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). Grant funding will be used to purchase study related supplies (e.g. DiAs System, insulin pump cartridges, insulin pump infusion sets, Continuous Glucose Monitor (CGM) supplies, study phone, ketone meter, ketone strips, etc…). You will need to provide your own glucometer, insulin and blood glucose strips.

Key Information About This Research Study

Principal Investigator:	Marc D. Breton, Ph.D. University of Virginia Center for Diabetes Technology (CDT) Box 400888, Charlottesville, VA 22903 Telephone: 434-982-6483
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?

This study is trying to find out if the information from a CGM can help you take better actions to manage your diabetes. This study will use different programs that give you advice in different ways.

This is a research study to test a Decision Support System (DSS) which will give you information about how you manage your diabetes. It will look at how telling you about your diabetes management in different ways affects how you change the way you manage your diabetes. In this study, you will answer questions that are related to the management of your diabetes.

- The advice given can be a suggestion such as '*your basal rate in the afternoon may be low*'; this **intervention is called Informative.**
- The advice given can be a specific number such as '*set your basal rate to 1.5 units per hour from 2PM to 8PM*'; **this intervention is called Prescriptive.**

One goal of this study is to see how different people respond to different ways of providing treatment suggestions.

DSS has not been proven to be safe or helpful. The system is not approved by the U.S. Food and Drug Administration (FDA). So far, this system has not been tested in humans. 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 at least 18 years old and have received the diagnosis of Type 1 Diabetes.

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 or may improve your ability to manage your diabetes. You will not be helped by being in this study, but the information gained by doing this study 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:

- This study is using equipment that is not approved by the FDA
- You will be asked to answer 3-4 questions each day for 10 to 14 days at a time, and will need to answer least 48 questions during each specific phase of the study lasting 2 months each
- Your participation in the study lasts for about 7 months

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:

- Switch your insulin pump to a Tandem research insulin pump if you will use an insulin pump in this study and use a study CGM
- Be trained on study devices, such as an app on the study phone, a continuous glucose monitor, and an insulin pump if you will use an insulin pump in this study
- Be required to complete questionnaires; there may be physical or emotional risks to completing questionnaire.

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

- You do not have to participate in this study. If you decide that you do not want to be in this study, the management of your diabetes at UVA will not be treated differently and your regular care will not be impacted.

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 answer questions each week about yourself and the study devices (Figure 1)
- You will use study devices and technology that will give you information about your diabetes care

You may need to come to UVA for 1-2 visits; the other 5 visits may occur over the phone.

What other treatments may I receive if I decide to not take part in this study?
The following alternative treatments are available to you if you decide not to take part in this study:

- If you do not participate in this study, you will still be able to receive normal care for your diabetes.

Up to 150 people will be in this study at UVA.

How long will this study take?

Your participation in this study will require about 7 study visits over 7 months. The study team may choose to do these visits through the use of telemedicine (e.g. video conferencing) or perform the visits at the Center for Diabetes Technology. Visit 1 may take about 2-3 hours. Visit 2 may take about 4 hours. Visits 3-5 may occur over the phone or you may come to the clinic. These visits may take about 1 hour to complete. Visit 6 and 7 may take about 15-30 minutes to complete.

All procedures are completed for research purposes only.

What will happen if you are in the study?

VISIT 1: Screening, Enrollment & Randomization (visit will last 2-3 hours)

(Day -16 or -29)

Screening

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 that it is safe for you to participate. These tests include:

- 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, etc.)

- A blood test to obtain a hemoglobin A1c, liver, thyroid functioning, white blood count, etc… You may have the blood/urine drawn at a local laboratory (i.e. LabCorp). Lab values dated within 14 days of the screening appointment may be considered to replace this lab test.
- A blood/urine pregnancy test that must be negative in order to participate in this study.

Enrollment (Study Training Session)
If these tests show that you are eligible to participate in the study, you may immediately be placed in the Study Training Session or the visit may be postponed for up to 30 days.

You will be asked to keep a glucagon emergency kit on hand at home. If you need a prescription for the glucagon emergency kit, you can ask your study doctor. You or your insurance will need to pay for this prescription.

You will be asked if you want to use an insulin pump or continue using multiple daily injections (MDI) during the study. You will continue this diabetes therapy throughout the study. If you decide to wear a study insulin pump, you will have an additional run-in of about two weeks to adjust your insulin parameters. The study physician can decide to extend that time if it will be beneficial to you.

You will be asked if you plan on counting carbohydrates before your meals. You will be asked to continue this choice until the end of the study.

You will be asked to answer questionnaires several times during the study. The questionnaires are completed electronically and will take about 5-60 minutes to complete. This variation of time depends on the number of questionnaires that you are asked to complete at that visit. You may complete these questionnaires from your home.

Diary Entries
You will also complete a “Daily Diary” for 2-3 days out of about a 14-day period. This diary will ask for you to complete 3-5 entries on each of the 2-3 days, and each entry will ask about 3-4 questions. This will be a minimum total of 48 questions. You will be asked to complete questions. These questions ask you about your daily experiences about the system, your well-being, your satisfaction, etc.

Figure 1: DSS Study Equipment

Visit 2: Study Device and Procedure Training (visit will last about 4 hours)

(Day -15 or -29) (About 4 weeks after completing visit 1)

The purpose of the training is to introduce you to the Diabetes Assistant, Insulin pump, CGM, ketone meters, and glycemic treatment guidelines. Using these devices together to manage your diabetes is called Sensor Augmented Mode (SAM).

Diabetes Assistant (DiAs) System

The Diabetes Assistant (DiAs) System which is a medical platform that uses a smart-phone to connect to a continuous glucose sensor to insulin pump and run closed-loop control. DiAs accesses the "cloud" which is a service that run on the Internet, instead of locally on your computer. The cloud stores and processes data. In this study, Amazon Web Services (AWS) may be used as a cloud storage service.

You will be provided a study procedure manual that will show you different pictures of DiAs. It will also advise you what to do if DiAs show you that you have a low or high blood glucose value.

Insulin Pump (insulin pump users only)

A qualified system trainer will train you on the use of the insulin pump. The trainer will discuss differences between the study insulin pump and your home pump. Topics include the calculation of insulin on board, correction boluses, infusion site initiation, cartridge/priming procedures, setting up the pump, charging the pump, navigation through menus, and bolus procedures including stopping a bolus among others.

You will be provided the appropriate insulin pump supplies and instructions to use during the course of your study participation.

CGM Training
You will receive training on the use of the study CGM that is being provided for the purpose of this study only). The study team may have you watch the Dexcom training video as well. (https://www.dexcom.com/training-videos). You will stop using your personal CGM when you 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 appropriate CGM supplies and instructions to use during the course of your study participation.

Upon request, the study team will provide a Dexcom receiver to allow you to share your CGM data with your personal care providers.

Ketone Meter Training
You will be provided with a study ketone meter (for the purpose of this study only) to be used at home. You will be provided instructions on how to test for ketones.
Glucagon Emergency Kit
A home glucagon emergency kit will be required. If you currently don't have one, the study physician will provide you a prescription.

At the conclusion of the training session, you will provide the study team's contact information. You should promptly notify the study team in the event that you experience an illness, sustain an injury, obtain medical treatment, or have study equipment issues at any time during the study. You should notify the study team in the event that you receive a positive COVID-19 test result.

Sensor-Augmented Mode (SAM) Run-In
Home Use x 2-4 weeks

You will use DiAs in Sensor Augmented Mode (SAM) and wear a study CGM during this Run-In Phase. This Run-In Phase allows you to get comfortable with the study equipment and determine if you are eligible to continue the study. The length of time that you wear this equipment is dependent upon how frequently you are currently using a CGM (prior to enrollment in this study).

You will be asked to complete the following questionnaires during the last week of this Run-In Phase.

During this study, you will be asked to fill out some questionnaires. These questionnaires ask about:

- how you are feeling
- your lifestyle habits
- medicine use
- diet

- daily activities
- how you feel about taking part in this study

These questionnaires will take about 5-20 minutes to complete.

Visit 3: Eligibility Assessment, Randomization, and Training (visit will last about 1 hour)

(Day 1)

This visit may occur in the clinic or by web conferencing tools where both you and a member of the study team will see each other face to face.

The study team ask you:

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

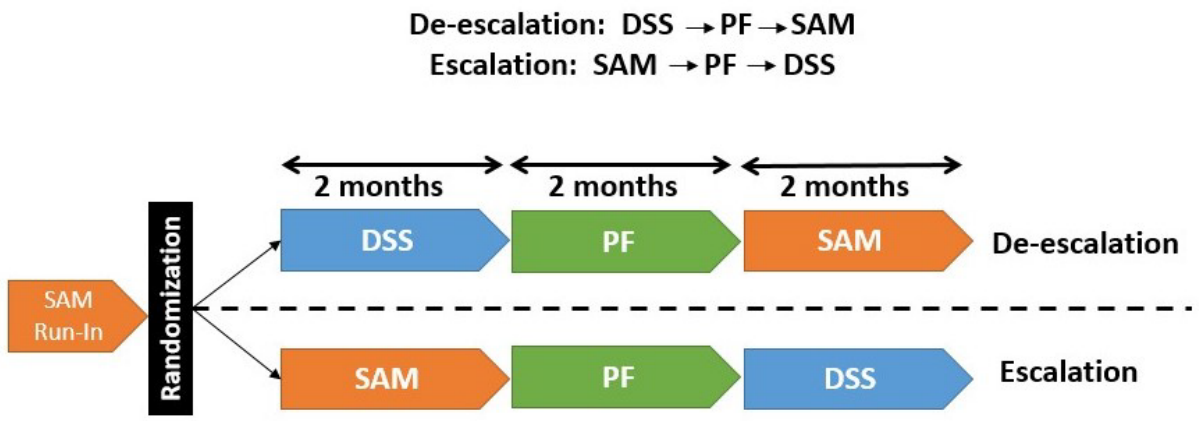
Eligibility Assessment

The study team will review the data collected during your Run-In Phase to make sure that you wore the study insulin pump with the DiAs system, and the study CGM enough days to continue the study.

Randomization

Eligible participants will be randomized assigned (like the flip of a coin) to 1 of 2 study groups (De-escalation Group or the Escalation Group). 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. You will participate in all three treatment phases regardless of the randomization.

- DSS – Decision Support System: You will receive advice about your risk of hypoglycemia during exercise and sleep. This module will analyze the previous 30 days of the study CGM, your insulin usage, and meal information to provide you an updated advice about your insulin parameters (i.e. carbohydrate ratio, carbohydrate factor, and basal rate).
- PF – Personalized Feedback: You will receive feedback from the system that track your insulin sensitivity, risk for hypoglycemia and insulin on board (IOB). You will receive weekly advice about your glycemic control regarding what went well and what would be good to focus on during the next week.
- SAM – Sensor-Augmented Mode: You will use only the DiAs system and the study CGM during the time. You will not receive information from the study equipment.



Training

You will be trained on the system that you are randomly assigned to for the first phase (SAM or DSS). After completing training, you will be given all the related supplies and study devices for this phase.

Study Equipment Use At Home

Then you will use the DiAs program in either DSS or SAM for a minimum of 8 weeks.

You will also complete a "Daily Diary" for 2-3 days out of about a 14-day period.

You will be asked to complete a series of questionnaires. The questionnaires are completed electronically and will take about 5-60 minutes to complete. This variation of time depends on the number of questionnaires that you are asked to complete at this visit.

Visit 4: Phase 2 Initiation (visit will last about 1 hour)

(Day 61)

This visit may occur in the clinic or by web conferencing tools. Your study equipment will be updated so you can begin the Personalized Feedback (PF) phase. You will use this system for 8 weeks at home.

You will need to have a blood/urine pregnancy test that must be negative in order to continue to participate in this study.

You will also complete a "Daily Diary" for 2-3 days out of about a 14-day period.

You will be asked to complete a series of questionnaires.

The study team ask you:

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

Visit 5: Phase 3 Initiation (visit will last about 1 hour)

(Day 121)

This visit may occur in the clinic or by web conferencing tools. Your study equipment will be updated. Participants randomized to de-escalation will have any questions answered about resuming use of the DiAs system in SAM. Participants randomized to escalation will have any questions answered about resuming use of the DiAs system in Decision Support System mode. You will use this system for 8 weeks at home.

You will need to have a blood/urine pregnancy test that must be negative in order to continue to participate in this study.

You will also complete a "Daily Diary" for 2-3 days out of about a 14-day period.

You will be asked to complete up a series of questionnaires. The questionnaires are completed electronically and will take about 5-60 minutes to complete. This variation of time depends on the number of questionnaires that you are asked to complete at this visit.

The study team ask you:

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

Visit 6 – Study Exit (visit will last about 1 hour)

(Day 182)

This visit may occur in the clinic or by web conferencing tools. During this visit, you will answer the final questions for your randomized group.

After you complete the study procedures, you will return to your standard diabetes care. The study team will be available to answer questions about your insulin parameters. You will also need to return of all the study equipment (e.g. study insulin pump, study CGM, study phone, remaining supplies, etc…).

You will be asked to return all study devices either via mail or at an office visit. Participants may keep the ketone meter after the study team has downloaded the meter if needed.

Visit 7: Post Study Check-In Visit (about 15 minutes)

(about Day 184)

The study team will contact you approximately 24-48 hours after completing the study to ask you:

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

Your participation in the study will be completed after this check-in visit.

Study Visits and Procedures Schedule

	Visit 1 Screening and Questionnaires	**Visit 2 Study Device and Procedures Training**	**SAM Run-in**	**Visit 3 Eligibility Assessment, Randomization and Training**	**DiAs Use in Phase 1 Mode**	**Visit 4 Phase 2 Initiation**	**DiAs Use in Phase 2 Mode**	**Visit 5 Phase 3 Initiation**	**DiAs Use in Phase 3 Mode**	**Visit 6 Study Exit**	**Visit 7 Post Study Check in**
Location	Clinic	Clinic	Home x 2-4 weeks	Web Conference or Clinic	Home x 8 weeks	Web Conference or Clinic	Home x 8 weeks	Web Conference or Clinic	Home x 8 weeks	Phone or Clinic	Phone or Clinic
Informed Consent	X										
Medical History	X										
Medications	X										
Physical Exam (including vital signs, height/weight)	X										
Pregnancy Test (if childbearing potential)	X					X		X			
Blood Testing: TSH, CMP (additional labs as necessary)	X										
Questionnaires	X		X	X	X	X	X	X	X	X	
Equipment Training		X									
DiAs in SAP Mode Training		X									
Glycemic Treatment Guidelines Training		X									
Glucagon Emergency Kit Training		X									
Use of DiAs in SAM			X								
Eligibility Assessment				X							
Review of your health related problems				X		X		X		X	
Randomization				X							
DiAs Phase 1 Mode Training				X							
Daily Diary Training				X							

	Visit 1 Screening and Questionnaires	**Visit 2 Study Device and Procedures Training**	**SAM Run-in**	**Visit 3 Eligibility Assessment, Randomization and Training**	**DiAs Use in Phase 1 Mode**	**Visit 4 Phase 2 Initiation**	**DiAs Use in Phase 2 Mode**	**Visit 5 Phase 3 Initiation**	**DiAs Use in Phase 3 Mode**	**Visit 6 Study Exit**	**Visit 7 Post Study Check in**
Location	Clinic	Clinic	Home x 2-4 weeks	Web Conference or Clinic	Home x 8 weeks	Web Conference or Clinic	Home x 8 weeks	Web Conference or Clinic	Home x 8 weeks	Phone or Clinic	Phone or Clinic
Use of DiAs in Phase 1 Mode					X						
Daily Diary Surveys					X		X		X		
DiAs Phase 2 Mode Training						X					
Use of DiAs in Phase 2 Mode							X				
DiAs Phase 3 Mode Training								X			
Use of DiAs in Phase 3 Mode									X		
Review diabetes management & review of your health related problems				X		X		X		X	X

What are your responsibilities in the study?
You have certain responsibilities to help ensure your safety. These responsibilities are listed below:

- You 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

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.

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

During the study, you are taking part in an investigational procedure using the Decision Support System. The purpose of this participation is NOT to diagnose any disease or abnormality you may have. Because the test is investigational there is no way for the study leader to understand if the results are "normal" or "abnormal". However, if any test results are concerning, your study leader will let you know. In addition, as the research moves forward, your study leader will keep you informed of any new findings about the research itself that may be important for your health or may help you decide if you want to continue in the study. The final results of the

research will not be known until all the information from everyone is combined and reviewed. At that time, you may ask for more information about the study results.

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

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.

Risks related to using a Continuous Glucose Monitoring Sensor:

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 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.

Risk related to Fingersticks

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

Rare

- Infection at site of lancet use

Risk of Sharing the Insulin Pump, Continuous Glucose Monitor, and Ketone Meter: The FDA approved the 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 discarded after use.

Risks from Completing Questionnaires and Daily Diaries

- 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 to the next question
- You can decide to take a break or stop taking part in the study at any time. The questionnaire will cause physical or emotional risks. The questionnaires are de-identified, meaning your name is not associated with your answers.

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.

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 or condition. You can get the usual treatment for your T1DM even if you choose not to be in this study. The usual treatment would include continuing your home insulin regimen.

However, in order to do this study, we must change the equipment that you use in usual treatment. This means wearing the study insulin pump and study CGM. We must change your insulin dosing and allow the algorithm (complex mathematical formula) to calculate your insulin dosages.

- 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 will not be affected if you decide not to participate in this study.

Could you be helped by being in this study?

You will not benefit from being in this study. However, the information researchers get from this study may help others in the future.

Will you be paid for being in this study?

You will be paid $1,000.00 by check for finishing this study. You should get your payment about 4 weeks after finishing the study. The income may be reported to the IRS as income.

- Study Training Visit 2: $150
- Study Training Visit 4: $150
- Study Training Visit 6: $150
- Completing Entire Study: $550

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, Dexcom receiver, remaining study supplies, etc.…)

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 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?

You will pay for the cost of the glucometer, blood glucose test strips and the insulin that you use in this study as you do in your normal care.

Your insurance company will also not be billed for the DiAs System, study insulin pump and supplies, and the ketone meter and supplies.

You and/or your insurance company must pay for the glucagon emergency kit.

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

The following procedures/tests, which are being done for research purposes, will be provided at no cost to you or your health insurance: lab tests, DiAs System, insulin pump, CGM, physical examination, vitals, and urine pregnancy tests.

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.

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) New information shows the treatment will not work or is not safe for you
e) You do not follow your doctor's instructions
f) The study principal investigator closes the study for safety, administrative or other reasons
g) Adverse events from the study drug that may be not be safe for you to continue
h) Study equipment issues that may be not be safe for you to continue

If you decide to stop being in the study, we ask that you notify the research team so any future appointments can be cancelled. The DiAs System, study insulin pumps and study CGM remain property of the CDT and will need to be returned. Any medications not taken 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?

- 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 (e.g. National Institute of Health)
- 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 drug or device 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.

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.

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.

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: Marc D. Breton, Ph.D.
University of Virginia Center for Diabetes Technology
PO Box 400888
Charlottesville, VA 22908 Telephone: 434-982-6484

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?

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

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 the study team:

- Obtaining information from my medical records
- Phone call
- Sending me questionnaire
- 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