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

Principal Investigator:	Sue Brown, MD University of Virginia Center for Diabetes Technology (CDT) Box 400888 Charlottesville, VA 22903 434-982-0602
Sponsor/Funding Source:	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.

What problem is this study trying to solve?

You are being asked to take part in this study because you have received the diagnosis of Type 1 Diabetes and use a Tandem t:slim X2 insulin pump with Control-IQ Technology as part of your regular clinical care.

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

1) AID (Automated Insulin Delivery) technology: Includes artificial pancreas, hybrid closed loop systems, and other systems including your Tandem t:slim X2 insulin pump.
2) Control-IQ technology: This is the software on your insulin pump.
3) ABC (Adaptive Behavioral Control): This includes both the BAM (behavioral adaptation module) and the ATM (auto titration module) as defined below.
4) BAM (Behavioral Adaptation Module): A tool which helps a person work with the AID pump by providing additional information. The purpose of this study is to examine the addition of the BAM.
5) ATM (Auto Titration Module): The ATM tells you about your insulin needs and makes suggestions on insulin treatment.
6) WST (Web Simulation Tool): The web application that allows the ability to view information from different modules.

Current automated insulin delivery (AID) technology systems (i.e. artificial pancreas, hybrid closed loop systems) does 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 "Adaptive Biobehavioral Control" (ABC) application. This investigational ABC application has several parts. First, there is a "Behavioral Adaptation Module" (BAM) that helps a person to work with the AID pump by giving the person information about their diabetes and about current risks for changes in blood sugar. Second, there is a "Auto Titration Module" (ATM) that tells a person about changes in their insulin needs and makes suggestions on insulin treatment settings.

You will interact with these modules on a **web-based simulation tool** (WST) that will allow you to:

1) see information about your diabetes;
2) see what would have happened to your glucose levels if you had changed some of your diabetes treatment decisions;
3) get results shown in numbers and in graphs.

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

The study team is going to compare the following:

- The current AID technology (Control-IQ technology) with ATM / WST for 6 weeks
- The current AID technology (Control-IQ technology) with ATM / WST and BAM for 6 weeks

The ABC application is investigational and is not approved by the U.S. Food and Drug Administration (FDA). So far, **this ABC application has not been tested in humans and has not yet been proven to be safe or helpful**. The ABC application being studied in this trial has been tested in a computer only using insulin parameters that have been collected from thousands of people with type 1 diabetes. This is called computer simulation. The ABC application is the only device that is being studied in this research.

This study is trying to find out if the ABC 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.

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 ABC application which is not approved by the FDA
- Your participation in the study will last for about 8-10 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 12 months, and you may go to a local lab to have your blood drawn.
- Use the ABC application system that includes BAM and ATM / WST applications
- Continue to use your Tandem insulin pump with Control-IQ Technology
- Be trained on the investigational ABC application.
- The study will give you a CGM that includes a Dexcom G6 transmitter and sensors. Your ketone levels will be measured using the Abbott Precision Xtra meters and strips. These devices are FDA-approved for the intended use in this study.
- Complete questionnaires about how you liked using the ABC application. It will take you less than 15 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 up to 9 study visits.
- You will use the investigational application (the ABC Application) that is not approved by the FDA.

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.

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. One of the lead investigators who is working on the study has a financial conflict of interest with one of the companies that is providing study supplies. This investigator is not a medical doctor. He will be developing the software being used in this study. Decisions regarding your participation in the study and safety are made by a person (other than this investigator) who is a medical doctor.

How long will this study take?

Your participation in this study will require 9 study visits over 8-10 weeks. The screening appointment (visit 1) will take about 1-2 hours. The Run-In Phase (visit 2) and the Randomization visit (visit 3) may take about 1 hour each. Each Check In visit (visits 4-8) will last about 30 minutes. The final visit (visit 9) may take about 1 hour.

Up to 45 people will be in this study at UVA.

What will happen if you are in the study?

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

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 in the study, there will be a screening period. You will have tests and procedures during this time to make sure you are eligible and it is safe for you to participate. These include the following:

- 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 (including GLP-1 agonists, pramlintide, DPP-4 inhibitors, SGLT-2 inhibitors, sulfonylureas). 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 year 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 (Only the urine pregnancy test can be done remotely with results sent to the study team). 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 taking part in the study
- how you feel about the investigation application
- how you feel about the automated insulin delivery (AID) system

These questionnaires will take less than 15 minutes to complete.

Visit 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: Run-In Phase (visit will last about 1 hour)

(Day 2-29)

A run-in phase is a period of time that you participate in after signing the consent form, but before you are randomized to a group. This period of time helps you and the study team to set up for the main period of the study by learning the systems you must use, collecting basic information about your diabetes management, and to give you time to use the devices and ask any questions. This phase helps both you and the study team to perform our roles as best we can during the main study.

This visit may occur in the clinic or by telecommunication. For visits occurring by telecommunication, the relevant devices will be shipped to you.

A study smartphone may be provided for training purposes or if you prefer not to use your personal phone 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 G6 app, the Tandem t:connect Mobile App, and access to the ABC system 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 Clarity cloud. The Tandem t:connect Mobile App will be downloaded to the phone in order allow you to stream insulin pump data to the Tandem t:connect cloud. Study staff will register a subject account and login so that you can access the ABC system via the smartphone.

If you choose to use a personal smartphone, the Dexcom G6 app and the Tandem t:connect Mobile App will be downloaded to your phone if they are not already installed.

In both cases, you will have the option of using your personal Dexcom and Tandem t:connect 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 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 CGM and ketone meter. You will be asked to wear this equipment at home for approximately 14 days. The study team may ask you to repeat this run-in period if there is a problem with the data. You will be asked to perform fingerstick blood glucose measurements (if needed) in accordance with the labeling of the CGM device (e.g. if calibrations are requested by the device or if your symptoms are not matching the blood glucose).

You will also be trained on the insulin pump and blood glucose meter if needed.

Because you are a current user of Control-IQ, you should not require training on the insulin pump. 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.
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 allowed to make your usual insulin dosing decisions during this run-in phase, but you will be asked to avoid changing your insulin pump settings during this time.

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

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

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

(Day 30)

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

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 + Auto Titration Module (ATM) and Web Simulation Tool (WST) for 6 weeks
GROUP 2: Control-IQ + Auto Titration Module (ATM) and Web Simulation Tool (WST) **+ Behavioral Adaptation Module (BAM) for 6 weeks**

You will be trained on the Investigational Applications (Auto Titration and BAM) that you are assigned to during this study.

All participants in both groups will be trained on the ABC application.
Autotitration / WST training consists of:

- 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 parameters being adjusted (e.g. basal rates, correction factors)
- Review of frequency of parameter updates (i.e. once weekly)
- 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 interrupt the results displayed on the screen

If you are randomized to Group 2 you will also receive BAM training and will generally consist of the following:

- Review of how to access the BAM application components and troubleshooting.
- Hands-on training of identification of information modules components and how to access the information modules and an explanation of those modules
- Hands-on training of how to access prescriptive modules on demand and an explanation of those modules
- You will be notified that eA1c is for informational purposes only and not to be used for short-term changes to insulin settings

Information Modules will include:

- *Hypoglycemia Risk Indicator* based on pattern recognition and risk assessment;
- Daily glycemic profile forecast;
- *Estimated A1c* (*eA1c*) which will assist with tracking average glycemia and goal setting, and
- *Variability tracker* highlighting glycemic patterns related to behavioral challenges such as meals and

exercise.

Study staff will be available 24/7 to assist you and troubleshoot the BAM and auto-titration modules.

You will receive recommendations by email once a week on whether you need to change your insulin treatment settings or not. There could be no changes or several recommended changes each week. 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 with the study team.

If you are randomized to Group 1, you will be asked to have at least weekly interaction these modules to review and implement the weekly parameter settings.

If you are randomized to Group 2, you will be asked to have at least weekly interaction with these modules to review and implement the weekly parameter settings. You will be asked to have **daily** contact during the BAM module.

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 weekly recommendations. This would include not making any changes on your own after looking at the information from the behavior adaptation module or web-based simulation tool (for example, the WST replay information or average glucose estimates such as the estimated A1c). These types of displays provided in this study are for informational purposes only.

- A pregnancy test for women of child-bearing potential, if applicable, will be obtained that must be negative to continue study participation.

Visit 4-8: Check-In Visit (visit will last about 30 minutes)

(Day 37, 44, 51, 58, 65)

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

You will check in with the study team one time weekly for five weeks. During this visit, the study team will ask you questions about the study, the ABC application, any new medications, any updates to medical conditions, any health-related problems, and ketone readings.

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.

Visit 9: Final Visit (visit will last less than 1 hour)

(Day 72)

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 about how you liked using the ABC application. It will take you less than 15 minutes to complete this questionnaire.
- Blood will be drawn for HbA1c (which can be done on-site or locally)
- Pregnancy test for women of child-bearing potential, if applicable, will be obtained.
- You will be asked to return all study devices (e.g. study 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 9.

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

(Day 74)

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 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 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9
Description	**Screening**	**Device Training & Run-In**	**Randomization**	**Weekly Check-In**	**Weekly Check-In**	**Weekly Check-In**	**Weekly Check-In**	**Weekly Check-In**	**Final Visit ****
Days	**Day 1**	**Day 2-29**	**Day 30**	**Day 37±3**	**Day 44±3**	**Day 51±3**	**Day 58±3**	**Day 65±3**	**Day 72±3**
Location	O/P	O/P	O/P	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: CMP, TSH if applicable	X								
Pregnancy test (if applicable)	X	X	X						X
Physical Exam	X								
Vital Signs (including height/weight)	X								
Training on Relevant Devices or Modules		X	X						
Randomization			X						
Questionnaires			X						X
Review diabetes management and AEs	X	X	X	X	X	X	X	X	X

* O/P – Outpatient

** Participants who withdraw from the study will be asked to complete visit 9.

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 visits 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. 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.

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.

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 and thyroid stimulating hormone) we will take less than 6 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.

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)

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.

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 the continuous subcutaneous insulin infusion (CSII) insertion: 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.

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 $300.00 for finishing this study by check.

- Visit 2 and 4 – 8: $25 per visit ($150)
- Visit 9: $100 for completing the study and returning the study devices
- Completion of study questionnaires: $50

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, 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

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 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 CGM and other supplies remain the 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 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: 434-924-9634

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.

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:
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:

4) 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