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?

The study is being funded by the University of Virginia Launchpad Program.

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, procedures, and duration of this study?

Setting basal insulin parameters typically takes several weeks and requires frequent consultation with your treating physician. The purpose of this study is to see if using an insulin pump could assist, and potentially accelerate, identifying the correct basal rates.

The Automated Insulin Delivery (AID) system used in this study will be the Tandem t:slim insulin pump with Control-IQ Technology and the FDA approved Dexcom G6 CGM. If you agree to participate, you will be randomly assigned to one of two study groups.

You are being asked to take part in this study because you have been diagnosed with type 2 diabetes

for at least one year and have been using only basal insulin for at least 6 months to manage your diabetes.

Why would you want to take part in this study?

You might like to take part in this study because this study may improve your understanding of your diabetes or may improve your ability to manage your diabetes. While there is no direct benefit to you to participate in this study, the information gained from this study may help other persons with type 2 diabetes mellitus at some future time.

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

You might **not** want to take part in this study because:

- You may need to wear the Artificial Pancreas (AP) System – the Tandem t:slim insulin pump with Control-IQ Technology.
- You will wear a continuous glucose monitor (CGM) provided by the study. A CGM measures your blood glucose values every 5 minutes and provides you with a real-time look at your glucose readings. On two different occasions, the CGM will be blinded to you, and you will not see the blood glucose values.
- You will need to discontinue wearing your personal CGM, if applicable.
- The insulin pump infusion set will need to be replaced approximately every 3 days. Reinserting the infusion set may cause you pain.
- The CGM sensor will need to be replaced every 10 days during the study. Reinserting the sensor may cause you pain.
- You will be instructed not to adjust your insulin parameters without speaking with the study physician.

What will I have to do if I take part in this study?

Full details of all the procedures are found later in this form. If you take part in this study, the following things will be done differently than if you do not take part in this study.

- Meet with a study doctor to see if you meet the criteria to participate in the study.
- The study team will contact you regularly during the study to check on your health and check on your use of the study equipment.
- You will be provided instructions on how to handle low and high glucose values.
- You will need to immediately return (i.e., mail) the Dexcom G6 Pro to the study team after wearing the device for 10 days.
- You will need to return the study equipment (i.e., AID System, study CGM supplies, study glucometer, remaining supplies, etc.) at the end of the study. The study the study glucometer will be returned to you once the study team has obtained the glucose values from the equipment or the meter's app.
- You will need to notify the study team of any illness, injury, hypoglycemic or hyperglycemic events during the study.
- Willingness 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.
- Willingness to discuss any medication changes with the study physician prior to making the change.

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 may use AID technology.
- You will use CGM provided to you by the study team.
- 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 20 people will be in this study at UVA.

How long will this study take?
Your participation in this study will require 10 study visits in about 33 days. The screening visit (Visit 1) and the equipment training visit (Visit 3) will each take about 60 minutes. Visit 2 and visit 6 will last about 15 minutes and then will continue for 10 days at home. Visits 4, 5, 7, 8, 9, and 10 are phone check-in visits that will take less than 15 minutes each. A videoconferencing tool (e.g., WebEx) may be used for remote visits.

What will happen if you are in the study?
NOTE: All procedures/assessments and tests described in this consent are completed for research purposes only.

Visit 1: Screening Visit (will last about 1 hour)
(Day 1/Remote or Clinical Research Unit (CRU) Visit)

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:
- 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. A hemoglobin A1c value that was obtained within the past 4 weeks prior to 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. Lab results within one year of your screening appointment may be used.
- A urine or blood pregnancy test will be completed if you are a female of childbearing potential. You will be asked if you are currently pregnant or might be pregnant. You are not able to participate in this study if you are pregnant or plan to get pregnant during the study period. This pregnancy test must be negative for you to participate in the study.

Note: Potential eligibility may be assessed as part of a routine-care examination. A physical exam documented in the prior 12 months can suffice for the physical exam but will not serve as an exclusionary criterion if not available. Any labs required may be obtained at a local laboratory (e.g., LabCorp) convenient to you.

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

Visit 2: Blinded CGM Run-In and Randomization

- Day 2-11 (Phone/Remote)

The study team will provide you with and train you on the use of a blinded Dexcom G6 Pro. Blinding the CGM means that you will not be able to see your glucose values. You will wear this blinded CGM at home for 10 days. It is important that you return these supplies to the study team promptly after removing the equipment. The study team will provide you with a shipping envelope. The CGM must be used 7 out of 10 days to successfully complete this phase. If there isn't enough data, the study team will ask that you repeat this data collection phase one time.

You will be randomly assigned (like the flip of a coin) to 1 of 2 study treatment 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. You will be informed of the randomization after you complete the Blinded CGM Run-In Phase. But if your doctor needs to know, the people doing this study can find out.

- **GROUP 1:** EXPERIMENTAL **(EXP)** GROUP – You will use an Automated Insulin Delivery (AID) System with a CGM. .

- **GROUP 2:** CONTROL **(CTR)** GROUP – You will use your insulin, a CGM, and will adjust the basal insulin doses with the assistance of the study physician.

Visit 3: Basal Insulin Titration (BIT) Training Visit
(Day 12/ Phone, Remote, Email)

- Equipment training

If you are randomized to the **EXP Group**, you will participate in insulin pump training. The study system includes the Tandem t:slim X2 with Control-IQ technology and the Dexcom G6 CGM. You will use this study equipment for 10 days. The study physician will prescribe the insulin that is necessary to use in the study insulin pump.

The study team will create a Dexcom account for you for use during the BIT Phase of the study. If you choose to use your personal smartphone, the Dexcom G6 app may be downloaded to your phone. A study smartphone may be provided if you prefer not to use your personal smartphone during the study. Use of a study Dexcom Clarity account is preferred versus using your personal account if you have one.

If you are randomized to the **CTR Group**, you will continue using your insulin with your current basal insulin parameters. As is typical with adjusting your insulin parameters, you and the study physician will discuss the adjustments of your insulin parameters.

You will be instructed not to adjust your insulin parameters without speaking with the study physician.

You will be instructed to record a fasting blood glucose measurement each morning and at bedtime each day of the study.

The study physician may extend your participation by 7 days if additional insulin information is needed from you.

Visit 4: Check-In Visit (about 15 minutes)
(Day 14/ Phone, Remote, Email)

You will be contacted by the study team to discuss the following topics:

- your basal insulin therapy parameters

- any low or high blood glucose events
- recording of blood glucose measurements each day
- any illness or injury
- any new medications
- any issues that you may have had with the equipment

Visit 5: Check-In Visit (about 15 minutes)
(Day 18/ Phone, Remote, Email)

You will be contacted by the study team to discuss the following topics:

- your basal insulin therapy parameters
- any low or high blood glucose events
- recording of blood glucose measurements each day
- any illness or injury
- any new medications
- any issues that you may have had with the equipment

Visit 6: Maintenance Visit
(Day 22/ Phone, Remote, Email)

If you are randomized to the **EXP Group**, you will stop using the insulin pump and return to using your insulin pen. You will use the insulin parameters that were calculated during the BIT Phase.

If you are randomized to the **CTR Group**, you will continue using your insulin and will use the insulin parameters calculated with you and the study physician during the BIT Phase.

You will use a blinded Dexcom G6 Pro at home for 10 days. It is important that you return these supplies to the study team promptly after removing the equipment. The study team may provide you with a shipping envelope.

You will be instructed not to adjust your insulin parameters without speaking with the study physician.

You will be instructed to record a fasting blood glucose measurement each morning and at bedtime each day of the study.

Visit 7: Check-In Visit (about 15 minutes)
(Day 24/ Phone, Remote, Email)

You will be contacted by the study team to discuss the following topics:

- your basal insulin therapy parameters
- any low or high blood glucose events
- recording of blood glucose measurements each day
- any illness or injury
- any new medications
- any issues that you may have had with the equipment

Visit 8: Check-In Visit (about 15 minutes)
(Day 28/ Phone, Remote, Email)

You will be contacted by the study team to discuss the following topics:

- your basal insulin therapy parameters
- any low or high blood glucose events
- recording of blood glucose measurements each day
- any illness or injury
- any new medications
- any issues that you may have had with the equipment

Visit 9: Study End Visit
(Day 31/ Phone, Remote, Email)

At the conclusion of the Post-Session Check-In Visit 9, the study physician will assist in transitioning you back to your home insulin regime. You will be instructed about the risk of low and high blood glucose levels during this time. The study physician will be available for questions during this adjustment.

You will return all study equipment to the study team. The study team will provide you with a shipping envelope. Once your study glucometer is downloaded, the study team will return the glucometer to you.

Visit 10: Post-Study Check-In Visit
(Day 33/ Phone, Remote, Email)
About 48 hours after you Study End Visit, the study team will contact you to discuss:

- any low or high blood glucose events
- any illness or injury

Study Schedule

	Screening	Blinded CGM Phase	BIT Phase Visit	BIT Check-In Visits	Maintenance Phase Visit	Maintenance Check-In Visits	Study End Visit	Post-Study Check-In Visit
Visits	1	2	3	4 & 5 (+/-1 day)	6	7 & 8 (+/-1 day)	9	10 (+/-1 day)
Day	1	2-11	12-21	14 & 18	22-31	24 & 28	31	33
Informed consent	X							
Eligibility assessment	X							
Medical history	X							
HbA1c	X							
Screening labs (Chemistry panel, liver functioning, hematocrit, thyroid stimulating hormone)	If needed *							
Pregnancy test (if applicable)	X							
Physical exam	X							
Vital signs (height/weight)	X							
Demographic survey	X							
Randomization		X						
Study equipment training		X						
Blinded CGM download			X				X	
Use of AID (EXP)			X	X				
Use of usual insulin treatment (EXP)		X			X	X		
Use of blinded CGM		X			X	X		
Use of unblinded CGM (CTR)			X	X				
Use of usual insulin treatment (CTR)		X	X	X	X	X		
Blood glucose measurements			X	X	X	X		
Review diabetes management & AEs	X	X	X	X	X	X	X	X

* The study physician may ask that you repeat screening labs.

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 will be asked to call the study leader during periods of illness with an elevated temperature greater than 101.5 degrees Fahrenheit (38.6 degrees Celsius), periods of significant illness, or during periods of use of medications such as epinephrine for the emergency treatment of a severe allergic reaction or asthma attack in addition to use of oral or injectable glucocorticoids to determine if automated insulin delivery should be temporarily discontinued.
- You should report any issues with the study equipment.
- Inform the study doctor or study staff as soon as possible if you must 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

The blood we take will be tested to measure your hemoglobin A1c which is a blood test used to monitor how well you're managing your diabetes. This blood we will take less than a ½ teaspoon of blood. If you require a pregnancy test, the blood test to determine if you are pregnant will need less than a ½ teaspoon of blood.

If the study physician requests that you obtain a blood test to check your thyroid or kidney functioning, the total amount of blood that we will take for these two blood tests will be less than a teaspoon of blood.

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

the study results.

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

During the study you are 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 may ask for more information about the study results.

What are the risks of being in this study?

Risks and side effects related to treating type 2 diabetes (with or without using study equipment):

Likely

- Risks of possible mild to moderate low blood sugar and possible symptoms of low blood sugar (hypoglycemia), such as sweating, jitteriness, trembling, difficulty thinking, dizziness, feeling unwell, and feeling uncoordinated.
- Risk of possible mild to moderate high blood sugars and symptoms of high blood sugars (hyperglycemia) such as thirst and frequent urination. You may have a higher level of sugar in your urine.
- Infusion set failures that may cause high blood sugars (hyperglycemia).

Rare but serious

- Risk of severe temporary low blood sugar (hypoglycemia) that can lead to fainting (unconsciousness), hypoglycemic seizure, hospitalization or even death.
- Risk of prolonged high blood sugar (hyperglycemia) leading to diabetic ketoacidosis (DKA), hospitalization, and coma. DKA can lead to renal failure (kidney failure), cardiac arrhythmia (irregular heartbeat), myocardial infarction (heart attack), rhabdomyolysis (muscle breakdown), and even death.

Risks related to use of Insulin Pump

Likely

- Risk of pump site failure and need to re-establish a functional pump site for insulin delivery

Rare but Serious

- Risk of symptoms related to the inserting of an infusion set: sensitivities to adhesives resulting in skin irritation, bruising, and bleeding. Risk of the tissues in your body not absorbing the insulin properly.
- Risk of low blood sugar (hypoglycemia): 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 high blood sugar (hyperglycemia): One of the ways this could happen is if the insulin pump tubing gets bent and is unable to dispense insulin properly.

Risks related to using a Continuous Glucose Monitoring Sensor:

Likely

- Failure or lack of sensitivity of the continuous glucose monitor sensor that requires replacement and or insertion of new sensor in your abdomen
- Discomfort from insertion of sensor into the skin

Less Likely

- Bruising less than ½ inch in circumference
- Bleeding less than ¼ teaspoon
- Sensitivity to adhesives with use of continuous glucose monitor resulting in skin irritation, redness, blistering, scarring, systemic allergic reaction (shock with breathing problems, heart failure)
- CGM sensor reads higher or lower than your actual glucose level
- Risk of a false hypoglycemia alarm is pressing on the sensor (e.g., sleeping on the sensor)
- CGM sensor stops working or cannot communicate with the system. If this occurs, the insulin pump will start delivering its preset basal rates within 30-60 minutes

Rare but serious

- Local skin infection at site of sensor needle placement
- Swelling or redness at insertion site
- Allergic reaction to the adhesives (glue) used on the sensor
- Psychological reaction to viewing the continuous glucose monitor information or attending to continuous glucose monitor alarms or finger stick blood glucose values.
- Breakage of the continuous glucose monitor sensor under the skin with possible symptoms of skin irritation and inflammation. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Please call the study team or seek immediate medical assistance. Seek professional medical help if you have symptoms of infection or inflammation – redness, swelling or pain – at the insertion site.
- 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 of Fingersticks:

Likely

- Pain at site of lancet (finger-pricking needle) use
- Bleeding at site of lancet use
- Small scar that may last for several weeks

Less Likely

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

Rare but serious

- Local infection at site of lancet use

Risks associated with performing a urine pregnancy tests (women who can become pregnant):

Less Likely

- False positive or false negative results.

Risks associated with having your blood drawn:

Having blood drawn may cause:

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

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

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

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

Risk of Sharing (reusing) the Insulin Pump, Continuous Glucose Monitor, glucometer, and ketone meter:

Insulin pump, continuous glucose monitor, blood glucometers, 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 be spread if used with multiple patients. All devices will be cleaned thoroughly with a diluted mixture of bleach or another appropriate cleaner after use per approved cleaning procedure.

The CGM sensor will not be shared, and it will be discarded after use.

Risks from Completing a Survey:

- The survey should not cause any physical risks. These documents are de-identified, meaning your name is not associated with your answers. Rather, the survey is assigned a study subject number only. Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

Risks for women:

Being in this study might hurt your unborn baby, so you will not be able to join or stay in the study if you become pregnant. You must use an effective method of birth control during the study if you are a female of child-bearing potential. You should also not get pregnant until you have completed the study. If you have questions about birth control, please ask the study leader. If you are pregnant now or get pregnant during the study, please tell us right away.

Loss of Privacy:

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

- The study team will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible but participating in research may involve a loss of privacy and the potential for a breach of confidentiality. All identifiable information about you will be replaced with a code. A list linking the code, and your identifiable information will be kept separate from the research data.
- We encourage you to discuss the risks with your study doctor or any other health care professional who may understand our process.
- The hotel session will have other study participants also in attendance.
- The study team is not able to restrict other participants from sharing photographs that include you (e.g., social media).

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. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include:

- managing your illness as recommended by your personal health care team.

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 $200.00 by check for finishing this study. You will be paid an extra $100 if you attend in-person visits at UVA, totaling a reimbursement of $300. 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.

- Completion of the Visit 3: $100 (additional $50 if in-person visit)
- Completion of the Visit 9: $100 (additional $50 if in-person visit)
- Travel Stipend: a $100 if you need to travel for an in-person visit (one-time payment)
- Insulin Compensation (EXP participants only): a $35 gift card covering the cost of the insulin will be provided (one-time payment)

The study team may provide additional reimbursement up to $100 to government program recipients (e.g., Medicaid, Medicare, Medicare Part D, and others) if they incur charges related to the purchase of the study insulin that exceeds the gift card allowance of $35.

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

Payment for study visits completed will be provided after the study supplies (e.g. insulin pump, CGM supplies, glucometer, and ketone meter) has been returned to the study team. The study glucometer will be returned to you once the study team has confirmed that the data has been collected from the device or the cloud storage.

By agreeing to be in this study, you are donating your blood samples for research, and giving up any property rights you may have to these specimens or the results of the research. The results of this research using your donated materials may have commercial value. However, you will not receive any payments.

Will being in this study cost you any money?

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, study systems, infusion set, and CGM supplies. Any additional laboratory tests the study physician requested from you to participate in this study will not cost you additional money nor will your insurance be billed. A one-time travel stipend of $100 will be provided to compensate you for the time spent traveling for in-person visits to UVA. See the "Will you be paid for being in this study?" section of this form for more information.

You will be responsible for the cost of your insulin that you use during the study. You will be responsible for any costs related to using your personal smartphone during the study.

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

What if you are hurt in this study?

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

What happens if you leave the study early?

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

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include:

a) Your study physician is concerned about your health

b) Your condition gets worse
c) The side effects of the study procedures are too dangerous for you
d) You do not follow your doctor's instructions
e) The study sponsor closes the study for safety, administrative or other reasons

If you decide to stop being in the study, we ask that you notify the research team so any scheduled sessions may be cancelled. The study insulin pump and other supplies remain property of the CDT and will need to be returned.

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
- 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.
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the

law may require us to let people in authority know so they can protect you and others.

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

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.

Your information, collected for this study, will be protected by a Certificate of Confidentiality from the federal government. If UVA receives a subpoena or court order demanding information from the study records that would identify you, we will use the Certificate to resist the demand. However, UVA will not use it in the following cases.

- You have agreed in writing to allow UVa to share the information with your employer, your insurance company for billing purposes, or someone else
- Reports to authorities where there is a danger that you may harm yourself or others, or if there is evidence of probable child or elder abuse or neglect.

In addition, the Certificate does not prevent government authorities who oversee research from reviewing this study. This Certificate does not mean that the government either approves or disapproves of this study. It just helps protect your privacy.

Please contact the Principal Investigator listed 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
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: 434-924-2620

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the UVA Study Tracking Number (at the bottom of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

You may also report a concern anonymously by calling the UVA Compliance Hotline phone number at 1-800-235-8700.

Would you agree to the electronic consenting process?

The study team will provide you with the best way for you to sign this consent form. Signing the consent form can occur in person or electronically. You will need to provide two forms of identification to verify your identity prior to signing the consent form electronically.

You do not have to agree to sign the consent form electronically.
PLEASE INDICATE YOUR CHOICE BELOW:

Yes_____ I agree to sign this consent form electronically.
If you agree to electronic consenting, the study team will ensure that you have a copy of the signed consent.

No_____ I DO NOT agree to sign the consent form electronically.

Would you like the study team to communicate with you by email or text

message?

If you choose to communicate with the study team by unsecure email (email that is not encrypted) or text message to your personal phone, there is some risk that your health information could be read or accessed by someone else while the information is sent or saved by your email or phone provider.

Your personal email or phone provider may also share or release your information because they do not have to follow the privacy laws that UVA follows. Sometimes email and phone providers release information to marketing companies for use in direct advertising. If you choose to communicate by email or text messaging, UVA cannot control this potential loss of privacy, but we want to tell you about this possible risk.

You do not have to agree to communicate with the study team by email or text message to be in this study. If you agree to texting or emailing, the study team will collect your phone and /or email address from you that you would like them to use to contact you. Please note, if you agree to text messaging, charges may apply depending on your data/text plan with your phone provider.

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

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

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

Would you like to be contacted about future studies?

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

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

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

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

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

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

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form, it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

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

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

Person Obtaining Consent

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

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

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 check box the identified individual(s):

☐ Subject
☐ Parent(s)/Guardian of the subject
☐ Subject's surrogate

IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE

Notification of My Health Care Provider

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

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

Health Care Provider Name: _____

Health Care Provider Address:
Study team will send a copy of the consent form to the health care provider.

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

Leaving the Study Early

Check one option below:

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

The follow up information will be collected by the study team:

- Obtaining information from my medical records
- Phone call
- In person follow up visit if requested by the study physician

____ I am withdrawing my consent for this study. No additional information may be collected about me including follow-up information from my medical records.

Consent From Adult

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

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

Person Obtaining Consent

By signing below, you confirm that you have fully explained the implications of withdrawing from the study to the subject and have answered all their questions.

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