NCT04201496

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 National Institute of Health (NIH). Tandem Diabetes Care, Inc. will provide the insulin pumps infusion sets, and associated supplies for this study. Dexcom, Inc. will provided the continuous glucose monitors, sensors, and other associated supplies for this study. Grant funding will be used to purchase other study related supplies (e.g. study medication, glucometer, ketone meter, test strips, etc…).

Key Information About This Research Study

Principal Investigator:	Ananda Basu, MD, FRCP Department of Endocrinology and Metabolism UVA Center for Diabetes Technology (CDT) Box 400888, Charlottesville, VA 22903 Telephone: (434) 924-5177
Sponsor:	National Institute of Health (NIH)

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 decide whether to participate.

What problem is this study trying to solve?
This study is trying to find out if this medication (Empagliflozin) is safe for persons with Type 1 Diabetes while wearing a Tandem t:slim insulin pump with Basal-IQ Technology and the Tandem t:slim insulin pump with Control-IQ Technology.

You are being asked to take part in this study because you are between the ages of 18 to 65 years old and have received the diagnosis of Type 1 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 1 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 the Tandem t:slim X2 with Control-IQ Technology and the study medication are not approved for use in persons diagnosed with Type 1 Diabetes. There are side effects with this medication, especially an increased chance of diabetic ketoacidosis (DKA).

As you know, type 1 diabetes may cause your blood sugar to be high or low even when using the study pump and study CGM. The CGM sensor will need to be replaced during the study. Reinserting the sensor may cause you pain.

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, you will:

- Meet with a study doctor to see if you are healthy and meet the criteria to participate in the study
- You may need to change your insulin to lispro (Humalog) or aspart (Novolog) if not already using it
- Wear the study Basal-IQ insulin pump and study CGM with or without the study medication
- Wear the study Control-IQ insulin pump and CGM with or without the study medication
- You will be asked to follow the Glycemic Treatment Guidelines during home use of the study equipment
- You will need to return the study equipment at the end of the study
- You will need to notify the study team of any illness, injury, hypoglycemic or hyperglycemic events during the study

What is the difference between being in this study and getting usual care?
You do not have to participate in this study. If you decide that you do not want to be in this study, you will not be treated differently. Also, your regular care will not be impacted.

This is a research study to test the Artificial Pancreas System called the Control-IQ System and the Basal-IQ System while also using Empagliflozin, an experimental drug that has not been proven to be safe or helpful with people living with Type 1 Diabetes.

This is a research study to test the Artificial Pancreas System called the Control-IQ. This technology has been approved for use in people with type 1 diabetes. This system has been used in over 1,300,000 hours of outpatient human use and in several centers in the U.S. and Europe. It is not approved for people who use Empagliflozin.

Empagliflozin (trade name: Jardiance) is not approved by the FDA for use in adults with Type 1 Diabetes. The medication is approved for use in adults with Type 2 Diabetes (T2D) to improve glycemic control and to reduce the risk of cardiovascular death. In a study evaluating the use of empagliflozin in patients with type 1 diabetes (The EASE Trials) in over 400 subjects taking empagliflozin 10 mg, HbA1c and weight was lower after at least 26 weeks; however, genital infections and diabetic ketoacidosis occurred more with empagliflozin 10 mg than in participants not taking empagliflozin. Risks are further explained in the *"What are the risks of being in this study"* section of 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.

- You will wear a Tandem t:slim insulin pump with Basal-IQ technology for 2 weeks
- You will wear a Tandem t:slim insulin pump with Control-IQ technology for 4 weeks
- You will take the trial medication (Empagliflozin), if randomized to take this medication
- You will be asked to drink fluids regularly each day, preferably water, and record it on an activity tracker
- You will answer questions about the use of these insulin pumps

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 developed by your physician.

Up to 60 people, ages 18 to 65 years old, will sign the consent and will be in this study at UVA with the goal of having 40 people complete the study, 10 in each group.

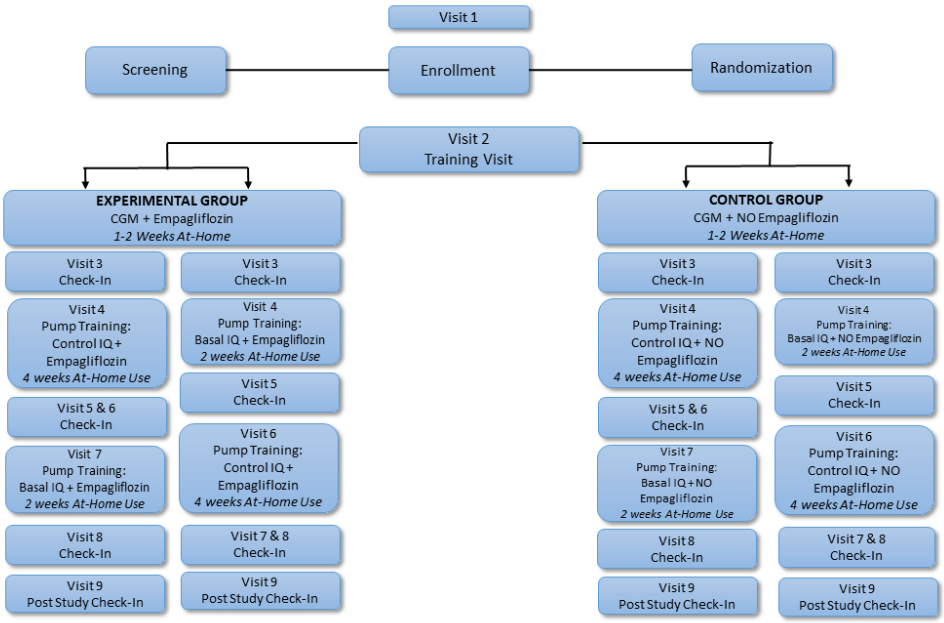
Is there a possible conflict of interest?

When a person or an organization has a financial or other interest large enough to seem as if it could affect their judgment, it is called a conflict of interest. Members of the Center for Diabetes Technology the investigators created the algorithm used in this Control-IQ. They have assigned all patent rights to the University of Virginia. The UVA Licensing and Ventures Group handles all further transactions, licensing, and other issues related to these technologies. UVa may receive compensation now that this is a FDA approved device.

How long will this study take?

Your participation in this study will require about 9 study visits, including check-in visits, over a 10-week period of time. The screening visit and randomization visit will take about 1-2 hours. The study equipment training and medication training visit will take about 4 hours. The study team will call you to check on you after each training visit. After using the first insulin pump, you will return to CDT to train on the other study insulin pump. Study team will call you after the end of the study. This follow-up call may take about 15 minutes. Virtual study visits may take the place of in-person study visits.

What will happen if you are in the study?



SCREENING, ENROLLMENT & RANDOMIZATION (visit will last about 2 hours)

Visit 1 (Day 1):

Screening

If you agree to participate, you will sign this consent form before any study related procedures take place. Before you can start in the study, there will be a screening period. You will have tests and procedures during this time to make sure you are eligible and that 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 (heart, weight, blood pressure, heart rate, temperature, electrocardiogram (EKG), etc.)
- A blood test to obtain a hemoglobin A1c, liver, thyroid functioning, white blood count, etc… If you have had these tests done within the last 14 days, you may not need to have

these tests repeated. You may have the blood/urine drawn at a local laboratory (i.e. LabCorp)

- A urine pregnancy test

Enrollment

If these tests show that you are eligible to participate in the study, you may immediately be randomized and participate in the Study Training Session or it may be postponed for up to 30 days.

You will be asked to keep a glucagon emergency kit on hand at home. If you need a prescription for the glucagon emergency kit, you can ask your study doctor.

Randomization

Two randomizations will occur in this study. The first randomization is the assignment to either take the study medication Empagliflozin or not to take Empagliflozin.

The second randomization is the assignment to use the insulin pump with Control-IQ Technology first or the insulin pump with Basal-IQ Technology first.

You will be randomly assigned (like the flip of a coin) to 1 of 4 study 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.

Experimental Group

Group 1: Empagliflozin 5 mg daily + Control-IQ insulin pump for 4 weeks and then Basal-IQ for 2 weeks ***OR***

Group 2: Empagliflozin 5 mg daily + Basal-IQ insulin pump for 2 weeks and then Control-IQ for 4 weeks

Control Group

Group 3: NO Empagliflozin 5 mg daily + Control-IQ insulin pump for 4 weeks and then Basal-IQ for 2 weeks ***OR***

Group 4: NO Empagliflozin 5 mg daily + Basal-IQ insulin pump for 2 weeks and then Control-IQ for 4 weeks

STUDY TRAINING SESSION (visit will last about 4 hours)

Visit 2 (Day 2 or may occur on same day of Screening Visit)

This training is to introduce you to the CGM, the use of the blood glucose and ketone meters, glycemic treatment guidelines, and the study medication Empagliflozin if randomized to the Experimental Group. Upon completion of this training session, you will use the equipment for 1-2 weeks at home. You will continue to use your personal insulin pump during this run-in phase.

The length of the run-in period is determined by the length of time it takes for you to get used to the study medication, if assigned to a group taking the study medication. The study physician will decide when you will complete this run-in phase and begin training on the insulin pump.

You will be asked to download all study equipment approximately 1 time each week or as recommended by the study team.

You will be provided study contact information. You are welcome to call the study team with any questions or concerns that you may have at any time.

CGM Training

You will receive training on the Dexcom G6. If you haven't used the Dexcom G6 CGM, the study team may have you watch the Dexcom training video (https://www.dexcom.com/training-videos). You will stop using your personal CGM when you start the study sensor. You will download Dexcom Apps onto a phone to monitor your CGM values and alerts in real-time. This App may be downloaded to a phone provided to you by the study team, or you may use your personal phone. The use of the Dexcom Apps on a personal phone may result in data and text charges. The University of Virginia is not responsible for the security of data on your personal phone.

If the CGM requires calibration, you will be asked to perform fingerstick blood glucose measurements according to the Dexcom User Manual.

You will be provided the appropriate CGM supplies to use during the study.

Run-In Phase CGM

If randomized to the Experimental Group, you will use the CGM and Empagliflozin for about two weeks so you can get used to the study medication.

If randomized to the Control Group, you will use the CGM alone for about two weeks.

Blood Glucose and Ketone Meter Training

You will be provided with a study blood glucose and ketone meter and test strips to be used at home. You will be provided instructions on how to treat your low or high blood glucose value while wearing the study equipment. You will be instructed on how to download these meters and how to record your readings during the day.

Recording your ketone readings during the day is very important to help the study team monitor ketone events that you may experience during the study.

If assigned to the Experimental Group, the ketone measurement schedule is very important to ensure that you are not developing ketosis. While at least 2 measurements are required each day, it is recommended that you obtain 4 measurements per day. The first measurement must be collected in the morning and before you eat or drink anything (fasting).

Activity Tracker
You will be provided an activity tracker (e.g. Fitbit) to wear during the study. The tracker will record your activity level and heart rate.

Study Medication – Empagliflozin (Experimental Group)
You will be instructed to take Empagliflozin 5 mg one time per day until the end of the study. Empagliflozin is available only in 10 mg and 25 mg film coated unscored tablets. For this study, you will be provided 10 mg tablets and a pill splitter. You will be instructed to split only 1 tablet at a time and take each half tablet (5mg each) on subsequent days. You will be cautioned against spitting more than one tablet at a time. You will be instructed about the side effects of the medication and how to notify the study staff in the event that you experience these side effects. It is very important that you are truthful about your medical history so the study team can determine if you are at higher risk.

Run-In Phase Check-In Visit (about 15 minutes)

Visit 3 (about Day 8)

During week 1 and 2 of using the study insulin pump, after starting the study, the study team will contact you to ask:

- How you are feeling
- About side effects of the study medication, if applicable
- If you have had any blood glucose values less than 60 mg/dL and more than 300 mg/dL
- Discuss insulin parameters, if necessary

INSULIN PUMP TRAINING SESSION (visit will last about 4 hours)

Visit 4 (about Day 16)

Insulin Pump Training

If you are randomized to Group 1 or 3, you will be taught how to use the Control-IQ pump at this training session.
If you are randomized to Group 2 or 4, you will be taught how to use Basal-IQ pump at this training session.

A qualified system trainer will train you on the use of the insulin pump. The trainer will discuss differences between the study insulin pump and your home pump. Topics include the calculation of insulin on board, correction boluses, infusion site initiation, cartridge/priming procedures, setting up the pump, charging the pump, navigation through menus, and bolus procedures including stopping a bolus among others.

You will be provided the appropriate insulin pump supplies to use during the study.

Check-In Visit (about 15 minutes)

Visit 5 (about Day 21)

The study team will contact you to ask you:

- How you are feeling
- About side effects of the study medication, if applicable
- If you have had any blood glucose values less than 60 mg/dL and more than 300 mg/dL
- Discuss insulin parameters, if necessary

Note: Two Check-in Visits will occur after starting the insulin pump with Control-IQ Technology (e.g. Visit 6 about Day 33).

STUDY TRAINING SESSION (visit will last about 4 hours)

Visit 7 (Group 1 and 3 – about Day 45; Group 2 and 4 – about Day 30)

Insulin Pump Training

If you are randomized to Group 1 or 3, you will be taught how to use the Basal-IQ pump at this training session.
If you are randomized to Group 2 or 4, you will be taught how to use Control-IQ pump at this training session.

A qualified system trainer will train you on the use of the insulin pump. The trainer will discuss differences between the study insulin pump and your home pump. Topics include the calculation of insulin on board, correction boluses, infusion site initiation, cartridge/priming procedures, setting up the pump, charging the pump, navigation through menus and bolus procedures including stopping a bolus among others.

You will be provided the appropriate insulin pump supplies to use during the study.

Check-In Visit (about 15 minutes)

Visit 8 (Group 1 and 3 – about Day 50; Group 2 and 4 – about Day 35)

During week 1 and 2 of using the study insulin pump, the study team will contact you to ask:

- How you are feeling
- About side effects of the study medication, if applicable
- If you have had any blood glucose values less than 60 mg/dL and more than 300 mg/dL
- Discuss insulin parameters, if necessary

End of Study (about day 60 for all groups)

After you complete the study procedures, you will return to your standard diabetes care. The study team will be available to answer questions about your insulin parameters. You will also need to return of all the study equipment (e.g. study insulin pump, study CGM, study medication, glucometer, ketone meter, activity tracker, remaining supplies, etc…). Once the study data has been downloaded by the study team, the glucometer and ketone meter may be provided to you.

Post Study Check-In Visit (about 15 minutes)

Visit 9 (about Day 62)

The study team will contact you approximately 24-48 hours after completing the study to ask you:

- How you are feeling
- If you have had any blood glucose values less than 60 mg/dL and more than 300 mg/dL
- Discuss insulin parameters
- Results of urine pregnancy test (study team will provide urine pregnancy test; you will be asked to send a photograph of the results to the study team)

Study Schedule

	Visit 1 Screening	Visit 2 Training Visit	Visit 3 Check-In Visit	Visit 4 Training Visit	Visit 5 & 6 Check-In Visit	Visit 7 Training Visit	Visit 8 Check-In Visit	Visit 9 Post-Study Check-In Visit
Location	**Clinic**	**Clinic**	**Check-In**	**Clinic**	**Check-In**	**Clinic**	**Check-In**	Check-In
Informed Consent	x							
Eligibility Assessment	x							
Medical History	x							
Blood Testing	x							
Pregnancy Test (if applicable)	x	X		x		x		x
Electrocardiogram (ECG)	x							
Physical Exam	x				x			
Vital Signs	x				x			
CGM Placement		X			x			
Empagliflozin Use		X	x	x	x	x	x	
Blood Glucose & Ketone Measurement		X	x	x	x	x	x	
Download Study Equipment			x	x	**x**	x	x	**x**
Review Diabetes Management			x	x	x	x	x	x
Return Study Equipment & Study Medication						x		**x**
Questionnaires	x					x		x

What are your responsibilities in the study?

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

- You must come to each study visit.
- You must be completely truthful about your health history.
- You must follow all instructions given.
- You should tell the study doctor or study staff about any changes in your health or the way you feel.
- You should report any issues with the study equipment.
- Ensure that the study drug is taken as instructed, keep the study drug in a safe place away from other persons, return any unused study drug at each visit, and report any lost or missed tablets.
- Ensure that the study drug is taken only by you, the person for whom it has been prescribed.
- Answer all of the study-related questions completely.
- Inform the study doctor or study staff as soon as possible if you have to take any new medications, including anything prescribed by a doctor or those that you can buy without a prescription (over-the-counter), including herbal supplements and vitamins. The study doctor will let you know if you can take these medications.

Blood Testing

We will take (or "draw") up to 1 tablespoon of blood during the screening visit. The total amount of blood we will take will be up to 1 tablespoon.
The blood we take will be tested to measure

- Hemoglobin A1C
- Comprehensive Metabolic Panel (a blood test measures glucose levels, the balance of electrolytes and fluid, the kidney function, and the liver function)
- Thyroid test
- Urine Pregnancy test, if applicable

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

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?

Risk related to using Empagliflozin

Likely

- Rapid onset of ketosis (raised levels of ketone levels that is related to a lack of insulin). This risk is ketosis is about 1 in 3 people taking empagliflozin and about 1 in 6 people not taking empagliflozin.
- Genital mycotic infections (fungal infection of the genital area that can occur because of excess sugar in the urine. This may cause redness and irritation locally. [Vulvovaginitis in women; Balanitis or Balanoposthitis in men]). This risk of genital mycotic infection is about 1 in 8 people taking empagliflozin and about 1 in 23 people not taking empagliflozin.

Less Likely (Possible)

- Risk of taking more than the prescribed 5 mg if cutting more than 1 pill at a time which may result in the side effects identified in this section.
- Risk of diabetic ketoacidosis (DKA) with or without high blood glucose levels. This risk of DKA is about 1 in 23 people taking empagliflozin and about 1 in 83 people not taking empagliflozin. DKA can lead to renal failure (kidney failure), cardiac arrhythmia (irregular heartbeat), myocardial infarction (heart attack), rhabdomyolysis (muscle breakdown), and even death.
- Hypotension – the risk of low blood pressure especially in patients with renal impairment, the elderly, and patients on diuretics is 1 in 50 people with empagliflozin.
- Serious urinary tract infections that may require hospitalization [Diagnosis of Urosepsis and Pyelonephritis]. The risk for UTI to occur is 1 in 10 people taking empagliflozin vs. 1 in 11 people not taking empagliflozin.
- Risk of severe temporary low blood sugar (hypoglycemia) when used with insulin and insulin secretagogues (medicines that stimulate cells to secrete insulin) that can lead to unconsciousness, hypoglycemic seizure, hospitalization or even death. This risk of

hypoglycemia 1 in 25 people taking empagliflozin and 1 in 33 people not taking empagliflozin.

Rare

- An infection that spreads quickly and results in the death of parts of the body's soft tissue. Symptoms include red or purple skin in the affected area, severe pain, fever, and vomiting [Diagnosis of Necrotizing Fasciitis of the Perineum (Fournier's Gangrene)].
- Acute kidney infections (AKI) that may require hospitalization and dialysis.
- Hypersensitivity reactions (e.g. andioedema – swelling that may occur in the face, throat, arms, legs, genital area)
- Increased blood values of low-density lipoprotein (LDL cholesterol, LDL-C)

Risks and side effects related to participating in this study include:

Risks related to treating type 1 diabetes (with or without using study equipment)

Likely

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

Rare but serious

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

Risks related to using a Continuous Glucose Monitoring Sensor

Likely

- Failure or lack of sensitivity of the 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

- 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)

Rarely
- Swelling or redness at insertion site
- 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.

Risk related to Fingersticks
Likely
- Pain at site of lancet (finger-pricking needle) use
- Bleeding at site of lancet use

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

Rare
- Infection at site of lancet use

Risk of Sharing the Insulin Pump, Continuous Glucose Monitor, Glucometer, and Ketone Meter:
The FDA approved the insulin pump, continuous glucose monitor, glucometer and ketone meter as '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 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 discarded after use.

Loss of Privacy
- 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 in 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.

Questionnaire Risks

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. Also, you can decide to take a break or stop taking part in the study at any time. The questionnaire will not cause any physical or emotional risks. The questionnaires are de-identified, meaning your name is not associated with your answers.

Risks of Sharing the Drug

Do not share the study drug with anyone. It is prescribed only for you and could hurt someone else. Keep it out of reach of children and people not able to read or understand the label.

Blood Donation

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

Risks of having your blood drawn:

Having blood drawn may cause:

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

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

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

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

Risks for women:
Being in this study might hurt your unborn baby, so you will not be able to join or stay in the study if you are pregnant. You must use an effective method of birth control during the study. Researchers have not studied the use of empagliflozin before, during or after pregnancy. Therefore, we recommend that you should also not get pregnant for one month after your last dose of the drug. If you have questions about birth control, please ask the study leader. If you are pregnant now, or get pregnant during the study, please tell us right away.

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

Could you be helped by being in this study?
You will not benefit from being in this study. However the information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?
You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include continuing your home insulin regimen.
However, in order to do this study we must change the equipment that you use in usual treatment. This would be wearing the study insulin pump and study CGM. We must change your insulin dosing and allow the algorithm (complex mathematical formula) to calculate your insulin dosages.
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 $500.00 by gift card for finishing this study. You should get your payment about 4 weeks after finishing the study. The income may be reported to the IRS as income.

- Study Training Visit 2: $100
- Study Training Visit 4: $100
- Study Training Visit 6: $100

- ❖ Check-In Visits (5 Visits): $100 ($20 per visit)
- ❖ Completing Entire Study: $100

Payment for study visits completed will be provided after the all study equipment has been returned to the study team and study downloads have been completed. The study will provide you with the following to use during the study:

- Study equipment and their associated supplies (e.g. Insulin pumps, CGM supplies, Study Medication, Glucometer, Ketone meter, Activity Tracker, remaining study supplies, etc.…)

By agreeing to be in this study, you are donating your blood samples for research and giving up any property rights you may have in them. 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?

Being in this study will not cost you any money. Your insurance company will also not be billed.

The following procedures/tests, which are being done for research purposes, will be provided at no cost to you or your health insurance: lab tests, study equipment, study medication, physical examination, vitals, and urine pregnancy tests.

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

You and/or your insurance company must pay for the glucagon emergency kit. You will be responsible for the cost of travel to come to any study visit, parking costs, and data and text charges if you use your personal phone 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 disease gets worse
c) The side effects of the treatment are too dangerous for you
d) New information shows the treatment will not work or is not safe for you
e) You do not follow your doctor's instructions
f) The study sponsor closes the study for safety, administrative or other reasons
g) Adverse events from the study drug that may be not be safe for you to continue
h) Study equipment issues that may be not be safe for you to continue

If you decide to stop being in the study, we ask that you notify the research team so any scheduled admissions may be cancelled. The study insulin pumps and study CGM remain property of the CDT and will need to be returned. Any medications not taken will need to be returned.

Any data collected about you up until the time you leave the study must be kept in order to determine the results of the study.

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Social Security number ONLY IF you are being paid to be in this study
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- Outside researchers from suppliers and potential funding agencies may observe the trial
- 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.

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.

Data obtained from you during this study may be used in future research. Your data 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 may 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 earlier in this form to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Ananda Basu, MD, FRCP
UVA Center for Diabetes Technology
Box 400888, Charlottesville, VA 22903
Telephone: (434) 924-5177

What if you have a concern about this study?

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

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

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

Signatures

What does your signature mean?

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

Consent From Adult

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

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

Person Obtaining Consent

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

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

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

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

Check one option below:

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

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

- Obtaining information from my medical records
- Phone call
- Sending me questionnaire
- 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