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) and the University of Virginia's Strategic Investment Fund (SIF). The study insulin pump and its associated supplies (infusion sets, cartridges), the study continuous glucose monitors (CGMs) and its supplies (sensors, transmitters), activity tracker, and the hotel/rented house (from here on "hotel" will be used for both hotel or rented house) admission will be purchased with grant funding.

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.

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 University of Virginia Center for Diabetes Technology (CDT) Box 400888, Charlottesville, VA 22903 Telephone: 434-982-0602
Sponsor:	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) & 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 assess how the UVA Model Predictive Control Artificial Pancreas (RocketAP) system, that the UVA Center for Diabetes Technology has developed, works when carbohydrate information at a meal is entered into the insulin pump and when it is not entered into the insulin pump. 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. This study requires one 76-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 not been used with 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.

You are being asked to take part in this study because you are between the ages of 18-70 years old. and have been diagnosed with type 1 diabetes mellitus.

Up to 36 subjects will take part in this Main Study.

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:

- This study is using the RocketAP system that is not approved by the FDA
- The study requires approximately 92-hour hotel admission with other study participants.
- You will need to use the RocketAP system and study activity tracker) during the hotel admission.
- You must wear the RocketAP system during the study. It may mean changing your fast acting insulin to Humalog or Novolog which are the only insulins that are used in the insulin pump. 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, telephone or video.
- You will be instructed to eat breakfast and dinner at approximately the same time for 4-5 days per week during this data collection phase. You will follow this same mealtime schedule during the hotel admission.

- You will eat the same breakfast, lunch, and dinner each day of the hotel admission.
- You will follow Center for Disease Control (CDC) and local COVID-19 guidelines in effect at the time of the study.
- You will be asked to provide proof of your COVID-19 vaccine, if available.
- You will be trained on how to use the RocketAP system, study CGM (if necessary), and the study activity tracker.
- 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 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 certain amount of carbohydrates during the dinner meals that we provide during the study admission. This meal may be more or less food than what you eat normally at dinner.

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 long will this study take?

Your participation in this study will require 5 study visits over 51 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 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 about 92 hours to complete.

What will happen if you are in the study?

Some of the study will be done by telephone, remote visits (i.e. a computer video connection) and some will be in person. Please note that any in-person parts of the study will require standard precautions as outlined by the CDC and local guidelines against COVID-19, that may include wearing a mask, washing hands, and maintaining social distancing of 6 feet when possible.

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/Remote or 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 18 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.
- A pregnancy test for all females of childbearing potential that must be negative in order to participate in this study. This will either be a urine or blood pregnancy test.
- You will be asked to complete Demographic Data Survey (date of birth, gender, race, ethnicity, where you live, your education level, etc.) as required by the study. You will complete electronically this survey with the use of your personal tablet or phone onto a secure study website.

If these tests show you are eligible, you will return to the clinic (within 60 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 (will last 1-2 hours)

(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 the participant in advance of the call.

This study visit will be followed by 4 weeks of CGM and pump data collection at your home/usual routine. You will be asked to have breakfast and dinner at approximately the same time at least 4-5 times per week during this period.

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 "Opt out" and 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 during the

outpatient data collection period. The Share app will not function on study equipment during the hotel admission.

If currently using the Dexcom G6 CGM, 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/Home)
If you do not currently use a Dexcom G6 CGM, you will wear a study CGM at home for about 14 days.

If you currently use a Dexcom G6 CGM, your personal CGM values may be used in place of this run-in period. The study physician may ask you to complete this run-in phase if there are questions about your CGM data.

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.

Data Collection Phase

(Day 18-46/Home)
You will wear a study CGM at home for approximately 28 days. You will be instructed to eat breakfast and dinner at approximately the same time for 4-5 days per week during this data collection phase. The timing of the breakfast will be requested to be at or before 8 am and the timing of the dinner will be requested to be between 6-8 pm. If currently using a Dexcom G6 CGM, up to 30 days of data may be obtained from your personal CGM and pump. If there is consistent timing of meals in the 30 days before enrollment, these data may be used instead, and a Data Collection Phase may not be required.

Any adjustments to your current insulin parameters during the data collection period will be done with the assistance of the study physician.

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

(Day 45/Telephone Call)
You will be contacted by the study team approximately 24-72 hours prior to the hotel admission by phone to verify the following:

- If you are not vaccinated, 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 an FDA authorized COVID-19 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,)
- Study team will verify that they have access to the CGM data collected during the 14 day at home use
- 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 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 92 hours)

(Day 47-51/Hotel)

- If you are not vaccinated, you will have a second COVID-19 test after arriving for the study.
- A urine pregnancy test that must be negative in order to continue to participate in this study.

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 three approaches to be used for three 24-hour periods during the study (two of these approaches involve not entering carbohydrate information into the pump and one that does). You will use all three approaches during your hotel admission. 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 92 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 48 hours before your arrival.
- The study team will provide dinner.

Hotel Admission (Day 1):

- 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 TruSteel 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 continue to use the activity tracker during the Hotel Study.
- 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 have breakfast, lunch, and dinner. One of those three meals will occur later than when you usually eat that meal.

- You will go to bed no later than 11 pm.
- You will follow the same breakfast mealtime schedule during the hotel admission as you did at home.
- At least two study team members (i.e. licensed medical physicians, nurses, technicians) 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.

After the Hotel Admission:

- 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 present 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 52/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 if you have questions related to adjusting back to your usual insulin parameters.

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	CGM Run-In Phase	Data Collection t	Pre-Admission Check-In	Study Admission	Post-Admission Check-In
Location	Clinic/ Remote	Clinic/ Remote	Home	Home	Phone/ Email/Text	Hotel/Rental House	Phone/ Email/Text
Visit	1	2	x	x	3	4	5
Day	1	2	2-17	18-46	45	47-51	52
Informed Consent	X						
Eligibility Assessment	X						
Medical History	X						
HbA1c	X						
Pregnancy test (if applicable)	X (Blood or Urine)	X (Blood or Urine)				X (Urine)	
Physical Exam	X						
Vital Signs (height/weight)	X					X	
Demographic Survey	X						
Randomization						X	
COVID-19 Testing if not vaccinated					X	X	
CGM Use			~14 days if needed	X		X	
Survey	X						
Review diabetes management and review health related problems			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 must attend each study visit.
- 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.
- You should report any issues with the study equipment.
- 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.

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. 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.
- 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 (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)

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 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 or emotional risks. These documents are de-identified, meaning your name is not associated with your answers. Rather, the survey are 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 (51 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 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 $450.00 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: $150 (unless the study team organizes your airfare or rail ticket)
- Data collection phase: $100.00
- Hotel Admission: $200.00

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.

You will receive a travel stipend of $150 for your travel expenses unless the study team organizes your airfare or rail ticket. In this event, the study team will purchase up to $1,000 per roundtrip ticket on your behalf. First class tickets are not permitted. The study team will not require copies of your travel receipts. The travel stipend of $150 for travel expense will be provided about 6 weeks after completing 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, pregnancy test, study equipment and their associated supplies (e.g. insulin pump, CGM supplies, study phone (if provided)).

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, 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.

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 disease 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 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 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.

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