# 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 Diabetes and Digestive and Kidney Diseases (NIDDK). Grant funding will be used to purchase continuous glucose monitoring (CGM) supplies and ketone meter and strips.

## Key Information About This Research Study

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|---|---|
| Principal Investigator: | Sue Brown, MD<br>University of Virginia Center for Diabetes Technology (CDT)<br>Box 400888<br>Charlottesville, VA 22903<br>434-982-0602 |
| Sponsor: | National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) |

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.

You are being asked to take part in this study because you have received the diagnosis of Type 1 Diabetes and are currently using the Tandem t:slim X2 insulin pump for the past 2 months as part of your regular clinical care.

You will need to have access to the Control-IQ Technology feature of your pump as prescribed by your regular care provider prior to Visit 2.

## What is the purpose, procedures, and duration of this study?

The purpose of this study is to test a Web-Based Information Tool (WIT). This software will provide additional information regarding your hypoglycemic risk, your hyperglycemia risks, your daily glycemic profile, and may suggest potential changes to your insulin parameters.

Current automated insulin delivery (AID) technology systems (i.e. artificial pancreas, hybrid closed loop systems) do not always perfectly manage a person's blood sugar. This study is trying to find out if people with type 1

diabetes on insulin pumps with automated insulin delivery can control their diabetes better by using an AID pump along with the WIT.

You might find the following information helpful as you read this document.

- AID (Automated Insulin Delivery) technology: Includes artificial pancreas, hybrid closed loop systems, and other systems including your Tandem t:slim X2 insulin pump.
- Control-IQ technology: This is the software on your insulin pump.
- WIT (Web Information Tool): This includes both the BAM (Behavioral Adaptation Module) and the PAM (Physiological Adaptation Module) as defined below.
- BAM (Behavioral Adaptation Module): A tool which helps a person work with the AID pump by providing additional information about their diabetes and about current risks for changes in blood sugar.
- PAM (Physiological Adaptation Module): A tool which tells you about your insulin needs and makes suggestions on insulin settings and allows you the ability to see what kind of glucose changes might happen if you were to change your pump settings.

You will interact with these modules on the Web-based Informational Tool (WIT) that will allow you to:

- see information about your diabetes
- see what would have happened to your glucose levels if you had changed some of your diabetes treatment decisions
- get results shown in numbers and in graphs

For WIT to work, the study team will collect insulin, glucose, and meal data from your insulin pump. The WIT application will require you to move scroll bars, click on buttons or make selections from drop-down lists. This information will show you what would happen if you made changes to your insulin therapy settings.

The WIT application is investigational and is not approved by the U.S. Food and Drug Administration (FDA). So far, this WIT application has been tested in 30 humans. It has not yet been proven to be safe or helpful. However, the FDA has allowed WIT application to be used in this research study for people with Type 1 Diabetes. The WIT application being studied in this trial 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 WIT application is the only device that is being studied in this research.

This study is trying to find out if the WIT application can help you take better actions to manage your diabetes. This study will use different computer programs that give you advice in different ways. This advice will suggest that you change your insulin parameters to better control your blood glucose levels. However, the overall care of your diabetes will not be affected by your participation in this study.

As the owner of the patent of web-based informational tool (WIT), the University of Virginia may make money if this study has good results.

## 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 may or may 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:

- This study is using the WIT application which is not approved by the FDA
- Your participation in the study will last for about 26 weeks

## 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:

- Be required to attend a screening visit. It is the preference of the study team that this appointment is performed in person, but a video visit can be substituted for parts of the visit. If this is done with a video visit, you may use a physical exam record from the previous 18 months, and you may go to a local lab to have your blood drawn.
- Continue to use your Tandem insulin pump with Control-IQ Technology
- Be trained on the investigational WIT application
- Use the WIT application system
- The study will give you a an FDA approved Dexcom continuous glucose monitor (CGM) System (e.g. G6 or G7). Your ketone levels will be measured using a commercially available ketone meters and strips.
- Complete questionnaires include one that asks about how you liked using the WIT application. It will take you less than 30 minutes to complete these questionnaires.

## 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 attend check in visits with the study team every other week.
- You will be asked to interact with the WIT application daily during the 20 weeks of the study.
- You will use the investigational application (the WIT application) that is not approved by the FDA.
- You will use an app on a smart phone during the study.

## What other treatments may I receive if I decide to not take part in this study?

You may continue your diabetes care (personal insulin pump) as you normally do.

## How many people will take part in this study?

Up to 90 people will sign consent at UVA. The goal of this study is to test this system on 72 people.

## How long will this study take?

Your participation in this study will require 14 study visits for approximately 26 weeks. The screening appointment (visit 1) will take about 1-2 hours. The Baseline Data Collection (visit 2), and the Randomization visit (visit 3) may take about 1 hour each. You will have two additional check-in visits (visits 2a and 2b) if you

are not currently using the Control-IQ feature of your insulin pump. Check-in visits (visits 4-13) will last about 15-30 minutes. The final visit (visit 14) may take about 1 hour.

**Note: All procedures, tests and assessments noted in this consent are being done for research purposes only.**

# What will happen if you are in the study?

## Visit 1: Screening Visit (visit will last about 1-2 hours)

(Day 1)

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

- A review of your medical and surgical history, allergies, and current medications.
    - **Note**: In order to participate in this study, you may not be using any non-insulin glucose-lowering agent other than metformin or GLP-1 receptor agonists (e.g. semaglutide). Non-insulin glucose lower agents that are not allowed (include pramlintide), DPP-4 inhibitors (e.g. sitagliptin), SGLT-2 inhibitors (e.g. empagliflozin), and sulfonylureas (e.g. glimepiride). A member of the study team will review these medications with you.
- A physical examination and vital signs (height, weight, blood pressure, heart rate, temperature). A physical history dated within the last 18 months may be substituted.
- Demographics (date of birth, gender, race and ethnicity, and socioeconomic indicators)
- Contact information (name, phone number, e-mail address, mailing address)
- Diabetes history including severe hypoglycemia history
- Urine or blood pregnancy test for all females of child-bearing potential. This test must be negative in order to continue study participation.
- HbA1c level
- If needed based on medical history, we may also collect blood to evaluate, including liver function tests, hematocrit and thyroid stimulating hormone (lab results within the last year of the screening appointment may be used)
- Diabetes Management Information: We will record your average total daily insulin use, carbohydrate ratio, correction factor (insulin sensitivity factor), and insulin infusion basal rate profile. Data from your insulin pump, your personal glucometer and continuous glucose monitor may be downloaded or recorded.

If these tests show you are eligible, you will return to the clinic (within 30 days) to begin study treatment.

During this study, you will be asked to fill out some questionnaires. These questionnaires ask about:

- how you feel about your sleep
- how you feel about taking part in the study
- how you feel about the investigation application
- how you feel about the automated insulin delivery (AID) system

- how you feel about hypoglycemia and hyperglycemia

These questionnaires will take less than 30 minutes to complete.

Visits 1 and 2 may be held at the same time once the study team says it is safe for you to participate in the study.

**NOTE: You are asked to immediately notify the study team if you receive a COVID-19 positive diagnosis. Depending on your symptoms, the study investigator may choose to remove you from the study.**

## Visit 2: Baseline Data Collection Visit (will last about 1 hour)

(Day 2)
This visit may occur on the same day as the screening visit once it is determined that you are eligible for the study. This visit may occur in the clinic or by telecommunication. For visits occurring by telecommunication, the relevant devices will be shipped to you.

The purpose of the visit is to obtain about 14 days of data while you were using your personal t:slim X2 study pump and Dexcom CGM while at home (prior to the start of the study). If baseline data are not available from the prior two weeks, the study team will look at older data to identify a two-week data period when you wore the CGM more than 75% of the time. If you do not have this data, you may be provided with a study Dexcom CGM to collect data prior to visit 3.

**Visit 2a and Visit 2b**
If you are not currently using the Control-IQ Technology of your Tandem t:slim insulin pump, you will have two additional visits. During these check-in calls, the study team will:

- review any questions that you have about the device
- review any medical illnesses or medications that you may have started
- review your ketone readings (a download of your ketone meter may be necessary)
- review of your CGM and insulin pump data (a download of your equipment may be necessary)

**Equipment Training**
A study smartphone may be provided for training purposes or if you prefer not to use your personal smartphone during the study.

If you choose the study phone option, you will be provided a study phone with a data plan, an anonymous email account, the Dexcom app, the Tandem Mobile App, and access to the WIT application for the duration of the study. The Dexcom app will allow you to monitor the CGM values and alerts in real-time and stream CGM data to the Dexcom cloud. The Tandem Mobile App will be downloaded to the phone in order allow you to stream insulin pump data to the Tandem cloud. Study staff will register a subject account and login so that you can access the WIT application via the smartphone.

If you choose to use your personal smartphone, the Dexcom app and the Tandem Mobile App will be downloaded to your phone if they are not already installed. The study team may need access to your username and passwords for these accounts. For iOS (Apple) phone users, the study team will need to add the unique device identifier (UDID) of your phone into our account. The WIT app will also be installed on your phone to permit you access to the website.

In both cases, you will have the option of using your personal Dexcom and Tandem accounts or anonymous, study-provided accounts. If you do not wish to use your personal accounts, or do not have personal accounts and do not wish to create one, you will be provided with an anonymous account created by study staff.

If you elect to use a phone provided by the study team, you will be trained on the basic functioning of the phone (e.g. charging, password entry, accessing apps).

All participants will be asked to verify successful installation of apps (where applicable) and account access.

You will be trained on the use of the insulin pump, Dexcom CGM, blood glucose meter, and ketone meter, as needed. If you are a current user of Control-IQ, you should not require training on the insulin pump. If you have not been actively using the insulin pump in CLC mode prior to Visit 2, pump training will be required. You will be instructed on how to use the system if insulin is delivered by any means other than the Control-IQ pump (e.g. injection of subcutaneous insulin via syringe in the event of infusion site failure). If insulin is delivered by any means other than the study pump, you will be instructed to turn off Control-IQ for approximately four hours.

**Additional notes:**
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 will be asked to avoid changing your insulin pump settings during the study except during the every other week suggested changes provided during the BAM+PAM phase. If you feel you need to change your insulin pump settings outside of those times, then we ask that you contact the study team.** You will receive training on how to change insulin parameters and will demonstrate to the study team your ability to change parameters.

You will be allowed to continue wearing your personal Dexcom CGM equipment during the study. The study team will provide you with Dexcom CGM supplies.

A pregnancy test will be repeated as needed if more than 30 days have passed since the prior pregnancy test.

## Visit 3: Randomization Visit (will last about 1 hour)

(Day 14)
This visit can occur between 14-28 days from Visit 2. This visit may occur in the clinic or by telecommunication (something like a Zoom application).

A pregnancy test for women of child-bearing potential, if applicable, will be obtained if more than 30 days from date of last study pregnancy test. Test results must be negative to continue study participation.

After obtaining at least 2 weeks of baseline data, you will be randomly assigned (like the flip of a coin) to 1 of 2 study groups. You have an equal chance of being assigned to any one of the groups. Neither you nor your doctor

can choose which group you are assigned.

**GROUP 1:** Control-IQ for 2 weeks followed by Control-IQ+ BAM for 4 weeks followed by Control-IQ+ BAM and PAM for 16 weeks

**GROUP 2:** Control-IQ+ BAM and PAM for 16 weeks followed by Control-IQ+ BAM for 4 weeks followed by Control-IQ for 2 weeks

You will be trained on the Web-Based Information Tool (WIT).

**PAM training consists of:**

- You will have access to the module that adjusts your settings whenever you wish to interact with it but will be asked to evaluate the insulin parameter suggestions at a minimum of every two weeks.
- Review of how to access the web-based application (e.g. on a smart phone, iPad or computer).
- Review of menus of the application.
- Review of actual settings being adjusted (e.g. basal rates, correction factors)
- You will be instructed to contact the study team to review parameters updates at any time if they are concerned about appropriateness of adjustments
- You will be instructed to contact the study team to confirm the institution of parameter adjustments
- You will be instructed on to how to run a simulation and interpret the results displayed on the screen

**BAM training consists of the following:**

- You will have BAM updates daily and will be asked to check the BAM module each day during the twenty weeks of this trial (the BAM phase and the BAM + PAM phase).
- Hands-on training of identification of modules components and how to access the modules and an explanation of those modules
- You will be notified that Glucose Management Indicator (GMI) is for informational purposes only and not to be used for short-term changes to insulin settings

**Training on the Modules will include:**

- Time in range and Glucose Management Indicator (GMI)
- Hypo- and hyperglycemia risk gauge and calendar
- Ambulatory Glucose Profile (AGP) graph that displays glucose midpoint values over the last two weeks report

Study staff will be available 24/7 to assist you and troubleshoot the system modules.

You will receive recommendations via the mobile app and/or email for adjustments to insulin settings derived from the WIT every two weeks. There could be no changes or several recommended changes. Suggested changes could include, for example, a change in how much insulin you need for your meals. We will be asking you to make those recommended changes as suggested on your insulin pump. If you have concerns about the suggested settings or do not wish to make the recommended changes, we ask that you discuss these concerns with the study team.

The study team may choose to ask that you extend your participation or discontinue your participation in the study if you do not have regular interaction with these modules.

**IMPORTANT:** You will be asked not to make any other changes to your insulin settings on your own during the study except during the every other week recommendations. This would include not making any changes on your own after looking at the information from the BAM or PAM (for example, average glucose estimates such as the GMI). These types of displays provided in this study are for informational purposes only. If you think you need to change the settings for significant hypoglycemia or hyperglycemia outside of the every other week recommendations, we ask that you contact the study team.

You will again receive training on how to change insulin parameters and will demonstrate to the study team your ability to change parameters prior to using WIT including visit 2 and visit 3 if those visits are performed on different days.

## Visit 4-13: Check-In Visit (visit will last about 30 minutes)

**About every 14 days**

These visits may occur in the clinic, phone/email/text/telecommunication (something like a Zoom Application).

You will check in with the study team every other week until the end of the study. During these check-in calls, the study team will:

- review any questions that you have about the device and the study apps
- review any medical illnesses or medications that you may have started
- review your ketone readings (a download of your ketone meter may be necessary)
- review of your CGM and insulin pump data (a download of your equipment may be necessary)

You may contact the study team at any time between these visits if you have any questions.

The study team will also check to make sure that the data was completely downloaded or uploaded. If the study team has difficulty viewing your data, the team may ask you to download the data on any relevant devices, if applicable.

**Questionnaires:**

Group 1 participants will be asked to complete questionnaires after visit 4 and 6.
Group 2 participants will be asked to complete questionnaires after visit 11 and 13.

## Visit 14: Final Visit (visit will last less than 1 hour)

(Day 154)

This visit may occur in the clinic or by telecommunication (something like a Zoom Application).

At the final visit, you will be asked to complete the following:

- The study team will ask you questions about the study, the study device, any new medications, any updates to medical conditions, any health-related problems, and ketone readings.
- You will be instructed on how to transition back to your home insulin regimen. There may be a risk of severe hypoglycemia and severe hyperglycemia as you return to your usual insulin parameters. The study

clinicians will be available if you have questions. Study clinicians will decide if your settings need to be changed, and what those changes will be. The study clinicians will continue to be available during the post study check-in to make sure your transition is smooth.

- You will need to complete a questionnaire. It will take you less than 30 minutes to complete these questionnaires.
- Blood will be drawn for HbA1c (which can be done on-site or locally)
- You will be asked to return all study devices (e.g. study Dexcom CGM, study phone if provided, ketone meter) either via mail or at an office visit. You may keep the study ketone meter after it is downloaded. You will not have to pay for any costs of shipping devices.

If you need to stop the study early (for example you were unable to complete any visits after visit 5), you will be asked to complete final visit 14.

**Post-Study Check-in Visit (visit will last about 5 minutes)**

(Day 156)

Approximately 48 hours after completing the study, the staff will contact you via phone/email/text to ensure that you have completed the A1c test, have returned the study devices (e.g. study Dexcom CGM, study phone if provided, ketone meter), and if you have had any health issues since completing the study.

## Study Schedule

| Visit Name | Visit 1 | Visit 2 | Visit 2a & 2b | Visit 3 | Visit 4-13 | Visit 14 |
|---|---|---|---|---|---|---|
| **Description** | **Screening Visit** | **Device Training & Data Collection** | **Check-In visits for non-CIQ users** | **Randomization** | **Bi-Weekly Check-In** | **Final Visit** |
| Timing | 12 weeks to 0 days of Visit 3 | 4 weeks to 0 days of Visit 3 | V2a within 2 +/- 1 days of V2: V2b within 7 +/- 3 days of V2 | Day 1 | Every 14 +/-5 days | Day 154+/- 7 days (22 weeks) |
| Location (office visit, phone, email, text, or telecommunication visit may be used as recommended by the study team) | O/P | O/P | O/P | O/P | O/P | O/P |
| Informed Consent | X | | | | | |
| Eligibility Assessment | X | | | | | |
| Medical History | X | | | | | |
| HbA1c | X | | | | | X |
| Screening Blood Testing | X | | | | | |
| Pregnancy test (if applicable) | X | X | | | | |
| Physical Exam (if applicable) | X | | | | | |
| Vital Signs (including height/weight) | X | | | | | |
| Historical baseline data | | X | | | | |
| Training on Relevant Devices or Modules | | X | | X | | |
| Review CGM & pump downloads | | | X | | | |
| Randomization | | | | X | | |
| Questionnaires | | X | | | Only at the end of each phase: **Group 1:** Visit 4, 6 **Group 2:** Visit 11, 13 | X (Both Groups) |
| Review diabetes management and AEs | X | X | X | X | X | X |

* O/P – Outpatient; may include phone/email/text/telecommunications (like a Zoom Application)

** Participants who withdraw from the study will be asked to complete visit 14.

# What are your responsibilities in the study?

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

- You need to attend each study visit as instructed by the study team.
- 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 tell the study doctor or study staff if you receive a COVID-19 positive diagnosis. You will need to answer questions related to COVID-19 screening prior to or during in-person study visits.
- You will need to 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

The total amount of blood we will take for your hemoglobin A1c test will be less than a ½ teaspoon of blood. The blood we take will be tested to measure your hemoglobin A1c, which is a blood test used to monitor how well you are managing your diabetes.

If additional labs are needed (for example: liver function tests, hematocrit, pregnancy, and thyroid stimulating hormone), we will take less than 7 teaspoons of blood.

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 using an investigational application. The purpose of the application is NOT to diagnose any disease or abnormality you may have. Because the application is investigational, there is no way for the study leader to understand if the results are "normal" or "abnormal". However, if any 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 1 diabetes (with or without study devices):**

**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.

**Risk associated with using a web-based simulation tool:**
**Unknown**

- You are using the insulin parameters provided during simulation without consulting your personal health care team first.

**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)
- CGM sensor reads higher or lower than your actual glucose level
- 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**

- 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.
- 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 related to use of Insulin Pump**
**Likely**

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

**Rare but Serious**

- Risk of symptoms related to inserting an infusion set: sensitivities to adhesives resulting in skin irritation, bruising, and bleeding. Risk of developing subcutaneous hypertrophy or atrophy of tissues related to insulin infusion.

**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 move on to the next question

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

- False positive or false negative results.

**Risks of having your blood drawn:**
**Having blood drawn may cause:**

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

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

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

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

**Risks of 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 but serious**

- Infection at site of lancet use

**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. 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.

**Cybersecurity Risks**
Similar to 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 pumps, CGMs, activity trackers, 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 insulin pump settings which may cause 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 may or may not benefit from being in this study. Possible benefits include learning more about your diabetes management. In addition, 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 condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include:

- managing your condition as recommended by your endocrinologist

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 $600.00 for finishing this study by check.

- Visit 2-13: $25 per visit ($300)
- Visit 14: $200 for completing the study and returning the study devices
- Completion of study questionnaires: $100

You should get your payment about 6 weeks after finishing the study and after returning the study CGM and ketone meter. The ketone meter can be returned to you after the data is downloaded. The income may be reported to the IRS as income.

If you decide not to 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 for the visits that you have completed.

## Will being in this study cost you any money?

You will use your personal insulin pump, pump supplies, and insulin during this study.

You and/or your insurance company must pay for the glucagon emergency kit, which is a medication to help with severe low blood sugar. A prescription for this medication is considered part of usual care for a person with Type 1 Diabetes. You will be responsible for any costs related to using your personal smartphone during the study.

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, physical examination, vitals, pregnancy tests, study Dexcom CGM supplies, ketone meter supplies, and study phone with study apps.

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

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

## What if you are hurt in this study?

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

## What happens if you leave the study early?

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

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

a) Your study leader is concerned about your health
b) Your condition 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 closes for safety, administrative or other reasons

If you decide to stop being in the study, we ask that you notify the study leader and/or research team so any scheduled visits may be cancelled. The study Dexcom CGM and other supplies remain the property of the CDT and will need to be returned to the study team.

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?

- 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.

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 study leader listed on this form or complete the "Leaving the Study Early" part of this form and return it to the study leader. Then you will no longer be in the study. The study leader will still use information about you that was collected before you ended your participation.

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.

## 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.

## Please contact the Principal Investigator/Study Leader 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/Study Leader:**
Sue A. Brown, MD
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 22908
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 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.

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

# 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:
*The 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:

- Sending me surveys/ questionnaires at the end of your participation

____ 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 |