NCT02558491

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.

Parents' or Guardians' Permission for Your Child to Be in a Research Study

Agreement of a Child to Be in a Research Study

Age 15 to <18

In this form "you" means the child in the study *and* the parent or guardian.

- ✓ If you are the parent or guardian, you are being asked to give permission for your child to be in this study.
- ✓ If you are the child, you are being asked if you agree to be in this study.

In this form "we" means the researchers and staff involved in running this study at the University of Virginia.

Participant's Name_____ **Medical Record #** _____

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Sponsor: National Institute of Health (NIH)

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 signed copy of this form.

Who is funding this study?

This study is being funded by the National Institute of Health (NIH). The glucometer and the continuous glucose monitor supplies may be purchased with grant funding. If the inPen Smart Insulin Pen is used in this trial, the product will be provided by the manufacturer, Companion Medical, or the study team will pay for the supplies with grant money. No study data is provided to these manufacturers.

Why is this research being done?

The purpose of this study is to demonstrate the safety and feasibility of a Decision Support System aimed at reducing your glucose variability. The Decision Support System will be used on our portable medical application platform called Diabetes Assistant (DiAs) and will include your new insulin parameters and an exercise warning system. The exercise warning system is intended to predict your hypoglycemia at the start of exercise and will suggest alternative treatment.

This is a study about testing the decision support system and the exercise warning system.

The DiAs as a whole is not approved by the U.S. Food and Drug Administration (FDA) and is therefore considered investigational. So far, parts of this investigational system combined in different forms has been tested in over in over 183,000 hours with type 1 diabetes mellitus in testing sites in the United States, Italy, Israel, and France.

If you are a MDI user, the Companion Medical pen, known as the InPen, *may* be used in the trial. This "smart" insulin pen contains computer chip technology built into the base and has Bluetooth LE wireless capability. It will collect your data and then transmits it to an app that contains a dose calculator and also calculates real-time insulin on board (IOB). The insulin pen has remote monitoring, permitting you to inform the study team of your insulin dose, blood glucose values, and carbohydrates. This pen has not been approved by the FDA.

You are being asked to be in this study because:

- You are at least 15 and less than 65 years of age
- You have had Type 1 Diabetes Mellitus for at least 1 year
- You have been using an insulin pump to treat your diabetes for at least 6 months OR Multiple Daily Injections (MDI) for at least 6 months, consistent in amount and timing (administered at approximately the same time each day). The following MDI therapy will be permitted:
    - Subjects using Glargine (100 U/mL) once or twice daily.
    - Subjects using Detemir (100 U/mL) twice daily.
    - Subjects using Degludec (100 U/mL) once daily.

Up to 70 adults will be tested at the University of Virginia.

Is there a possible conflict of interest?

When a person or an organization has a financial or other interest large enough to seem as if it could affect their judgment, it is called a conflict of interest. Three study investigators have pending patent applications for the Diabetes Assistant (DiAs) and algorithms. Both the investigators and the University of Virginia may make money if this study has good results.

How long will this study take?

Your participation in this study will require 5 study visits within approximately 10 weeks. The first visit will be a screening visit at the Clinical Research Unit that will last about 2 hours. Visit 2 will be a Continuous Glucose Monitor Training session. Before starting the Experimental Admission, you will be asked to complete the data collection period that is detailed in visit 3. We will ask that you provide the study team a progress report/data download approximately 3-5 times during the data collection period. You may be asked to repeat some or all of the data collection period to verify that the correct amount of data is collected. You may also be asked to be repeated if the admission or the data collection is suspended or the data is inadequate. Visit 4 and 5 are two 48-hour testing admissions in a hotel/research house setting.

What will happen if you are in the study?

All procedures outlined in this consent form are being done for research purposes only.

SCREENING (will take about 2 hours to complete):

Visit 1 *(Day 1):*

If you agree to be in this study, you will sign this consent form before any study related procedures take place. Before you can start in the study, there will be a screening period. You will have tests and procedures during this time to make sure you are eligible and it is safe for you to participate.

These tests and procedures include the following:

- We will collect some basic information about you such as your date of birth, gender, race and ethnicity
- You will be asked to fill out a medical history form. You will be asked about your diabetes history, past and current medical conditions, surgical history, menstrual history (females), allergies, medications and supplements, birth control, social history (including drinking, smoking and drug habits), and whether or not you have various symptoms. You will also be asked about your current diabetes treatment, and your average daily insulin use over the past 7 days.
- Physical exam and vital signs (blood pressure, heart rate)
- Height and weight
- Standard blood tests (2 teaspoons of blood) to check certain salts, blood sugar, kidney function, liver function, blood counts, HbA1c (your blood glucose average over 8-12 weeks), and thyroid levels (TSH). This will also include a pregnancy test if you are a woman who can become pregnant. The pregnancy test must be negative in order to participate.
- Standard urine testing
- EKG – which is a tracing of the electrical activity in your heart
- You will be asked not to take medications containing acetaminophen (like Tylenol) 24 hours prior to wearing the continuous glucose monitor sensor and while you are wearing the sensor.
- If female and sexually active, must agree to use a form of contraception to prevent pregnancy while a participant in the study. A negative urine pregnancy test will be required for all premenopausal women

who are not surgically sterile prior to each visit. Subjects who become pregnant will be discontinued from the study.

If you have had blood work within the last month, those tests may be reviewed to determine if you are eligible for the study. If these tests show you are eligible, you will return to the clinic within 16 weeks to begin study procedures. You may also be referred to a lab facility (i.e. LabCorp) closer to home after signing the consent form. Visit 2 may occur on the same day as visit 1 after the study team verifies that it is safe for you to participate.

Randomization and Study Treatment

You will participate in both the Experimental and the Control Admissions. The order of the two admissions will be randomized (like a flip of a coin). During both study admissions, you will use DiAs and a continuous glucose monitor. You will carry DiAs with you at all times. Study staff will be present to assist you when you are interacting with DiAs. During the ***Experimental Admission***, you will use your new insulin parameters. More about these admissions is found later in this form.

VISIT 2 (Day 2) – Study Training (will take approximately 1-3 hours to complete depending on your knowledge of the continuous glucose monitor):

You will receive training on the continuous glucose monitor during this visit. This will include inserting the sensor, calibrating the equipment, and caring for the insertion site. You will be instructed on how to properly obtain a blood glucose value. The continuous glucose monitor will be blinded to you, meaning that you will not be able to read the blood glucose reading on the CGM receiver. The study team will have access to this information through remote monitoring during the study admissions.

You will be asked to avoid acetaminophen-containing medications (like Tylenol) while wearing the continuous glucose monitors as any acetaminophen-containing medications may affect the performance of the devices.

The study team will train you on the proper use of the study glucometer. **You will be required to obtain a minimum of 4 blood glucose values per day. Two of these measurements must be upon waking up and at bedtime.** Any home blood glucose tests normally done by the participant should continue without interruption.

Study staff will instruct you on how to download your continuous glucose monitor, and the glucometer.

You can call or visit the study team and study physician as needed. You will be given the telephone numbers of the study team so you call someone 24-hours a day.

Visit 3 (Day 3-31) – Data Collection Period Prior to Experimental Admission (approximately 28 days)

During this collection phase, the study team will collect your basal rates or basal insulin dose, insulin sensitivity factor (ISF), and carbohydrate ratio data. This information will be used to optimize your insulin parameters

(basal rates or basal insulin dose, insulin sensitivity factors, and carbohydrate ratios). It will then be entered into the DiAs during the Experimental Admission. **You will not be able to see these insulin parameters or make any changes.**

During this collection phase, you will follow your usual regimen for the full 28 day period. However, we will ask that you wear the continuous glucose monitor while maintaining your usual diabetes treatment. .

If using an insulin pump, you will be asked to use the bolus calculator function and to enter the carbohydrate information that you eat at each meal. You will be asked to record any bolus insulin treatments that you have provided yourself with use of an insulin pen or needle injection.

MDI users must currently be using Intensive Insulin Therapy including carbohydrate counting and use of pre-defined parameters for glucose goal, carbohydrate ratio, and insulin sensitivity factor. You will be asked to enter this information into 'MySugr', an app that helps keep track of blood sugar levels, insulin dosages, meals, activities and other information. The app will be installed on your Smartphone to help you keep track of this information.

You will wear a Fitbit on your wrist during this data collection phase. If the Fitbit should cause skin irritation, you are advised to call the study team. They may suggest that you alternate wrists or stop wearing the device.

You will be asked to download equipment and provide the data to the study team after approximately 7 and 14 days. **You will be asked that all meal information (i.e. carbohydrate quantity, insulin, SMBG, etc.…) be recorded during this Data Collection Phase.** Study team will review this data to check that the data is being collected correctly. If unsatisfactory, the study team may ask that you repeat this phase. Once the data has been successfully completed, the study team will use this data to create your new insulin parameters.
To help obtain the Fitbit data, we will ask to place the Fitbit App on your smartphone or on your personal laptop. You will then need to sync the phone/laptop and the Fitbit weekly (less than 7 days) in order to download the data from the device. If you are unable to download this data from home, we will ask that you return to the office so the study team may assist you.

You will be asked to bring your own insulin for the hotel/research house admission.

If a change in your basal (long-acting) insulin dose is recommended as part of your optimized parameters, you will be asked to use the new basal insulin dose(s) for approximately 5 days prior to the Experimental admission. You will be asked to perform at least 7 SMBGs per day. The study team will contact you within 72 hours after the basal rate change.

MDI subjects will be provided an insulin pen with short-acting insulin for treatment during the Experimental admission only. DO NOT SHARE INSULIN PENS.

Visit 4 (Day 32-34) – Hotel/Research House Admission (48 hours)

You will be provided a general overview of the DiAs interface, bolus advice, and exercise functionality.

During the Experimental Admission, you will test the new insulin parameters that have been created using your data from the previous 28 days. A study physician will review the new optimized basal rates before the experimental admission to make sure that it is safe. The DiAs will be programmed with the new optimized basal rates or basal insulin dose, insulin sensitivity factor(s), and carbohydrate ratio(s). These new parameters will be used for insulin dosing advice during the entire admission. MDI users will use the study insulin pen for meal insulin dosing, and the home insulin pen or syringe for Lantus (glargine) dosing. Pump users will use the home pump for both meal insulin dosing and basal insulin administration during the admission. The only time insulin can be suspended based on the current CGM value is prior to exercise if the system advises it. Note that you may manually suspend insulin if you feel your blood glucose is too low. We will ask that you participate in two 45-minute exercise sessions at the gym. These sessions are divided into three 15 minute periods. You will wear a heart rate monitor during exercise so you and the team can monitor your heart rate.

During the Control Admission, you will use your own insulin parameters, including basal rate, insulin sensitivity factor and carbohydrate-insulin ratio, and determine your own insulin usage. You will interact with DiAs as a conventional bolus wizard. We will ask that you participate in two 45-minute exercise sessions at the gym. These sessions are divided into three 15 minute periods. You will wear a heart rate monitor during exercise so you and the team can monitor your heart rate.

Day 1 of admission: We will ask that you arrive at the hotel/research house at approximately 4-5 pm. You will begin using DiAs prior to dinner. We will provide you an evening snack if that is your usual care. This snack will be repeated at each both admissions. You will be asked to retire to bed at 11 pm.

Day 2 of admission: You will be awakened at 7:00 AM to begin your usual personal care. You will participate in a 45-minute exercise session at 11:00 AM. You will participate in quiet activities during the remainder of the day.

Day 3 of admission: You will be awakened at 7:00 AM to begin your usual personal care. You will participate in a 45-minute exercise session at 10:00 AM. You will participate in quiet activities during the remainder of the day.

At meal time during the Control Admission, you will determine the amount of carbohydrates and the meal bolus. This information will be entered into the DiAs meal screen along with your blood glucose level.

At meal time during the Experimental Admission, you will determine the amount of carbohydrates. This information along with your blood glucose level will be entered into the DiAs meal screen by study staff. Your new insulin parameters will determine the bolus amount. You will not be permitted to see this information.

The same meals will be repeated during the Control and Experimental Admissions. Snacks between meals will not be permitted during either admission. You may eat a snack in the evening with the option of using insulin per your usual care. If chosen, this snack must be replicated at both admissions. You will inform DiAs of the carbohydrates in the snack and current blood glucose level by activating the meal screen of the system if insulin will be given with the snack. If you are not providing yourself insulin, the snack carbohydrates will be entered into DiAs using the hypoglycemia treatment screen. DiAs will advise an insulin dose using your usual carb ratio during the Control admission and using the optimized ratio during Experimental admission. You will administer the DiAs-advised insulin dose which will be supervised by the study staff.

Meal Times during Admissions
Breakfast: 8:00 – 9:00 AM
Lunch: 12:00 – 1:00 PM
Dinner: 6:00 – 7:00 PM

Fingerstick Collection Times during Admissions
You will be asked to perform fingersticks prior to meals and snacks, before and after each 15 minute exercise bout, and at bedtime (23:00). Once a fingerstick is obtained for any reason during the time that DiAs is active, Glycemic Treatment Guidelines will determine timing of subsequent fingersticks.

Procedures Related to Discharge
You will continue to wear the continuous glucose monitor until approximately 4 PM on the day of discharge to continue to collect data on control during the day following overnight control. At that time, DiAs and the CGM will be discontinued, and you will resume your normal home insulin therapy.

You will be discharged by approximately 6 PM if your fingerstick value is 80-300 mg/dL, ketones are <0.6mmol/L and your glucose trend is stable. A meal will be offered to you.

You will be asked to check BG before dinner, at bedtime, and upon awakening the following day and to monitor for possible symptoms of hypoglycemia since discharge.

Visit 5 (Day 35-37) – Hotel/Research House Admission (48 hour admission)
If you participated in the Control Admission during Visit 4, you will participate in the Experimental Admission at visit 5. If you participated in the Experimental Admission during Visit 4, you will participate in the Control Admission at visit 5. There will be 4 weeks between these admissions. You will have up to 3 months to complete this second admission; otherwise, we will need to discontinue your participation in the trial.

STUDY SCHEDULE

Study Procedures	Screening	Study Training	Data Collection	Research Admission	Research Admission
Visit	1	2	3	4	5
Days	1	2	3-31	32-34	35-37
Duration (approximate times)	2 hours	~2 hour	28 days	48 hours	48 hours
Location	CRU	CDT	Home	Research House	Research House
Informed Consent	X				
Clinical exam & medical history	X				
Inclusion/Exclusion Criteria	X				
Screening Labs	X				
Urine pregnancy test (women able to become pregnant)		X		X	X
CGM Use		X	X	X	X
DiAs Use				X	X
Equipment Downloads			3-5 times	X*	X*

CRU = Clinical Research Unit *Post admission

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 as advised by the study staff.
- 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.
- 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.
- You must not use acetaminophen (like Tylenol) 24 hours prior to wearing the continuous glucose monitor sensor and while you are wearing the sensor.

Blood Testing

We will take (or “draw”) up to 2 tablespoons of blood during the screening visit. You will take fingersticks during the trial to measure your blood glucose levels. The physician may ask that you take more fingersticks to help monitor your glucose levels. No other blood sampling will be completed during the trial.

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). When these tests are done, any remaining sample will be thrown away. It will not be stored for any future testing.

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

During the study you are having an investigational test done. The purpose of the test 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 can ask for more information about the study results.

What are the risks of being in this study?

Possible side effects that may occur during this study include:

Risks related to treating type 1 diabetes (with or without using DiAs):

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

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, hospitalization, and even death.

Risks associated with continuous glucose monitor insertion:

Likely:

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

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 or secondary skin infection

Rarely:

- Swelling or redness at insertion site
- Psychological reaction to viewing the continuous glucose monitor information or attending to continuous glucose monitor alarms or fingerstick 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 of insulin pen use:

Likely:

- Inadequate mixing of insulin, leading to improper dosing

Less Likely:

- Leaving an insulin needle attached to the pen, contributing to air bubbles accumulating within the insulin and pen and leading to improper dosing of insulin or insulin contamination.

Rarely:

- Sharing insulin pens may result in a bloodborne pathogen (a bacteria or a virus that can cause disease)

Risk of symptoms related to wearing the Fitbit:

Rarely:

- Skin irritation or redness

Risks and side effects related to blood glucose collection via fingerstick:

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

Risks associated with performing a serum (blood) or urine pregnancy tests (women who are able to become pregnant):

Less Likely:

- False positive or false negative results

Risks associated with staying at the research house:

Likely

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

Risk of sharing the Continuous Glucose Monitor

We will use the continuous glucose monitor equipment with other study subjects. The sensors will not be shared. The transmitter wirelessly sends your glucose information from the sensor to the receiver. The transmitter, which snaps into the sensor, will be cleaned thoroughly with a diluted mixture of bleach or another appropriate cleaner after use. 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 bloodborne pathogen, such as Hepatitis B, may be spread if used with multiple patients.

Risk of sharing an Insulin Pen (MDI users only):

Insulin pens should never be used for more than one person, even when the needle is changed. The insulin pen provided to you during this trial will be properly labeled with your name to ensure that the correct pen is used exclusively by you.

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 of Videotaping/Audio taping:

With your permission, we may photograph or videotape your participation in this trial. Photographs and videotapes will be used in presentations at conferences, to potential study subjects, and to potential research donors. Your willingness to have photos taken is independent of your participation in this trial. Your photo or videotape will not be used without your consent. Your identity can remain anonymous.

_____ Initials ☐ I agree to be photographed/videotaped during this trial.

_____ Initials ☐ I agree to be photographed/videotaped during this trial but would like to remain anonymous.

_____ Initials ☐ I do **NOT CONSENT** to being photographed/videotaped during this trial.

Risks for women:

You must use an approved form of birth control during this study. You will be told to ask your doctor for more details about the proper birth control method. If you become pregnant during this study, you are told to inform your study doctor right away. Your study doctor will discuss her treatment and the effect of the study on your pregnancy.

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 will not benefit from being in this study. However 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 illness or condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include continuing your home insulin regimen.

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.

Will you be paid for being in this study?

You will be paid $200 when you complete both the Experimental and Control Admissions. Payment will be processed upon receipt of all study equipment, including the experimental inPen Smart Insulin Pen if used, and data has been returned to the study team. You should receive your payment by check about 4 weeks after finishing the study. The income may be reported to the IRS as income.

Due to the importance of the data collection period and the Experimental Admission, the payment is based on successful completion of both visits.

- Completion of Visit 3: $50
- Completion of Visit 4: $50
- Completion of Visit 5: $50
- Completion of the study: $50

There is no payment for visit 1 and 2.

If the study leader says you cannot continue or you elect to withdraw from the study, you will be paid for the visits that you have completed.

You will also be reimbursed the mileage rate established by the Commonwealth of Virginia from your home address to the hotel/research house (maximum 900 miles). You should get your reimbursement about 4 weeks after you submit your receipts/ mileage.

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.

Will being in this study cost you any money?

Being in this study will not cost you any money. Your insurance company will also not be billed.
The study will provide you with the following to use during the study:

- Smartphone device (DiAs)
- Continuous Glucose Monitor System and sensors
- Commercially available insulin pens with short acting insulin during the Experimental admission
- Blood Glucose Meter and Test Strips
- ***You will use your own insulin.***
- You will be permitted to keep the study glucometer and the commercially available insulin pen at the end of the study, but all other equipment will be returned to the study team.

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 for an estimate of your financial costs. You may also wish to check with your insurance company before the study starts. Ask what they will cover and if they require you to get their permission before you decide to be in the study.

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?

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. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

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) New information shows the treatment will not work or is not safe for you
e) You do not follow your doctor's instructions

If you decide to stop being in the study and you are wearing the study CGM and Fitbit, we will ask you to return it to the Center for Diabetes Technology. The CGMs and Fitbits remain property of the study sponsor and will need to be returned.

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 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.
- Researchers from outside of UVa may be present during your study visits. They will be observing to learn how to conduct this study and to train on the use of the equipment in order to conduct the trial at their own sites in the future.

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.

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.

Research House (if used)

The University of Virginia has granted the Center for Diabetes Technology the use of a facility designated home to perform the outpatient studies related to the Artificial Pancreas Project. The guesthouse is a 4 bedrooms/4 bath home. The study team may test 3-4 study participants at the same time. Consequently, there are important confidentiality issues that you may want to consider when participating in this trial:

- A bedroom will be designated specifically for your use, but you may need to share a bathroom with another study participant.
- Study staff will introduce you to other study participants by using only your first name. Any other level of personal information (i.e. last name, profession, etc.) disclosed to other participants is your choice.

- Both men and women may be admitted to the guesthouse at the same time.
- Other participants may witness the study team attending to your needs (i.e. when your blood glucose level is low or high). Other participants do not have access to the DiAs information on your cell phone.
- Internet service is available for your use, but the IP addresses of any personal devices (laptop, tablet, smartphone, etc.) used to access the internet via the house's network will be tracked and visible to those people and entities that have access to the network traffic and physical system.

ZIP Folder

Data from your equipment may be downloaded and submitted to the study team. We strongly recommend submitting your data in an encrypted folder attached to an otherwise blank email. The study team will provide you instructions on how to do this. We are requesting an encrypted folder and a blank email to add additional security to your private information within these files. Should you decide to attach the unencrypted, separate files in an email to the study team, you are accepting the risk that your information may be compromised. Email messages, by themselves, are not secure and even if your home or work computer is on a protected server, the email may pass through an unsecure server in transit.

Carelink Pro & Diasend:

For this study, you will be asked to download study-critical diabetes devices via Diasend or Carelink and provide CDT access to the data. Diasend and Carelink are commercial, online diabetes device collection, storage, and analysis services used for personal, clinical, and research purposes; they are operated by Diasend and Medtronic respectively. You will be provided with instructions on the use of the service(s) as needed. If you are unable to download from home, you will be asked to come to the CDT office for assistance.

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. 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 researchers 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

Daniel Cherñavvsky, M.D.
University of Virginia, Center for Diabetes Technology
Box 400888 Charlottesville, VA 22908
Phone: 434-243-1395

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

Parental/ Guardian Permission

By signing below you confirm you have the legal authority to sign for this child.

_____	_____	_____
PARENT/GUARDIAN (SIGNATURE)	PARENT/GUARDIAN (PRINT NAME)	DATE
_____	_____	_____
PARENT/GUARDIAN (SIGNATURE)	PARENT/GUARDIAN (PRINT NAME)	DATE

If you are unable to obtain parental permission from both parents/guardians, explain why not:

_____

Person Obtaining Parental/Guardian Permission

By signing below you confirm that you have fully explained this study to the parent/guardian, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING PARENTAL/ GUARDIAN PERMISSION (SIGNATURE)	PERSON OBTAINING PARENTAL/GUARDIAN PERMISSION (PRINT NAME)	DATE

Assent from Child (15-17 years of age)

Consent from the parent/guardian MUST be obtained before approaching the child for their assent.

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

Person Obtaining Assent of the Child (15-17 years of age)

Consent from the parent/guardian MUST be obtained before approaching the child for their assent.

By signing below you confirm that the study has been explained to the child (less than 18 years of age), all questions have been answered and the child has voluntarily agreed to participate.

_____	_____	_____
PERSON OBTAINING ASSENT (SIGNATURE)	PERSON OBTAINING ASSENT (PRINT)	DATE