Medical Record #:_____

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 _____

Principal Investigator: Marc D. Breton, PhD
UVA Center for Diabetes Technology
Box 400888, Charlottesville, VA 22903
Telephone: (434) 982-6483

Sponsor: National Institutes of Health (NIH)

What is the purpose of this form?

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?

For people with Type 1 Diabetes, controlling blood sugar is extremely important and can be difficult – particularly when exercising. This study is trying to find out if a new artificial pancreas (AP) system can stop high or low blood sugars from happening during and after exercise. An AP is an algorithm (mathematical formula) that takes information from certain sources (such as a continuous glucose monitor or activity tracker) and decides how much insulin to tell the insulin pump to give you.

You are being asked to take part in this study because you are between 18 and 65 years old, have Type 1 Diabetes, and currently use an insulin pump.

Why would you want to take part in this study?

You might like to take part in this study because you may have better blood sugar control while using the study device. Your participation may also help gather information that may help others in the future.

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

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

Medical Record #:_____

- You may have worse control of your blood sugars during this study
- You will be required to maintain a certain exercise regimen during a portion of the study.
- You will be required to stay at a hotel at two different times for about 36 hours each.

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:

- Wear a study activity tracker (Fitbit, Sony Smartband)
- Wear a study continuous glucose monitor (CGM)
- Perform regular exercise as outlined in this consent
- Record your carbohydrates and use the bolus calculator of your insulin pump
- Wear your personal insulin pump during the data collection phase
- Use the study artificial pancreas systems during the exercise admissions

The visit times vary and are outlined later in this form.

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. All procedures performed in this study are for research purposes.

- You will be asked to come to UVA for Screening and Training. Each visit will last about 1-3 hours.
- You will be asked to wear study equipment and to exercise regularly during a data collection phase. You will manage your blood sugars as you normally would during this time.
- You will come to two exercise admissions at a local hotel where you will wear study equipment and perform an exercise activity. During this time, the artificial pancreas system will manage your blood sugars.

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

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

- You may continue your current diabetes care plan or you may discuss with your personal physician any other alternatives that are available.

Who is funding this study?

This study is being funded by a grant from the National Institutes of Health (NIH).

Medical Record #:_____

Why is this research being done?

The AP being tested in this study, has the ability to anticipate and detect when you are going to exercise or are actively exercising. It uses information gathered from the continuous glucose monitor (CGM) and activity tracker with the goal of changing how much insulin you are getting depending on if you are exercising or not.

This is a study about the EnMPC artificial pancreas system, which is an experimental device that has not been proven to be safe or helpful. The EnMPC system consists of the AP software, CGM, activity tracker, and Tandem t:AP insulin pump.

- The EnMPC AP software is not approved by the FDA (Food and Drug Administration) to manage blood sugar.
- The CGM used in this study is approved by the FDA to measure your blood sugar.
- The activity tracker used in this study is a commercially available activity tracker (i.e. Fitbit, Sony Smartband).
- The t:AP insulin pump is not approved by the FDA to administer insulin.

So far, the device has not been tested in people but simulation testing has been completed on virtual patients in computer models that the FDA has found can replace pre-clinical testing.

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

How long will this study take?

Your participation in this study will require 6 study visits over up to 4 months. Each visit is outlined in detail in the next section.

What will happen if you are in the study?

*****Please note that all procedures are performed for research purposes only*****

SCREENING (visit will last about 2-3 hours)

Visit 1 (Day 1)

If you agree to participate, 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:

- Collection of information about you: contact information, your diabetes history, past and current medical conditions, surgical procedures, menstrual history (females), allergies, medications and supplements, social history (including drinking, smoking and drug habits), and whether or not you have various symptoms
- Your pump settings and average daily insulin use over the past seven days

Medical Record #:_____

- Physical exam (including height, weight, and vital signs)
- Electrocardiogram (ECG) to see how well your heart is working
- HbA1c to test for your average blood sugar over the last 3 months
- Current exercise patterns
- A urine or blood pregnancy test if you are a woman who can become pregnant. The pregnancy test must be negative in order for you to participate and will be repeated at each follow-up clinic visit during the study.

The study physician may request laboratory values if your study doctor has any concerns about medical conditions that might affect your participation in the study. Blood testing (results collected within the last 52 weeks may also be acceptable); laboratory testing may be completed at LabCorp after signing the consent form. These laboratory test may include:

- Comprehensive Chemistry Panel: to see how well your kidneys and liver are working and to check for salts and sugars
- Thyroid studies: to see how well your thyroid is working
- The amount of blood taken for these test is about 2 tablespoons
- Additional blood tests may be requested

If these tests show you are eligible, you may participate in Visit 2 to begin study procedures. This visit may begin on the same day as your Screening visit.

STUDY EQUIPMENT TRAINING (will take approximately 1-3 hours to complete depending on your knowledge of the equipment)

Visit 2 (Day 2)

You will be trained on the use of the study equipment and instructed on how to download the equipment. These devices require accounts to be created with the device company. We will create an anonymous account for you with these companies to protect your identity.

- Continuous Glucose Monitor (CGM)
  - You will receive a study CGM to use each day during the study.
  - If you are not familiar with the study CGM, you will be trained on how to use it during the study. You will be trained on how to insert the CGM sensor into your abdomen.
  - You will receive study CGM supplies.
  - You may continue to wear your personal CGM along with the study CGM during the study as long as the study team is able to download their personal equipment.
- Activity Tracker
  - You will wear an activity tracker on your wrist during the entire study. **Since this is an exercise-driven study, wearing the activity tracker at all times is extremely important.**

- You may remove the activity tracker before bathing.

- Smartphone
  - In order for us to get the data from the CGM and activity tracker, the devices need to download to a smartphone app.
  - During the Data Collection Phase, you may choose to use your personal smartphone and download the apps. If you do not want to use your own smartphone, the study can provide you one to use for the study.

If an insulin therapy change is recommended or required, it will have to be approved by the study medical doctor. If a change happens, you may be asked to extend the data collection period.

You can call or visit the study team and study medical doctor as needed. You will be given the telephone numbers of the study team.

DATA COLLECTION PHASE (about 28 days)

Day 2 to approximately Day 29

After training is complete and you are wearing the devices, you will continue to wear them at home for about 28 days. You will be asked to download equipment and provide the data to the study team approximately every 7 days. The study team will review this data to check that the data is being collected correctly. You may be asked to do more frequent downloads or to extend this collection phase if the data quality is inadequate.

At-Home Exercise Regimen

During the data collection period, you will need to perform a consistent exercise regimen:

- Moderate exercise activity (i.e. jogging, biking) at least 4 days per week
- You are required to exercise regularly between the hours of 4 p.m. – 7 p.m.
- Each exercise session should be at least 30 minutes long
- You should maintain a heart rate of about 110-140 beats per minute

Insulin Pump and Carbohydrate Info

During the Data Collection Phase, you will follow your usual regimen for the full 28-day period. You will need to document all of your carbohydrates. **You will be asked to consistently use the bolus calculator (or "wizard") of your insulin pump during this Data Collection Phase.**

Hotel admissions must occur within 90 days of completing your Data Collection Phase.

Medical Record #:_____

RANDOMIZATION

Visit 3

You will participate in two "exercise admissions" that will take place at a local hotel and gymnasium. Because we are testing two AP systems, one of the admissions will use the Control AP system (that does not anticipate exercise) and the other admission will use the Experimental AP system (that does anticipate exercise). The order of how they happen will depend on how you are randomized in the study.

You will be randomly assigned (like the flip of a coin) to 1 of 2 study groups. You have an equal chance of being assigned to any one of the groups. Neither you nor your doctor can choose which treatment you are assigned.

GROUP 1: Control Exercise Admission First, then Experimental Exercise Admission (EnMPC)

GROUP 2: Experimental Exercise Admission First (EnMPC), then Control Exercise Admission

PRE-ADMISSION CHECK-IN (about 15 minutes)

Visit 4

We will call you about 1 week before the first admission to:

- Ask about changes to your health
- Ask if you have experienced any hypoglycemic or hyperglycemic events
- Ask you about your pump profiles
- Remind you to replace the CGM sensor about 2 days before the hotel admission

STUDY HOTEL ADMISSIONS (about 33 hours each admission)

Visit 5 and Visit 7

Exercise Admission Procedures

All procedures during the Control and Experimental Admission are the same except for the AP system that is used during the admission. The two admissions need to be separated by at least 24 hours.

Day 1 (Arrival)

10:00 a.m.-11:00 a.m.

- Check-in at hotel
- Perform vital signs
- Ask about medical changes
- Stop your personal insulin pump
- Start the study insulin pump
- Make sure all study equipment is working properly

11:00 a.m.	Study staff will begin the Artificial Pancreas system
11:00 a.m. – 1:00 p.m.	Low-intensity activities
1:00 p.m.	Lunch
2:00 p.m. – 4:30 p.m.	Quiet activities
5:30 p.m.	Exercise session - Three 15-minute intervals of moderate exercise separated by 5 minutes of rest
7:00 p.m.	Dinner

Day 2

7:00 a.m.	Breakfast
8:00 a.m. – 1:00 p.m.	Low-intensity activities
1:00 p.m.	Lunch
2:00 p.m. – 7 p.m.	Quiet activities
About 7 p.m.	Discharge from hotel

Procedures Related to Discharge

1. At approximately 7:00 PM, you will be discharged if the fingerstick value is 70-300 mg/dL and ketone concentration is ≤ 0.6 mmol/L.
2. You will return the study equipment. If you are coming back for the second admission in a short time, the study team may let you keep some of the equipment until then.
3. You will resume your normal home insulin therapy. You may beginning wearing your personal CGM on the afternoon of Day 2 to allow for the equipment to warm up prior to your discharge. You will continue wearing the study CGM until discharge or until the current sensor expires.
4. You will be offered a dinner or a snack prior to discharge.

POST-ADMISSION CHECK-IN (about 15 minutes)

Visit 6 and 8

Study staff will contact you within 24-48 hours after discharge to see how you are doing and if any new medical events have occurred since discharge. If your second admission is 2 days after your first admission, this communication will be done in-person at the hotel.

END OF STUDY:

After you complete the study procedures, you will return to your standard diabetes care. You will return all study equipment at the end of the study.

Medical Record #:_____

Study Schedule

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8
	Screening	Training & Data Collection	Randomization	Pre-Admit Check-In	Hotel Admission #1	Post-Admit Check-In	Hotel Admission #2	Post-Admit Check-In
Study Day	**1**	**2-29**	**Within 90 Days of End of Visit 2**					**About 2 Days After Visit 7**
Informed Consent	X							
Review study eligibility	X							
Medical History	X							
Hemoglobin A1c	X							
Blood draw (for lab testing if applicable	Optional							
Vital signs	X				X		X	
Physical Exam	X							
Electrocardiogram (ECG)	X							
Pregnancy Test (urine or blood)	X				X		X	
Randomization			X					
Device Data downloads		X		X				
At-Home Exercise Regimen		X						
Review health related problems		X		X	X	X	X	X

Medical Record #:_____

What are your responsibilities in the study?

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

- You must complete 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.
- 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

We will take (or "draw") up to 2 tablespoons of blood during the screening visit. The blood we take at the screening appointment will be tested to measure your diabetes control, your thyroid function, how well your kidneys/liver work, the amount of certain salts and sugars, and to see if you are pregnant (females). No other blood sampling will be completed during the trial.

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/devices) include:

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 possible symptoms of high blood sugars such as thirst and frequent urination. You may have a higher level of sugar in your urine.

Medical Record #:_____

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 kidney failure, cardiac arrhythmia (irregular heartbeat), myocardial infarction (heart attack), rhabdomyolysis (muscle breakdown), and even death.

Continuous Glucose Monitoring Sensor Risk

Likely

- Failure or lack of sensitivity of the CGM that requires replacement/insertion of new sensor
- Fingerstick for calibration of the CGM
- Discomfort from insertion of sensor

Less Likely

- Bruising less than ½ inch
- Bleeding less than ¼ teaspoon
- Sensitivity to adhesives with use of the CGM resulting in skin irritation, redness, blistering, scarring, systemic allergic reaction, or secondary skin infection

Rarely

- Swelling or redness at insertion site
- Psychological reaction to viewing the CGM information or attending to CGM alarms or fingerstick blood glucose values
- Breakage of the CGM 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.

Fingerstick Risks

Likely

- Pain at site of lancet (finger-pricking needle) use
- Bleeding at site of lancet use

Less Likely

- Incorrect information from a false low or false high fingerstick value

Rarely

- Infection at site of lancet use

Wearing a Commercially Available Activity Monitor Risk

Rarely

- Skin irritation or redness

Performing a serum (blood) or urine pregnancy tests (females who are able to become pregnant):

Less Likely

- False positive or false negative results

Study-Related Exercise Activities Risk

Less Likely

- Risk of injury

Transportation to Study-Related Activities Risk

Rare

- Risk of harm from a motor vehicle accident

Risks associated with staying at the hotel for research purposes:

Likely

- Loss of privacy and 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

Risk of Sharing the Continuous Glucose Monitor

The FDA approved the continuous glucose monitor as a 'single use device'. 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. The sensors will not be shared. The transmitter wirelessly sends your glucose information from the sensor to the receiver. The transmitter may be reused between hotel admissions after cleaning per manufacturer or another hospital approved cleaning method.

Medical Record #:_____

Risk of Re-using the Blood Glucose Meter or Ketone Meter

The FDA approved these meters for 'single-patient use'. 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. The glucose or ketone meters may be reused between hotel admissions after cleaning per manufacturer or another hospital approved cleaning method.

Risk of Sharing the Insulin Pump

The FDA typically approves an insulin pump for 'single-patient use'. 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. The insulin pump handheld device may be reused between hotel admissions after cleaning per manufacturer or another hospital approved cleaning method.

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 of 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.

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 are pregnant. You must use an effective method of birth control during the study if you are sexually active. 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. Examples of effective birth control include the following:

- birth control pill
- birth control implant
- intra-uterine device (IUD)
- condom

If you are using a different method of birth control from the above examples, please let the study team know to see if it is okay for you to participate.

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 while being in this study by having better control of your blood sugar during the exercise admissions. In addition, the information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your Type 1 Diabetes. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include:

- Continue your standard diabetes management

However, in order to do this study, we must change the equipment that you use in usual treatment. This includes wearing the study equipment.

- If you are a patient at UVa, your usual care will not be affected if you decide not to participate in this study.
- 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 or classes 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 $500 for finishing this study by check. You should get your payment about 4 weeks after each study visit is completed. The income may be reported to the IRS as income.

If you do not finish the study, you will be paid for the visits that were completed according to this schedule:

- Successful Data Collection Phase: $200
- Hotel Admission #1: $150
- Hotel Admission #2: $150

Medical Record #:_____

If Data Collection is extended due to equipment failure, additional payment of $25 per week will be provided.

If you owe money to any Virginia state agency, the state can use the money you earn in this study to pay those debts. These state agencies include the UVa Medical Center, VCU Medical Center or a college or university. The money may be withheld to pay back debt for such things as unpaid medical bills, taxes, fines, child support. Even if this happens, the money you earn may be reported to the IRS as taxable income.

By agreeing to be in this study, you are donating your blood and bodily fluid samples for research, and giving up any property rights you may have in them. The results of this research using your donated materials may have commercial value. However, you will not receive any payments.

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: blood testing, study visits, pregnancy testing, study equipment, ECG's.

If you decide to use your personal cell phone during the Data Collection Phase, you will be responsible for any cellular charges related to the study.

You and/or your insurance company must pay for any tests or care given beyond what is required in this study. 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.

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?

Medical Record #:_____

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) You do not follow your doctor's instructions
d) The study sponsor closes the study for safety, administrative or other reasons

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?

- 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 device being studied and government agencies that provide oversight such as the Food and Drug Administration (FDA).

Medical Record #:_____

- 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.

Information about you and/or samples from you may be given to other researchers outside of the University of Virginia after all identifiers such as name, address, phone # have been removed.

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 and samples obtained from you during this study will not be used in future research. The study team will not be storing samples collected in this study for future use.

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.

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.

Medical Record #:_____

- 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

Marc Breton, PhD
UVA Center for Diabetes Technology
Box 400888, Charlottesville, VA 22903 Telephone: 434-982-6483

What if you have a concern about this study?

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

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

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the 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.

Signatures

What does your signature mean?

Medical Record #:_____

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.

Medical Record #:_____

Leaving the Study Early

Signatures should be obtained in this section if the subject decides to leave the study early.

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

Check one option below:

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

The follow up information will be collected by:

- Obtaining information from my medical records
- Check-In visit

____ 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