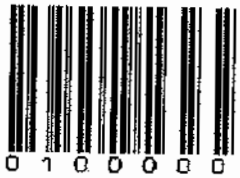

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Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name _____

Principal Investigator: Chiara Fabris, PhD
Center for Diabetes Technology
University of Virginia
P.O. Box 400888
Charlottesville, VA 22908

Sponsor: Juvenile Diabetes Research Foundation (JDRF)

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.

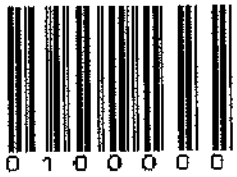
Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Who is funding this study?

This study is being funded by the Juvenile Diabetes Research Foundation (JDRF). All study equipment, which are commercially available products, have been purchased with study funding.

Why is this research being done?

The purpose of this study is to test a new method to calculate insulin boluses, which adjusts the amount of insulin given based on your sensitivity to insulin action: if you appear to be more sensitive to insulin than usual, your insulin dose will be reduced; if you appear less sensitive to insulin than usual, your insulin dose will be increased. Your sensitivity to insulin will be estimated using an algorithm (or formula) which relies on information received from your continuous glucose monitor (CGM) and subcutaneous insulin pump. In this study, the proposed bolus calculator will be compared to standard therapy (i.e., how you usually determine your insulin for a meal) in the control of one dinner meal following an afternoon exercise session.



The postprandial control will be assessed in terms of occurrence of hypoglycemia and percent time spent between 70 and 180 mg/dL as measured by CGM, which will be expected to be better when the optimized bolus calculator is used.

You are being asked to be in this study, because you are between the ages of 18-65, have been diagnosed with type 1 diabetes, and use an insulin pump.

Up to 25 subjects will take part in this study at UVA.

How long will this study take?

If there are NO Admissions repeated:
Your participation in this study will require four study visits and one 14-to-28-day at-home data collection period, over approximately four months. Visit 1 is a Screening Visit to determine your eligibility. This visit may take about two hours to complete. Visit 2 is a 1-hour visit to train you on the study requirements and devices. Visit 1 and 2 may occur on the same day if you meet study eligibility. Visit 3 and 4 are visits to our research center that last up to 24 hours (one Experimental and one Control Admission performed in random order). You will have a follow up check-in up to 48 hours after Visit 3 and Visit 4 to see if you are feeling well after the completion of the study. The 14-to-28-day Data Collection Period will happen between Visit 2 and Visit 3 and will serve to collect CGM data and insulin pump records needed for the SI-informed bolus calculator.

If any Admissions are repeated:
Visit 3 or Visit 4 may be repeated up to two times. (i.e., there may be up to six study visits over approximately two months).

Note: All procedures, assessments and tests described in this consent are being done solely for research purposes.

What will happen if you are in the study?

SCREENING (visit will last about 2 hours)

Visit 1 (Day 1):
If you agree to participate, you will sign this consent form before any study related procedures take place. Before you can start in the study, there will be a screening period. You will have tests and procedures during this time to make sure you are eligible, and it is safe for you to participate. These include the following:

- Collection of information about you: your diabetes history, past and current medical conditions, surgical procedures, menstrual history (females), allergies, medications and supplements, social history (including drinking, smoking and drug habits), and whether or not you have various symptoms
- Your pump settings and average daily insulin use over the past seven days
- Collection of your contact information
- Physical exam
- Electrocardiogram (ECG) to see how well your heart is working
- Blood testing (results collected within the last 4 weeks may also be acceptable)
    - HbA1c blood test to test for your average blood sugar over the last 3 months
    - Comprehensive Chemistry Panel blood test to see how well your kidneys and liver are working and to check for salts and sugars
    - Thyroid Stimulating Hormone (TSH) blood test to see how well your thyroid is working
    - Additional blood test if your study doctor has any concerns about medical conditions that might affect your participation in the study
- Current exercise pattern
- A urine pregnancy test if you are a woman who can become pregnant. The pregnancy test must be negative in order for you to participate and will be repeated at each follow-up clinic visit during the study.

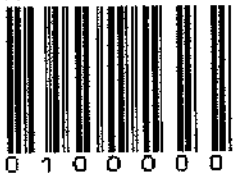
If these tests show you are eligible, you will return to the research site either that day or another day for Visit 2 to begin study treatment.

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 your insulin pump and your glucometer. You will use a study provided continuous glucose monitor (CGM) and a study activity tracker (i.e., Fitbit).

Experimental Admission *– Insulin Sensitivity-Informed (SI) bolus calculator will be used to calculate dinner meal bolus*

Control Admission *– Standard bolus calculator will be used to calculate dinner meal bolus*



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VISIT 2 (Day 2) – Study Equipment 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.

You will be taught how to calibrate the CGM per manufacturer's guidelines. You will be asked to perform all required calibrations with fingerstick glucose measurements. Any additional blood glucose (BG) tests normally done by you should continue without interruption.

You will be asked to not change your insulin therapy parameters for the duration of the study. If an insulin therapy change is recommended or required, it will have to be approved by the study medical doctor. If a change happens, you may be asked to extend the data collection period.

You will be asked to wear the study activity monitor during the data collection phase, removing prior to bathing and participating in water activities. You will also wear the activity monitor to collect information on activity, exercise, heart rate, and sleep. A study Gmail account will be established for you. The commercially available app associated with the activity monitor will be placed on your smartphone or personal laptop so you can download the data. If you currently have an account, you may use this account, but you would need to grant the study team access to the account.

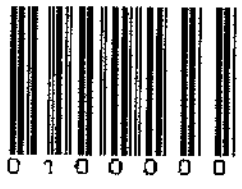
Study staff will instruct you on how to download the equipment (i.e., personal insulin pump, glucometer, study CGM, and study activity monitor).

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

Data Collection Period Prior to Control/Experimental Admission (approximately 14 to 28 days)

During this collection phase, the study team will collect information on your glucose values, activity measures and insulin settings.

During this collection phase, you will follow your usual regimen for the full 14-to-28 day period. However, we will ask that you wear the continuous glucose monitor along with your insulin



pump. You will be asked to use the bolus calculator function on your insulin pump and enter the carbohydrate information that you eat during the week. You will be asked to record in your pump any bolus insulin treatments that you have provided yourself with use of an insulin pen or needle injection.

You will need to wear an activity tracker during this data collection phase. If the tracker 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 about every 7 days. The study team will review this data to check that the data is being collected correctly. You may be asked to do more frequent downloads or to repeat this collection phase. **You will be asked to consistently use the bolus calculator (or "wizard") of your insulin pump to calculate meal and correction boluses during this Data Collection Phase, which may result in a different way of administering insulin than you normally do.** Once the data has been successfully completed, the study team will use this data to create a 24-hour SI profile that will be used in the optimized bolus calculator during the Experimental Admission.

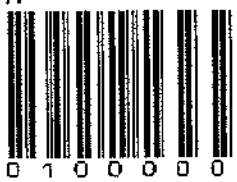
You will be asked to bring your own personal insulin pump, glucometer, and insulin for the study admission.

Study Procedures that will occur during both Visit 3 and Visit 4:

- Study admissions will occur at a local hotel and transportation will be provided to a local gym. Each admission will last about 24 hours; visit 3 and visit 4 should be at least 48 hours apart.
- **Note: the CGM used in this study is approved by the FDA to measure blood glucose and will be the primary way for the study team to keep track of what yours is. However, you may be asked to perform fingerstick measurements to calibrate the CGM and if directed by the study team.**

Prior to Visit 3 and Visit 4

1. The study team may ask you to insert new CGM sensor up to 48 hours prior to the start of Visit 3 and Visit 4.
2. You will be asked to avoid physical activity and alcohol consumption in the 48 hours prior to Visit 3 and Visit 4.



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3. The principal investigator will review the data collected during the at home Data Collection Period and will determine the set of parameters you will use during the Experimental and Control Admission in order to optimize postprandial glycemic control.
4. You will be asked to eat your normal breakfast before checking-in at the research location (caffeine permitted).

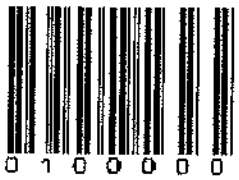
Procedures at beginning of Visit 3 and Visit 4

1. You will meet the study team and check in to the research location at approximately 9:00AM.
2. The study team will confirm that you have brought your insulin, insulin pump supplies, and regular medications.
3. You will have your vital signs measured.
4. You will not be allowed to start the study if you have a fever or had a significant illness within 48 hours of admission.
5. A fingerstick ketone measurement will be obtained.
6. Female subjects of childbearing potential will be required to complete a urine pregnancy test. If positive, you will be discontinued from the study. You will be asked to seek confirmation of this test result and seek appropriate medical care by your physician.

The admission may be rescheduled if these criteria are not met.

Procedures during Visit 3 and Visit 4

1. **Lunch:** A lunch meal will be served at approximately 12:00PM. You will estimate the amount of carbohydrates in the lunch meal. The amount of carbs designated will be consistent between the Control and Experimental admission.
2. **Exercise Session:** During both the Experimental and Control Admissions, you will be transported to a local gym at approximately 2:00PM to begin controlled exercise at 2:30PM. The exercise session will consist of three 15-minute bouts of moderate-intensity exercise (i.e., stationary bicycle). Activities will occur in an indoor setting with a licensed healthcare professional present. Upon the completion of the exercise session, you will be transported back to the hotel. Transportation will likely be provided by the hotel shuttle.



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3. Quiet activities will be conducted during the afternoon until the time of discharge.
4. **Dinner:** A dinner meal will be served at around 7:00PM. The amount of carbs that you designate will be consistent between the Control and Experimental admission.
    a. **Experimental Admission:** You will estimate the amount of carbohydrates in the dinner meal. The dinner meal bolus during the Experimental Admission will be determined with the use of the SI-informed bolus calculator. These calculations will be performed on a study smartphone (Diabetes Assistant = DiAs), approved by the study medical doctor, and subsequently communicated to you. The suggested insulin bolus will be administered through your insulin pump.
    b. **Control Admission:** You will estimate the amount of carbohydrates in the dinner meal. The dinner meal bolus will be based on your normal parameters (i.e., insulin-carbohydrate ratio, insulin sensitivity factor, etc....).
5. **Overnight:** At approximately 10:00PM you will be instructed to go to sleep and the following morning at approximately 9:00AM you will be discharged after being offered breakfast with no dietary restrictions.
6. Fingersticks will occur prior to calibration of CGM if calibration is requested by CGM or DiAs. Study personnel may also request additional fingersticks at their discretion.
7. All meal and correction insulin boluses will be based on CGM.
8. During both the Experimental and Control Admissions, you will be asked to consult with the study team for all insulin dosing decisions.
9. Hypoglycemia treatment (e.g., glucose tablets, glucose gel/liquid, and a glucagon emergency kit) will be available for treatment at all times.
10. You will be allowed to consume caffeine at breakfast before the admission and at the end of the admission before discharge; no caffeinated beverage consumption is allowed during the study admissions otherwise.
11. You will have access to ad lib glucose-free beverages.
12. A study medical doctor will be available for any clinical concerns and will approve the meal bolus for dinner during the experimental admission.
13. You will be accompanied by a medically qualified staff member (i.e. nurse) during the admissions.
14. Your glucose will be continuously monitored by the study team during the entire admission. If your blood glucose values reach certain levels (too low or too high), the medical doctor may check your ketones with a fingerstick and give you the appropriate treatment to correct your levels (hypoglycemia rescue carbs or hyperglycemia correction insulin boluses).

Procedures Related to Discharge

1. At approximately 9:00AM, you will be discharged once the CGM value is 80-250 mg/dL and

fingerstick ketone ≤0.6 mmol/L.

2. You may wear the study equipment home after the completion of Visit 3 per study team judgement. Equipment will be returned to the study team at the completion of Visit 4.
3. You will resume your normal home insulin therapy.
4. You will be offered breakfast prior to discharge.
5. You will be asked to check blood glucose values and to monitor for possible symptoms of hypoglycemia since discharge.
6. The study team may ask you to repeat up to two study admissions. Repeated admissions may be needed because:
    a. Infusion site failure
    b. Inadequate data capture

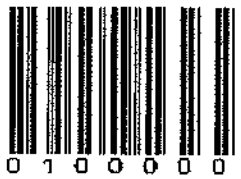
FOLLOW UP:

Study staff will contact you by phone within 24-48 hours after discharge to ask how you are feeling.

STUDY SCHEDULE

Study Procedures	Screening	Study Training	Data Collection	Research Admission	Research Admission
Visit	1	2		3	4
Days	1	2	2-30	31	32
Duration (approximate times)	2 hours	~1-3 hour	14-28 days	9-12 hours	9-12 hours
Location	CRU	CRU	Home	Hotel	Hotel
Informed Consent	X				
Clinical exam & medical history	X				
Inclusion/Exclusion Criteria	X				
Electrocardiogram (ECG)	X				
Screening Labs	X				
Urine pregnancy test (women able to become pregnant)		X		X	X
CGM Use		X	X	X	X
Exercise				X	X
Equipment Downloads			~7, 14 & 28 days	X*	X*
Follow-up Call				X*	X*

CRU = Clinical Research Unit *Post admission



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What are your responsibilities in the study?

You have certain responsibilities to help ensure your safety.

These responsibilities are listed below:

- You must attend every study visit.
- You must be completely truthful about your health history.
- Follow all instructions given.
- You should tell the 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.

Blood Testing

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

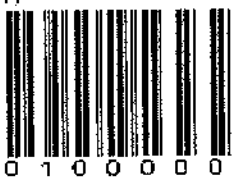
When these tests are done, any left-over sample will be thrown away or they will be de-identified. This means there is no information that could be used by anyone to determine who the sample came from.

You will take fingersticks during the trial to calibrate your CGM. The study medical doctor may ask that you take more fingersticks to help monitor your glucose levels.

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

During the study, the study team will let you know of any test results that may be important to your health. In addition, as the research moves forward, the study team 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.

Possible risks and side effects that may occur during this study include:



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Risks related to treating type 1 diabetes (with or without using study equipment that utilizes the SI bolus calculator)

Likely:

- Risk of possible mild to moderate low blood sugar and possible symptoms of low blood sugar, such as sweating, trembling, difficulty thinking, dizziness, and feeling uncoordinated.
- Risk of possible mild to moderate high blood sugars and possible symptoms of high blood sugars such as thirst and frequent urination. You may have a higher level of sugar in your urine.

Rare but serious

- Risk of severe temporary low blood sugar (hypoglycemia) that can lead to unconsciousness, hypoglycemic seizure, hospitalization or even death.
- Risk of prolonged high blood sugar leading to diabetic ketoacidosis, 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.

Continuous Glucose Monitoring Sensor Risk

Likely:

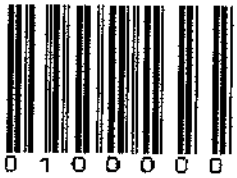
- Failure or lack of sensitivity of the continuous glucose monitor sensor that requires replacement / insertion of new sensor
- Fingerstick for calibration of the continuous glucose monitor
- Discomfort from insertion of sensor

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.

Fingerstick Risks

Likely:

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

Less Likely:

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

Rarely:

- Infection at site of lancet use

Wearing a Commercially Available Activity Monitor Risk

Rarely:

- Skin irritation or redness

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

Less Likely:

- False positive or false negative results

Study-Related Exercise Activities Risk

Less Likely:

- Risk of injury

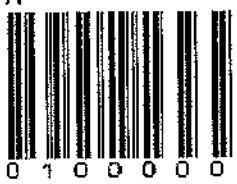
Transportation to Study-Related Activities Risk

Rare:

- Risk of harm from a motor vehicle accident

Risk of Sharing the Continuous Glucose Monitor

We may 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 blood borne pathogen, such as Hepatitis B, may be spread if used with multiple patients.

Blood Donation

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

Risks of having your blood drawn:

Having blood drawn may cause:

- ✓ pain (common),
- ✓ a bruise (sometimes),
- ✓ fainting or passing out (not very often), and
- ✓ infection (rare).

If the people doing the study are exposed to your blood or body fluids in a way that could give them a disease, your blood may be tested. The tests might check for:

- ✓ hepatitis,
- ✓ HIV (Human Immunodeficiency Virus), or
- ✓ other infections.

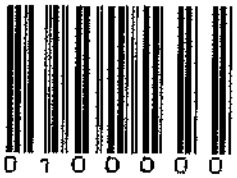
You and the person exposed would be told the test results. However, your name would be kept private. If your test is positive for hepatitis or HIV or any other infection that may affect your clinical care, we will tell you the results and help you understand what the results mean for you.

Risks for women:

Being in this study might hurt your unborn baby, so you will not be able to join or stay in the study if you are pregnant. You must use an effective method of birth control during the study if you are sexually active. If you are pregnant now, or get pregnant during the study, please tell us right away. Examples of effective birth control include the following:

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

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



Other unexpected risks:
You may have side effects that we do not expect or know to watch for now. Call the study team 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 for your T1DM even if you choose not to be in this study. The usual treatment would include continuing your home insulin regimen.

However, in order to do this study, we must change the equipment that you use in usual treatment. This would be wearing the study CGM. We plan to use the activity calculator to calculate your insulin dosage needed for your dinner meal during the experimental admission.

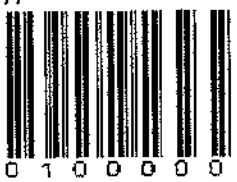
- If you are a patient at UVa, your usual care will not be affected if you decide not to participate in this study.
- If you are an employee of UVa, your job will not be affected if you decide not to participate in this study.
- If you are a student at UVa, your grades or classes will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?
If no admissions are repeated, you will be paid up to $250 for finishing this study.

You will receive payment after the study equipment has been returned to the study team.
You should get your payment by check about 4 weeks after finishing the study. The income may be reported to the IRS as income.

- Completion of Visit 2 (Study equipment training & data collection period): $100/if repeated $200.00.
- Completion of Visit 3 (Experimental or Control Admission): $75
- Completion of Visit 4 (Experimental or Control Admission): $75

If you are required to repeat data collection due to mechanical issues or issues beyond your control as determined by the Principle Investigator, you will be paid an additional $100.00.



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If you have repeated admissions for Visit 3 or Visit 4: You will be compensated the above rates if the study team asks you to repeat an admission (i.e. $75 for one extra admission; $150 for two extra admissions) which is a payment of $325 for repeating one admission and $400 for repeating two admissions. If the principal investigator says you cannot continue, you will be paid the full amount ($250) for the study.

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?

All of the procedures in this study will be provided at no cost to you or your health insurance. You will be responsible for using your own insulin pump, insulin and glucometer. Parking is available at no cost at the research sites.

You and/or your insurance company must pay for any tests or care given beyond what is required in this study. In addition, you and/or your health insurance may also have to pay for other drugs or treatments that are given to help you control any side effects. You will have to pay for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask your insurance company for an estimate of what these costs might be or if pre-approval is required.

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

What if you are hurt in this study?

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

What happens if you leave the study early?

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, someone from the study team can take you out of the study. Some of the reasons for doing so may include

a) Your study medical doctor 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
f) 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 CGM and activity tracker study equipment remain property of the CDT 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

Medical Record Number: _____

- 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.

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.

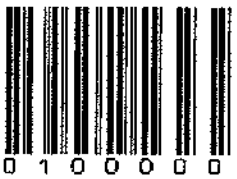
A description of this clinical trial will be available on *http:// www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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 researchers listed below to:



Medical Record Number: _____

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

What if you have a concern about this study?

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

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

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

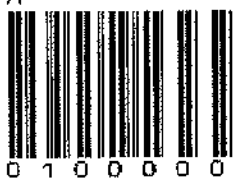
What does your signature mean?

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.



Medical Record Number: _____

Person Obtaining Consent

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

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

Notification of My Health Care Provider

Please indicate below whether you want us to notify your health care provider that you have agreed to take part in this study.

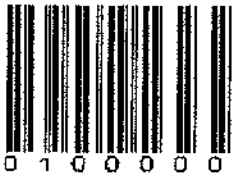
_____ Yes, I want the study doctor to notify my health care provider that I have agreed to take part in this study.

Health Care Provider Name: _____

Health Care Provider Address: _____

Study team will send a copy of the consent form to the health care provider.

_____ No, I do not want the study doctor to notify my health care provider that I have agreed to take part in this study or I do not have a health care provider.



Medical Record Number: _____

Leaving the Study Early

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

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

Check one option below:

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

- **Phone call within 36 hours after subject withdraws from the study.**

____ 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