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 Tandem Diabetes Care, Inc. (San Diego, CA). Supplies needed for this study will be purchased with this funding as well as the hotel/rented house (from here on "hotel" will be used for both hotel or rented house).

Note: You will need to provide your own insulin.

Key Information About This Research Study

Principal Investigator:	Marc Breton, PhD University of Virginia Center for Diabetes Technology Box 400888, Charlottesville, VA 22903 Telephone: 434-982-6484
Sponsor:	Tandem Diabetes Care, Inc. San Diego, CA

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

This is a research study about the UVA Automated Insulin Delivery System known as Adaptive NETwork (AIDANET). This system consists of an insulin pump, continuous glucose monitor, and an automated insulin dosing algorithm (complex mathematical formula) which is installed on a study phone called Diabetes Assistant (DiAs). This system delivers insulin automatically trying to keep blood sugars in target range more often. It is referred to as a "fully closed loop" (FCL) system because the system will deliver all insulin for you, including background insulin (or basal insulin) and insulin for meals, without you needing to count carbohydrates or enter bolus (mealtime)

insulin doses into the insulin pump. We will test the system for 3 days and 2 nights (about 36 hours) in a hotel or rental house setting with study staff, including nurses, with you 24 hours each day to make sure the system is performing safely. Then, after the supervised study, you will continue to use the AIDANET system at home for another 7 days and 6 nights for diabetes management. While you are at home, the study staff will monitor your blood sugar levels remotely to help make sure the system is performing safely.

If you are randomized (like a flip of a coin) to Group A, you will be asked to collect one week of Usual Care data at home before the hotel session. Group B, you will be asked to collect one week of Usual Care data at home after the hotel session. You will use your personal insulin pump and CGM equipment when collecting this Usual Care data.

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 30 minutes to complete.

What is the purpose of this study?
The purpose of this study is to test the safety of an algorithm called Automated Insulin Delivery Adaptive NETwork, or AIDANET. Current commercial brands of insulin pumps require you to notify the insulin pump when you are eating. The AIDANET algorithm is designed to deliver all insulin for you, including background insulin (or basal insulin) and insulin for meals, without you putting in meal information. This system has been tested before, using software that was "larger" and therefore would not be able to be programed in a commercial insulin pump chip. In this study, we want to evaluate if a "smaller" version of the same code is still safe. This study will also evaluate if how well the system controls your glucose levels if you prefer to notify the system when you are eating or/and the amount of carbohydrates in that meal.

The AIDANET algorithm is investigational device and is not approved by the U.S. Food and Drug Administration (FDA). A variation of this algorithm has been tested in approximately 34 people. It has not yet been proven to be safe or helpful. The algorithm has been tested in a computer using insulin settings that have been collected from thousands of people with type 1 diabetes. This is called computer simulation. The algorithm is the only device that is being studied in this trial.

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. 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 of the following reasons:

- This study uses an algorithm called 'AIDANET' which is not approved by the FDA.
- Your participation in the study will last about3 weeks.
- You will need to share up to 6 months of your data from your insulin pump, CGM, and glucometer.
- You will need to stay at a local hotel with other study participants for about 36 hours. The study team will determine the hotel session dates when the hotel has availability. You will be asked if you can participate during those dates. If you are unable to participate during that time, you will not be able to participate in the 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 agree to take part in this study, you will:

- Wear a study issued or your personal CGM during the study. If personal CGM is the G7 model, you will be provided with a study G6 CGM to wear when using the study equipment. You will be provided with these supplies at no cost.
- Use a study glucometer to test your blood glucose values, if necessary. You will be provided with these supplies at no cost.
- Be instructed not to adjust your insulin parameters without speaking with the study physician before you make any changes.
- Need to share your personal CGM data and insulin data with the study team.
- Need to participate in one hotel session lasting up to 36 hours. Your hotel lodging will be provided for you at no cost.
- Eat the same breakfast/lunch/dinner during the hotel session, with the same amount of carbohydrate, protein, and fat. You will be provided with these meals at no cost.
- Not eat snacks with carbohydrates during the hotel session unless it is for the treatment of a low blood sugar. You will be provided with these treatments at no cost.
- Be permitted to eat non-carbohydrate snacks throughout the hotel session at the discretion of the study physician.
- You will be asked to complete questionnaires to tell the study team about your expectations with the study equipment and then your experience with the study equipment.

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 participate in both remote (e.g., video chat, phone call, text message and/or email) and in-person study visits. You will have to give permission later in this

consent form to be contacted via email or text message as it is optional.
- You will need to have access to internet and willingness to upload data during the study.
- You will use study equipment (e.g., DiAs study phone, insulin pump, Dexcom G6 CGM) during the study.
- You will have regular check-in visits with the study team to see how you are feeling.

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 take part in this study:
- You may continue your personal care for management of your diabetes developed by your physician.

How many people will take part in this study?
Up to 12 people will sign consent.

When a person or an organization has a financial or other interest large enough to seem as if it could affect their judgment, it is called a conflict of interest. Members of this study team have a conflict of interest with this study. As owner of the intellectual property rights in AIDANET algorithm, the University of Virginia and some members of this research team may make money in the future if this study has good results.

How long will this study take?
Your participation in this study will require 8 study visits over about 3 weeks. The screening visit (visit 1) will take about 60 minutes and may be completed by video, phone call, and/or in-person clinic visit. The Usual Care At-Home data collection (visit 2) for Group A will be about 1 week. Visit 3 is a check-in visit with the study team and will take about 15-30 minutes each to complete and may also be completed by email or text messaging as well as video chat, phone call, and/or in-person clinic visit. The hotel sessions (Visit 4) will last about 36 hours. Visit 5 will be a week of at-home use of the study equipment for Group A and B. Group A will complete the study at the end of this week. Group B will begin their one-week of Usual Care data collection. A Post-Study Check-In Visit (visit 6) will take about 15-30 minutes. This visit may be completed in person, telephone, video chat, email, and/or text messaging.

What will happen if you are in the study?

Visit 1: Screening Visit
(Day 1) This visit may be completed in person, by telephone, or video chat and will last about an hour.

If you agree to participate, you will sign this consent form before any study-related procedures take place. Before you can start, 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:

- Demographics (date of birth, gender, race, and ethnicity)
- Contact information (name, phone number, e-mail address, mailing address).
- 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 6 months may be substituted.
- Blood may be taken from your finger to obtain a hemoglobin A1c test. This is the same test that you may have done at your endocrinologist's office every 3 months to measure your blood glucose level over the last 3 months. A hemoglobin A1c value that was obtained within the last four weeks prior to the screening visit may be used for this test.
- If needed based on your medical history, the study physician may request a thyroid function or kidney/electrolyte blood test for laboratory testing. Changes in these lab results may help show changes in your insulin resistance (when cells in your muscles, fat, and liver don't respond well to insulin). Lab results within 6 months of your screening appointment may be used.
- If you are capable of becoming pregnant, a urine pregnancy test will be performed and must be negative for you to participate in the study. A blood test may be collected if other lab tests are necessary.

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

Note: Potential eligibility may be assessed during a routine-care physical examination. Any labs required may be obtained at a local laboratory (e.g., UVA, LabCorp, Quest) that is convenient to you.

If these tests show you are eligible, you will be asked to complete a Demographic Data Survey (date of birth, gender, race, ethnicity, where you live, your education level, etc.). You will complete electronically this survey with the use of your personal tablet or phone on a secure study website.

Visit 2: Randomization

Once you have been determined eligible to participate in the study, you will be randomly assigned (like the flip of a coin) to 1 of 2 study intervention 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 A: Usual Care→AIDANET
Participants will complete one week At Home Usual Care before the use of the AIDANET system at the hotel session.

GROUP B: AIDANET→ Usual Care
Participants will complete one week At Home Usual Care after the use of the AIDANET system at the hotel session.

Visit 3: Usual Care Data Collection Phase

(Day 3-10) Data collection will occur at home and will last about 1 week.

This data collection phase is to gather information on your normal insulin doses and amount of carbohydrates that you typically use each day. You are asked to follow your normal routine involving diet, exercise, and insulin administration.

During the Usual Care period, you will continue to use your personal insulin pump. You may use your insulin pump either in manual or automated mode, but this mode must permit downloading of the data by the study team. You will also be asked to wear your personal Dexcom G6 or G7 continuous glucose monitor (CGM) and will be asked to share your CGM data with the study team. It is important to wear your CGM continuously during this phase of the study. This data will be stored in a cloud account. (The use of the Dexcom Apps on a personal phone may result in data and text charges.) You will be provided with a study glucometer and will be asked to share your glucometer data with the study team at the conclusion of the study. You will be instructed to follow your normal routine involving diet, exercise, and your diabetes management.

Visit 4: Pre-Hotel Session Check-In Visit

(About Day 11) This visit will be completed by phone, email, text, or video call and will take about 15-30 minutes.

You will be contacted by the study team approximately 1-3 days before the hotel session to:

- Ask you about any changes to your medical history and medication.
- Verify that a new CGM sensor was placed approximately 24-72 hours prior to the hotel session for proper warm-up.
- Remind you that the CGM reading should be less than 200 mg/dL at the start of the study at the hotel. The study physician may call you if you are experiencing low or high blood glucose levels prior to the hotel session.
- Remind you to bring your insulin and other medications that you will need during the study.
- You will be reminded to bring quiet activities to enjoy during the hotel session.
- You will be asked to complete the INSPIRE and Technology Acceptance questionnaires prior to the hotel session. These questions will take about 15 minutes to complete.
- Should any concerns regarding your health or unforeseen issues arise, the hotel session may be canceled at the discretion of the study physician.

Visit 5: Hotel Session

(Day 12-14) This visit will be completed in-person and will last about 36 hours.

After arrival at the hotel, you will be trained on the AIDANET system (DiAs study phone with the algorithm, insulin pump, Dexcom G6 CGM) and then start using it to manage your diabetes. You will eat 3 meals each day of your choice and participate in at least 30 minutes of mild- intensity exercise (a walk) on hotel Day 2. There will be 6 participants during the hotel session at the same time.

Participants will be supervised at all times by research staff. There will be research staff present in the hotel overnight to perform overnight glucose testing as needed.

The hotel sessions will be the same for each group regardless of which group you are randomly assigned.

Hotel Session Arrival:

- You will come to a hotel for admission for about 36 hours.
- The study team will confirm that you brought your insulin and regular medications to the hotel session.
- You will have vital signs (e.g., blood pressure, pulse, heart rate) completed.
- Your CGM reading and ketone values will be recorded. The study physician may recommend treatment if your CGM is not reading between 80-250 mg/dL.
- Your home insulin pump will be discontinued, and the study insulin pump will be initiated. The study team will ensure the proper function of the CGM and insulin pump.
- You are not permitted to eat snacks containing carbohydrates during the hotel session. The study team will provide snacks with carbohydrates (the sugar found in food) if you need treatment for hypoglycemia (low blood sugar). Non-carbohydrate snacks may be allowed if permitted by the study physician.

Hotel Session:

- Any adjustments to your current insulin parameters during the hotel session will be done with the assistance of the study physician.
- You will eat three meals per day during the hotel session. You will use your usual insulin:carbohydrate ratio at the dinner meal on one of the two nights. You will not bolus (give yourself insulin) for any other meals. The study team will record the time of these meals so they can evaluate the performance of the AIDANET algorithm.
- You will participate in a mild 30-minute walk on Day 2. The CGM value must be at least 80 mg/dL to begin the walk. You are also free to engage in additional low-intensity exercise during the hotel session. You must be accompanied by staff if you want to leave the hotel.
- Any CGM reading below 70 mg/dL or any potential low blood glucose symptoms will be confirmed with a fingerstick blood glucose using the study glucometer.
- At least two study team members (e.g., technician, nurse, physician, nurse practitioner, or physician assistant) will be present during the day and overnight hours of the hotel session. A study phone number will be provided to you so you can contact the study team.

Hotel Discharge:

- Your CGM value will need to be stable and between 80-250 mg/dL. Your ketone levels need to be stable (less than or equal to 0.6 mmol/L.). The study physician will talk with you about any treatment that you may need before you are discharged.
- You will be asked to monitor your ketone levels for up to 24-48 hours after discharge from the hotel session if ketones were elevated within 12 hours prior to discharge. Urine ketone strips may be provided to you, if needed.

Visit 6: Study Equipment Training

As you use the FCL system during the hotel session, the study team will be training you on the use of this equipment (e.g., DiAs study phone, insulin pump, and CGM) so you are able to use this same equipment during the At-Home FCL phase of the study. You will learn how to stop the system. You will also receive glycemic treatment guidelines on how to manage low blood glucose and high blood glucose events. You will be instructed on charging the insulin pump, the DiAs study phone, menu navigation, give yourself insulin, and infusion site changes.

Visit 7: At-Home FCL Phase

(Day 14-21) Home

Prior to discharge from the hotel, you will receive a brief refresher training on the AIDANET system, and you will be discharged home to continue to use the system at home to manage your diabetes for the next 7 days/6 nights. You will be instructed to follow your normal routine involving diet, exercise, and your diabetes management during the At-Home FCL phase.

While at home you will eat at least three meals per day of your choice. It will not be necessary to record most of your mealtimes. However, you will be asked to:

- enter your usual insulin-to-carbohydrate ratio for all meals one full day (from waking to bedtime).
- announce when you begin to eat on one full day (from waking to bedtime).

Exercise will not be required at home. Instead, you should continue with your usual activities and exercise. Study staff will be monitoring your blood glucose levels remotely, using the Dexcom app. Study staff will contact you if glucose is less than 55 mg/dL at any time, less than 70 mg/dL for 20 minutes, greater than 300 mg/dL for 60 minutes, and no sensor data for more than 60 minutes to ensure safety and help guide you in treating high and low blood glucose levels.

At the completion of the At-Home FCL data collection period, you will return to using your personal equipment (e.g., insulin pump and CGM) and using your usual insulin parameters. A qualified clinical study team member (e.g., MD, NP, PA, CDE) will be available to discuss the

transition back to your usual care if you have questions.

You will be provided with a pre-paid shipment label to promptly return all study equipment (e.g., DiAs study phone, insulin pump, glucometer, and remaining CGM supplies). The glucometer can be returned to you after the study team has downloaded the data.

You will be asked to complete the INSPIRE and Technology Acceptance questionnaires at the conclusion of the At-Home FCL phase. These questions will take about 15 minutes to complete.

Data collection for Group A will be completed at the conclusion of the At-Home FCL phase. Group B will begin their one-week of Usual Care data collection. Data collection for Group B will be completed at the conclusion of the Usual Care phase.

Visit 8: Post-Study Check-In Visit

(Day 22) This visit will be completed by phone, email, text, or video call and will take about 15 minutes.

The study team will contact you about 24-48 hours after completing the post-hotel data collection period to ask you:

- Ask you about any changes to your medical history and medication.
- Review any hypoglycemic events that are less than 60 mg/dL that you may have experienced.
- Review any hyperglycemic events that are more than 300 mg/dL that you may have experienced.
- If you have any questions regarding the study. You can talk with the study physician or physician's assistant if you have questions related to adjusting back to your usual insulin parameters.

A member of the study data team may contact you if there are questions related to your data collection or equipment.

End of Study Participation:

After the Post-Study Check-In Visit 8, your participation in the study is complete. You will be referred to your primary care provider/or specialist for standard-of-care treatment.

STUDY SCHEDULE

Contact type is clinic visit (CV), Remote (R), Phone (Ph) which includes text messages and emails.

	Screening	Randomization	Usual Care Data Collection	Pre-Hotel Check In	Hotel Session with FCL	FCL Equipment Training	1-week at-home FCL	Post Study Check-In
Location	CV/R/Ph	CV/R/ Ph	Home x 1 week	R/Ph	House/ Hotel	House/ Hotel	Home x 1 week	Home
Visit	1	2	3	4	5	6	7	8
Timeframe	1	2	3-10	11	12-14	12	14-21	22
Informed Consent	X							
Eligibility Assessment	X							
Medical History	X							
HbA1c	X							
Pregnancy Test (if applicable)	X							
Blood Testing: BMP, Liver Functioning, Hematocrit, TSH (if requested by MD)	X							
Physical Exam (H&P within 6 months permitted as substitute)	X							
Vital Signs (including height/weight) (self-reported values permitted)	X				X			
Demographic Data Survey (if eligibility is met)	X							
Randomization		X						
Study Equipment Training						X		
CGM Use			X	X	X	X	X	

Fully Closed Loop (FCL) Use (e.g., AIDANET, DiAs)					X	X	X	
Questionnaires					X		X	
Current medications	X				X			
Review diabetes management and any new illnesses or injuries			X	X	X	X	X	X

What are your responsibilities in the study?

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

- You 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 1 teaspoon of blood for screening. The blood we take will be tested to measure your hemoglobin A1c, a blood test used to monitor how well you're managing your diabetes. The total amount of blood we will take is less than 1 teaspoon of blood if tested at a laboratory and a droplet of blood if tested in the clinic.

If the study physician asks for additional labs (for example: hematocrit, pregnancy, and thyroid stimulating hormone) at your screening appointment, we will take less than 1 teaspoon of blood. The study physician may request these blood tests as these results may help show changes in your insulin resistance (when cells in your muscles, fat, and liver don't respond well to insulin).

When these tests are done any leftover sample will be thrown away. 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, 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?

Loss of Privacy:

A risk of allowing us to collect information about you is a potential loss of privacy. The University of Virginia will do its best to protect your records so that facts about you and your health will be kept private. The chance that information identifying you will be given to someone else is very small. However, we cannot guarantee it will be safe.

- 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 of 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 session will have other study participants also in attendance.
- The study team is not able to restrict other participants from sharing photographs that include you (e.g., social media).

Risks and side effects related to treating type 1 diabetes (with or without using study equipment):

Likely

- Risks 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.

Rare but serious

- Risk of severe temporary low blood sugar (hypoglycemia) that can lead to unconsciousness, hypoglycemic seizure, hospitalization or even death. One of the ways this could happen is if the system delivers too much insulin when a meal was not eaten but

the system detected what looked like a meal based on the CGM increasing.

- Risk of prolonged high blood sugar leading to Diabetic ketoacidosis (DKA), hospitalization, and coma. DKA can lead to renal failure (kidney failure), cardiac arrhythmia (irregular heartbeat), myocardial infarction (heart attack), rhabdomyolysis (muscle breakdown), and even death.

Risks related to using a Continuous Glucose Monitoring Sensor:

Likely

- Failure or lack of sensitivity of the CGM sensor that requires replacement and or insertion of new sensor
- Discomfort from insertion of sensor into the skin

Less Likely

- Bruising less than ½ inch
- Bleeding less than ¼ teaspoon
- Inserting the sensor may cause infection, bleeding, or pain, and wearing the adhesive patch can irritate your skin
- CGM sensor reads higher or lower than your actual glucose level
- CGM sensor stops working or cannot communicate with the system.
- Skin irritation or allergic reactions to the sensor adhesives
- Uncomfortable with study team members seeing your CGM values

Rare but serious

- Using an unsecured Wi-Fi could expose the system to viruses and hacking
- 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.
- 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 performing a urine pregnancy tests (women who can become pregnant):

Less Likely

- False positive or false negative results.

Risks associated with staying at the hotel for research purposes:

Likely

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

Risk of Exercise:

There is a risk of musculoskeletal symptoms or injury from participating in an exercise regimen. There are cardiovascular or cerebrovascular risks (including but not limited to dizziness, lightheaded, syncope, arrhythmia [abnormal heart rhythm], or ischemia [inadequate blood supply to an organ]) associated with participating in an exercise regimen.

Cybersecurity Risks:

Similar to other computer systems, medical devices may experience security breaches that may impact your safety. Manufacturers of these devices attempt to address these risks, but you should be aware that these risks do exist.

Connected Medical Devices, such as insulin pumps and CGMs, deliver care to you while collecting healthcare data through a wireless connection. Someone with advanced technical skills could potentially expose your personal health information or could potentially impact the safety of the device, such as changing your insulin pump settings which may cause hypoglycemia or hyperglycemia. We do what we can to decrease the chance of that happening, but it cannot be guaranteed.

Risks and side effects related to the algorithm include:

Even though the study algorithm has been tested in a computer simulation or in another clinical 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.

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-patient 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.

The glucometer will be returned to you once the data has been downloaded by the study team.

Other Unexpected Risks:

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Blood Donation:

If you participate in this study, it may affect your ability to donate blood. If you have any questions, call the organization where you donate blood and talk to one of their nurses.

Risks from Completing Questionnaires:

The questionnaires provided to you in this study should not cause any physical or emotional risks. These documents are de-identified, meaning your name is not associated with your answers. Rather, you will use your assigned study subject number only when replying to the questions.

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, 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.

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 $200.00 by check for finishing this study. You will be compensated $100 for travel to the hotel study session.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.

- All data collection phases: $100.00
- Hotel Session: $100.00
- Travel Compensation: $100

Payment for study visits completed will be provided after all study equipment has been returned to the study team, and study downloads have been completed. The study glucometer can be returned to you after the data is downloaded from the glucometer or the glucometer's app.

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

Will being in this study cost you any money?

The following procedures/tests, which are being done for research purposes, will be provided at

no cost to you or your health insurance:

- Hemoglobin A1c test
- Pregnancy test (if applicable)
- DiAs study phone
- Insulin pump and infusion sets
- CGM supplies
- Glucometer and test strips
- Any additional laboratory tests the study physician requested from you to participate in this study
- Hotel and the meals provided during the hotel session

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. 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 lost wages, disability, or discomfort. The sponsor will reimburse the reasonable cost of necessary and appropriate emergency and/or acute medical care for injury or illness that is determined by the principal investigator and sponsor to be directly related to the study. Injury related to the study does not include the normal progression of any disease or any underlying pre-existing medical conditions.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and, if you have health insurance coverage through Medicare, your Medicare Beneficiary Identifier (MBI). This is because the sponsor must check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

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 DiAs study phone, study insulin pump, remaining study CGM and other supplies remain property of the CDT and will need to be returned. The study glucometer may be returned to you once the study team has downloaded the data.

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 of this study, Tandem Diabetes Care, Inc., 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 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.
- Members of the Center for Diabetes Technology and other non-medical staff will be present during the study to both observe and support the hotel session'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.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

Information obtained from you during this study may be used in future research. Your information may be shared with other researchers inside or outside of the University of Virginia. They will not be sent with information that could identify you such as name, address, or phone number.

A description of this clinical trial will be available on *http:// www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form or complete the "Leaving the Study Early" part of this form and return it to the researchers. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

A copy of this consent form will be put in your medical record. (This is not the same as the record of this research study.) This means that everyone who is allowed to see your medical records will be able to find out that you are in this study. This is done so your regular doctors will know what you receive as part of this study. If you have other health problems during the study, they will be able to treat you properly.

Please contact the Principal Investigator listed BELOW 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 Breton, PhD
University of Virginia Center for Diabetes Technology (CDT)
Box 400888, Charlottesville, VA 22903
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 22903 Telephone: 434-924-2620

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.

You do not have to agree to use email or text message to be in this study.
PLEASE INDICATE YOUR CHOICE BELOW:

Yes_____ I agree to be contacted by email or text.
If you agree to texting or emailing, the study team will collect your phone and /or email address that you would like them to use. Please note, if you agree to text messaging, charges may apply depending on your data/text plan with your phone provider.

No_____ I DO NOT agree to be contacted by email or text.

Would you like to be contacted about future studies?
The researchers in this study would like to know if you wish to be contacted regarding participation in additional studies that may be appropriate for you. By agreeing to be contacted, you will allow a qualified member of the study team to contact you in the future to ask if you want to participate in additional studies. You have no obligation to participate in any study.

Declining will have no influence on your present or future status as a patient in this clinic. You will receive the same care as any other patient seen in this clinic. There will be no penalty or loss of benefits to which you are otherwise entitled. Your clinic records will indicate that you do not want to be asked about future research by or through anyone but your treating physician.

Participation in research may involve some loss of privacy. However, your records will be handled as confidentially as possible. Access will be limited to the study team organizing the study. No information will be used for research without additional permission. Your contact information will not be shared with anyone outside of UVA without your permission.

You do not have to agree to be contacted about future research to be in THIS study.
PLEASE INDICATE YOUR CHOICE BELOW if you are willing to be contacted about any future research studies.

____ Yes, I agree to be contacted about future research studies.

____ No, I do not want to be contacted about future research studies.

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