketone levels for up to 24-48 hours after discharge from the hotel admission if ketones were elevated at time of discharge. Urine ketone strips may be provided to you if needed.

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

**(Day 9/Phone, Text, or Email)**

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

You can talk with the study physician or physician's assistant if you have questions related to adjusting back to your usual insulin parameters.

**IMPORTANT:**
You will be asked to contact the study team if you have a positive COVID-19 test within 14 days of discharge from the hotel.

**END OF STUDY PARTICIPATION:**
At the conclusion of the Post-Admission Check-In Visit, your participation in the study is complete.

## Study Schedule

| | Screening | Study Equipment Training | Pre-Admission Check-In | Study Admission | Post-Admission Check-In |
|---|---|---|---|---|---|
| **Location** | **Clinic/** | **Clinic/ Remote** | **Phone/ Email/Text** | **Hotel/Rental House** | **Phone/ Email/Text** |
| **Visit** | **1** | **2** | **3** | **4** | **5** |
| **Day** | **1** | **2** | **3** | **4-8** | **9** |
| **Informed Consent** | **X** | | | | |
| **Eligibility Assessment** | **X** | | | | |
| **Medical History** | **X** | | | | |
| **HbA1c** | **X** | | | | |
| **Pregnancy test (if applicable) – Blood or Urine** | **X** | **X** | | **X** | |
| **Physical Exam** | **X** | | | | |
| **Vital Signs (height/weight)** | **X** | | | **X** | |
| **Electrocardiogram** | **X** | | | | |
| **COVID-19 Testing** | | | **X** | | |
| **CGM Use** | | | | **X** | |
| **Survey** | **X** | | | | |
| **Review diabetes management and review health related problems** | | | | **X** | **X** |

## What are your responsibilities in the study?

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

- You must attend each study visit.
- You must be completely truthful about your health history.
- Follow all instructions given.
- You will follow COVID-19 protocols in place at the time of study. This may or may not include wearing a mask when you are in common areas of the hotel or when you are in close proximity of other people.
- You should tell the study doctor or study staff about any changes in your health or the way you feel.
- You should report any issues with the study equipment.
- Answer all 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 team will let you know if you can take these medications.

## Blood Testing

If the study physician requests that you obtain screening laboratory tests, 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. If a female of child-bearing potential and having a blood serum pregnancy test done instead of a urine pregnancy test, you will have an additional ½ teaspoon of blood taken per blood serum pregnancy test.

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 high blood sugars (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. One of the ways this could happen is if the system delivers too much insulin when a meal was not eaten but the system detected what looked like a meal based on the CGM increasing.
- 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 (i.e. rash, itching, mild pain, etc.) 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)
- 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 Study-Related Exercise Activities:**

**Likely**

- Risk of musculoskeletal (i.e. bones, cartilage, ligaments, tendons, connective tissues) symptoms or injuries

**Less Likely**

- Risk of injury including a heart problems (i.e. dizziness, lightheaded, irregular heartbeat, or chest pains)
- Risks of injury including blood vessel problems (lightheaded, passing out, fainting)

**Risks associated with Transportation to Study-Related Activities:**

**Rare**

- Risk of harm from a motor vehicle accident

**Risks associated with staying at the hotel for research purposes:**

**Likely**

- Loss of privacy
- Disruption of daily routine similar to staying at a bed and breakfast

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

Insulin pump, continuous glucose monitor, and ketone meter are '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 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 will follow Centers for Disease Control and Prevention (CDC) COVID-19 guidelines that are in effect at the time of your admission to make this risk smaller.

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

**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 a Survey:**
The survey should not cause any physical risks. These documents are de-identified, meaning your name is not associated with your answers. Rather, the survey is assigned a study subject number only. Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

**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 (23 days), 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 might like to take part in this study because this study may improve your understanding of 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.

# 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 personal health care team

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 up to $500.00 by check for finishing this study. You should get your payment about 6 weeks after your participation in the study is complete. The compensation payment may be reported to the IRS as income.

- Travel Stipend: $200 (unless the study team organizes your airfare or rail ticket)
- Completion of the Hotel Admission: $300.00

If you do not finish the study, you will not be paid.
If the study leader says you cannot continue, you will be paid the full amount for the study.

Payment for study visits completed will be provided after all study equipment has been returned to the study team. The study will provide you with the following to use during the study: Study equipment and their associated supplies (e.g. insulin pumps, CGM supplies, remaining study supplies, etc.)

You will receive a travel stipend of $200 for your travel expenses unless the study team organizes your airfare or rail ticket. In this event, the study team will purchase up to $600 per roundtrip ticket on your behalf. First class tickets are not permitted. The study team will not require copies of your travel receipts.

## 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 test, study equipment and their associated supplies (e.g. insulin pump, CGM supplies,). 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 your insulin that is used during the study. As previously noted, using the Dexcom App 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.

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

## 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 mind about being in the study any time. You can agree to be in the study now and change your mind 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 mind, the study leader can take you out of the study. Some of the reasons for doing so may include

a) Your 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) You do not follow your doctor's instructions
e) 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 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 exercise 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 may 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.

Your information, collected for this study, will be protected by a Certificate of Confidentiality from the federal government. If UVA receives a subpoena or court order demanding information from the study records that would identify you, we will use the Certificate to resist the demand. However, UVA will not use it in the following cases.

- You have agreed in writing to allow UVa to share the information with your employer, your insurance company for billing purposes, or someone else
- Reports to authorities where there is a danger that you may harm yourself or others, or if there is evidence of probable child or elder abuse or neglect.
- Reports to authorities if you have an infectious disease that health care providers are required to report by law.

In addition, the Certificate does not prevent government authorities who oversee research from reviewing this study. This Certificate does not mean that the government either approves or disapproves of this study. It just helps protect your privacy.

# 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:**
Sue Brown, MD
University of Virginia Center for Diabetes Technology (CDT)
Box 400888, Charlottesville, VA 22903
Telephone: 434-982-0602

# 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.

# 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.

# 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**

| _____ | _____ | _____ |
|---|---|---|
| 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 |

# 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

*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 the study team:

- Obtaining information from my medical records
- Phone call
- In person follow up visit if requested by the study physician

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

**Consent From Adult**

| _____ | _____ | _____ |
|---|---|---|
| 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 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 |