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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_____ **Medical Record #** _____

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

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

Who is funding this study?

This study is being funded by the University of Virginia School of Medicine Launchpad Program. Medtronic Inc. will provide InPen™ at no cost to the study. The continuous glucose monitoring (CGM) supplies and other studies supplies will be purchased with grant funding.

Key Information About This Research Study

Principal Investigator:	Anas El Fathi, PhD University of Virginia Center for Diabetes Technology (CDT) Box 400888, Charlottesville, VA 22903 Telephone: 434-982-0602
Funding Source:	University of Virginia Launchpad Program

You are being asked to take part in a research study. You do not have to take part in this study. You should only agree to take part in this study after reading this consent form and discussing it with the study team. You may also discuss this with your family, friends, health care providers or others before you make a decision.

What is the purpose of this study?

Most people with type 1 diabetes mellitus (T1DM) have benefited from developments in artificial pancreas technologies that automatically monitor and adjust insulin doses. These technologies improve blood glucose control. People using MDI treatment have not had similar progress with new technologies that help their diabetes management. As a result, diabetes-related illnesses remain high for these people. This study proposes to test an artificial pancreas-like algorithm that may improve blood glucose control in people using MDI treatment.

The purpose of this study is to improve blood glucose levels after eating meals even when you are not able to exactly measure the carbohydrates in the meal. This study will test an investigational

algorithm (complex mathematical formula) called InsuLearn under the supervision of experienced doctors who recommend the amount of insulin to bolus with your meal. The study is aimed at people using multiple daily injections (MDI treatment) and having difficulty with counting carbohydrates.

You will initially start the study by collecting information (data) at home about how much insulin you use to eat your meals. You will use a smart insulin pen called InPen™ to deliver insulin, help calculate insulin doses and estimate carbohydrates for meals. The InPen is a reusable insulin pen available by prescription for people living with diabetes. The InPen can communicate wirelessly with your phone via a commercial app. You will be asked to use the InPen app to record and deliver your insulin doses. The app will be set to the "meal estimation" mode where you will select the meal category: if it is a breakfast/lunch/dinner/snack and if it has low/med/high carb amount.

You will also be asked to wear a continuous glucose monitor (CGM) during the study. A CGM is a small wearable device that measures and tracks your glucose levels in regular intervals, as frequently as every 5 minutes, then translates the readings into easy-to-read data and information.

After collecting this data at home, you will be asked to stay at a local hotel for 51 hours to test the algorithm. If you are randomized (like a flip of a coin) to Group A (InsuLearn then Usual Care), the data that you collected at home will be entered into the algorithm, and the algorithm will determine your new insulin dose for all your meals for the first day. The study physician will review this insulin recommendation provided by the algorithm before you administer your insulin dose. On the second day of the local hotel stay, you will take your insulin at mealtime like you usually do when you are home (usual care). If you are randomized to Group B (Usual Care then InsuLearn), you will take your insulin at mealtime like you usually do when you are at home (usual care). One the second day of the local hotel stay, the data that you collected at home will be entered into the algorithm, and the algorithm will determine your new insulin dose for all your meals for the second day.

The InsuLearn algorithm is investigational and is not approved by the U.S. Food and Drug Administration (FDA). This algorithm has not been tested on humans. 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 InsuLearn algorithm is the only device that is being studied in this trial.

You are being asked to take part in this study because you are 18 years old or older, and you are using MDI to treat your T1DM.

Why would you want to take part in this study?
You might like to take part in this study because this study may improve your understanding of your diabetes or may improve your ability to manage your diabetes. You will not be helped by being in this study, but the information gained by doing this study may help others in the future.

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

You might not want to take part in this study because of the following reasons:

- This study uses an algorithm called 'InsuLearn' which is not approved by the FDA.
- Your participation in the study will last about 6 weeks.
- You will need to stay at a local hotel with other study participants for about 51 hours. The study team will determine the hotel admission 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.
- You will need to use one of the following short-acting insulins during the hotel admissions: Novolog, Humalog, and Fiasp. If not using one of these insulins, you will be asked to contact your healthcare provider to change your prescribed insulin to one of these insulins as they are the FDA-approved insulins for use in the InPen. Your healthcare/insurance will have to pay for this insulin.

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 Dexcom or Medtronic continuous glucose monitor (CGM) during the study. You will be provided with these supplies at no cost.
- Be required to use a smart insulin pen, called InPen, to dispense your insulin. You will be asked to record information in the InPen app .
- Be instructed not to adjust your insulin parameters without speaking with the study physician before you make any changes.
- Be willing to remain on same dose of non-insulin glucose-lowering agent during the trial (including metformin/biguanides, GLP-1 receptor agonists, pramlintide, etc.) during the study's data collection phase (visit 3 through visit 8) if currently taking this medication.
- Be willing to discuss any medication changes with the study physician prior to making the change.
- Need to share your CGM and insulin data with the study team.
- Need to participate in a hotel admission consisting of two, 24-hour periods held back-to-back, lasting up to 51 hours.
- Eat the same breakfast/lunch/dinner during the hotel admission, 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 admission unless it is for the treatment of a low blood sugar. You will be provided with these snacks at no cost.

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 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 be in this study at UVA.

How long will this study take?
Your participation in this study will require 8 study visits over about 6 weeks. The screening visit (visit 1) and the equipment training visit (visit 2) will take about 60 minutes each. The Data Collection Period (visit 3) will be about 4 weeks. Visits 1, 2, and 3 visits may be completed by video chat, phone call, and/or in-person clinic visit. Visits 4 and 5 are check-in visits 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 admissions (Visit 6 and 7) will be two, 24-hour periods held back-to-back, lasting up to 51 hours. A post-study check-in visit (visit 8) 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 12 months may be substituted.
- Blood may be taken from your finger to obtain a hemoglobin A1c test. This is the same test that you 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 a female of childbearing potential, 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 test is 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) that is convenient to you.

If these tests show you are eligible, you will be asked to complete the AdultCarbQuiz and the 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. These surveys will take about 20 minutes to complete.

Visit 2: Study Equipment Training

(Day 2) This visit may be completed in person, by telephone, or video chat and will last about an hour. This visit may be scheduled as soon as you meet study eligibility, and it is convenient for you to attend the training visit.

You will be trained on how to use the study equipment. This training includes:

- CGM training: You will be taught how to use a CGM, how to review the CGM data, and how to use the cloud application (app).
- InPen(a smart insulin pen): You will be taught all the features of the InPen and how to record information in the app.
- Glucometer training: You will be taught how to use a glucometer, how to properly collect a blood sample which is called a fingerstick, and how to use the glucometer app.

This training may involve you watching manufacturer training videos. You will have the option of placing the apps for this equipment on your personal phone or be provided with a study phone. You will be responsible for any charges related to your personal phone.

The CGM equipment, InPen, and glucometer + test strips will be provided to you to use during the study. This equipment will be shipped to you via FedEx prior to the visit 2 appointment if you are completing this visit remotely. Otherwise, you will receive the equipment in-person at visit 2.

Visit 3: Data Collection Phase

(Day 3-33) Data collection will occur at home and will last about 4 weeks.

After the training session, you will begin a CGM Data Collection Phase for 4 weeks. You will be asked to wear the CGM continuously during this time. This data collection phase is a period of time after screening and before randomization (flip of a coin chance) to gather information on your normal insulin doses and amount of carbohydrates before the study intervention.

The CGM data will be stored in a cloud account. This information will be downloaded to establish your overall averaged CGM values and to determine the dosing measurements to be used during the hotel admission.

You will be required to record your insulin dose and the amount of carbohydrates (low/medium/high) at each meal in the InPen app for 4 weeks. The InPen app serves to record the insulin doses and the meal categories. It will help you calculate your dose of insulin, but it does not advise you on the amount of insulin that you should take. The pen injector allows you to dial the desired dose from 0.5 to 30 units in one-half (1/2) unit increments.

This phase may end early if you collect enough data for review. The study physician may ask you to collect more data if it is needed. This additional time may extend your participation by a day or 14 days depending on the quality of the data that you have collected.

Visit 4: Data Collection Phase Check-In Visit

(About Day 17)

During the Data Collection Phase, the study team member will contact you by phone, email, text, or video call (about 15-30 minutes) to:

- Ask you about any changes to your medical history and medication.
- Review of your CGM data.
- 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.
- Review your smart insulin pen use such as any issues entering data and any issues related to use of the smart pen.

Randomization

Once you complete the Data Collection Phase, 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: InsuLearn→Usual Care

During the first 24 hours of the hotel admission, the insulin dose that you will take will be determined by InsuLearn and reviewed by the study physician. The second 24 hours of the hotel admission, you will estimate the insulin dose like you normally do (usual care) at mealtime.

GROUP B: Usual Care→InsuLearn

During the first 24 hours of the hotel admission, you will estimate the insulin dose like you normally do (usual care) at mealtime. The second 24 hours of the hotel admission, the insulin dose that you will take will be determined by InsuLearn and reviewed by the study physician.

Visit 5: Pre-Hotel Admission Check-In Visit

(About Day 39) 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 admission 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 admission for proper warm-up.
- Remind you that the CGM reading should be 80-250 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 study admission.
- Remind you to bring your insulin and other medications.
- Make a menu selection based on the options provided to you for the hotel admission.
- You will be reminded to bring quiet activities to enjoy during the hotel admission.
- Should any concerns regarding your health or unforeseen issues arise, the hotel admission may be canceled at the discretion of the study physician.

Visit 6 and Visit 7: Hotel Admission

(Day 40-41) This visit will be completed in-person and will last about 51 hours.

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

Hotel Admission Arrival:

- You will come to a hotel for admission for about 51 hours. The study interventions are about 48 hours in duration.
- The study team will confirm that you brought your insulin, insulin pen, CGM, glucometer, and regular medications to the hotel admission.
- You are not permitted to eat snacks during the hotel admission. The study team will provide snacks with carbohydrates (the sugar found in food) if you need treatment of hypoglycemia (low blood sugar).

Hotel Admission:

- You will continue to use the InPen during the entire admission.
- Study physician will review and adjust your InPen app parameters.
- Your CGM value by reviewing the value on the InPen app. Your ketone value will be tested by the study team with a fingerstick and then reviewed on the ketone meter. The study physician may provide treatment if these values are too high. This treatment may include asking you to drink fluids, walk, etc. to reduce your ketones prior to the start of the hotel admission.
- You will eat three standardized meals at approximately 7 am, 12 pm, and 5 pm. For example, a low-carb breakfast, a medium-carb lunch, and a high-carb dinner.
- You can maintain your regular exercise pattern, but you must do it on both days with staff supervision. You are not allowed to leave the hotel for safety reasons unless there is a legitimate reason that is discussed with the study staff.
- You will go to bed no later than 11 pm.
- 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 admission. A study phone number will be provided to you so you can contact the study team.
- Any adjustments to your current insulin parameters during the hotel admission will be done with the assistance of the study physician.

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 admission if ketones were elevated within 12 hours prior to discharge. Urine ketone strips may be provided to you if needed.
- You will return the CGM, InPen, and glucometer to the study team. The glucometer will be returned to you once the data has been downloaded by the study team.
- You will return to using your personal MDI treatment. A qualified clinical study team member (e.g., MD, NP, PA, CDE) will assess and discuss the transition back to your usual care.
- You will be asked to complete the Informal Assessment of Technology Acceptance questionnaire which is meant to help us learn about your experience in using InsuLearn during the hotel admission. This questionnaire will take you less than 5 minutes to complete.

Visit 8: Post-Study Check-In Visit

(Day 42) 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 Hotel Admission 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.

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), videoconferencing (VC), Phone (Ph) which includes text messages and emails.

	Screening	Equipment Training	Data Collection	Check-In Visit	Pre-Admission Check-In	Hotel Admission #1	Hotel Admission #2	Post-Admission Check-In Visit
Location	In Person or Remote	In Person or Remote	Home	Phone/ Email/ Text	Phone/ Email/ Text	Hotel	Hotel	Phone/ Email/ Text
Visit	1	2	3	4	5	6	7	8
Day	1	2	3-33	About Day 17	About Day 39	40	41	42
Contact Type	CV/VC/Ph	CV/VC/Ph	Home	VC/Ph	VC/Ph	In-person	In-person	VC/Ph
Informed Consent	X							
Eligibility Assessment	X							
Medical History	X							
HbA1c	X							
Pregnancy Test (if applicable)	X							
Lab test (if necessary)	X							
Physical Exam	X							
Vital Signs	X							
Demographic Survey	X							
AdultCarbQuiz	X							
Study Equipment Training		X						
CGM Use			X	X	X	X	X	
InPen Use			X	X	X	X	X	
Randomization					X			
Review Diabetes Management			X	X	X	X	X	X
Current medications			X	X	X	X	X	
Informal Assessment of Technology questionnaire							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.
- Answer all the study-related questions completely.
- 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.
- 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 team 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 or they will be de-identified. This means there is no information that could be used by anyone to determine who the sample came from.

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

During the study, you are having an investigational test done. The purpose of this investigational system is NOT to diagnose any disease or abnormality you may have. Because the testing is investigational, there is no way for the study leader to understand if the results are "normal" or "abnormal". However, if any test results are concerning, your study leader will let you know.

In addition, as the research moves forward, your study leader will keep you informed of any new findings about the research itself that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time, you may ask for more information about the study results.

What are the risks of being in this study?

Loss of Privacy:
The 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.

All identifiable information about you will be replaced with a subject number and code. A list linking the subject number and 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 admission 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 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 Smart Insulin Pen:

Less Likely

- Uncomfortable with study team members seeing the information that you have stored in the smart insulin pen

Rare but serious

- Entering higher number of insulin units into the smart insulin pen and then administering this insulin may lead to hypoglycemia
- Entering low number of insulin units into the smart insulin pen and then administering this insulin may lead to hyperglycemia

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

Risks and side effects related to the InsuLearn 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 or fingerstick:

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 Pen, Continuous Glucometer, and Ketone Meter:

Insulin pen, CGM, Glucometer, and ketone meter are 'single use devices'. This means that they recommend that only one person use this device as there is a rare risk that a blood borne pathogen, such as Hepatitis B, may 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.

Risks from Completing Questionnaires:

- 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.

- Some of the questions asked may make you angry, emotionally upset, or stressed out, now or at a later time. If this occurs, you may contact the study coordinator or the study physician (Dr. Ralf Nass at 434-924-0000) for help**.** If you do not wish to answer a question, you may skip it and go to the next question.
- There could be a risk of discomfort and harm (to psyche, reputation, employability, insurability, social status, criminal or civil liability) that may occur as a result of participation. If you do not wish to answer a question, you may skip it and go to the next question.

Risks for women:
If you are pregnant now or get pregnant during the study, please tell us right away. 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. You will have a pregnancy test at the start of the study. This test must be negative for you to participate in the study. You should also not get pregnant during the 6 weeks that you are in this study.

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.

Cybersecurity Risks
Like 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 pens 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 CGM settings which may lead to hypoglycemia or hyperglycemia. We do what we can to decrease the chance of that happening, but it cannot be guaranteed.

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 personal care for management of your diabetes developed by your physician.

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 up to $350.00 by check for finishing this study and all study supplies have been returned to the study team. 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.

You will be reimbursed at a flat rate of $100 for your travel expenses to the hotel unless the study team organizes airfare or train tickets.

If you do not finish the study, you will not be paid. 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)
- InPen smart insulin pen
- CGM supplies
- glucometer supplies
- any additional laboratory tests the study physician requested from you to participate in this study
- hotel and the meals

You will be responsible for the cost of the insulin that you use during the study. You will be responsible for charges related to you using your phone.

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.

Your travel costs will also be reimbursed. See the **"Will you be paid for being in this study?"** section of this form for more information.

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 at any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include:
a) Your study physician is concerned about your health.
b) Your condition gets worse.
c) The side effects of the study procedures are too dangerous for you.
d) You do not follow your doctor's instructions.
e) The study sponsor or doctor 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 via phone or written notification so that scheduled hotel admissions may be canceled. The study InPen, CGM supplies remain the property of the CDT and will need to be returned. You will be asked to complete the Study End (visit 7) and/or Post Study Check-In (visit 8) by phone or email. However, you may choose not to participate in these visits.

Any data collected about you up until the time you leave the study must be kept 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.
- 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 can include sponsors and other companies that provide supplies, and government agencies that provide oversight such as the Food and Drug Administration (FDA) as 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.

Other participants may take photos of this event. Your face may be in these photos. Other participants may post these photos on social media without your permission.

Information about you may be given to other researchers outside of the University of Virginia after all identifiers such as name, address, and phone number have been removed. Some of the people outside of UVA who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

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

Information 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 and ask any questions regarding study procedures or study treatments/interventions.
- 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: Anas El Fathi, PhD
Address: University of Virginia Center for Diabetes Technology (CDT)
Box 400888, Charlottesville, VA 22903
Telephone: 434-982-0602

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: 434-982-0602

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 unsecured email (email that is not encrypted) or text message to your 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.

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-*To be completed by the participant if 18 years of age or older.*

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

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

Signature of Impartial Witness

If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions he/she had about the study. I also agree that the **identified individual(s)** freely gave their informed consent to participate in this trial.

Please indicate with a check box the identified individual(s):

☐ Subject

_____	_____	_____
IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE

Notification of My Health Care Provider

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

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

Health Care Provider Name:_____

Health Care Provider Address:_____

The study team will send a copy of the consent form to the healthcare 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 that I do not have a health care provider.

Leaving the Study Early

Whenever possible, obtain signatures from subjects if they decide to leave the study early. However, verbal withdrawal is acceptable and must be recorded in the subject's chart and/or study record.

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.

____ 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
- One phone call
- Follow-Up visit 7 and visit 8 (By Phone or Email)
    - medical physical if needed
    - discuss your blood sugar levels

____ 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- *To be completed by the participant if 18 years of age or older.*

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

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