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 pay for the hotel/rented house (from here on "hotel" will be used for both hotel or a rented house) sessions, meals, Dexcom G6 continuous glucose monitor (CGM) supplies, ketone meter, and ketone test strips.

Note: You will need to provide your own glucometer, insulin, and blood glucose strips.

Key Information About This Research Study

Principal Investigator:	Dr. Sue Brown, MD University of Virginia Center for Diabetes Technology (CDT) Box 400888, Charlottesville, VA 22903 Telephone: 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.

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

The purpose of this study is to assess the safety of two investigational systems called the Neural Net Implementation algorithm (complex mathematical formula) as compared to another algorithm called UVA Model Predictive Control Algorithm (UMPC) that the UVA Center for Diabetes Technology has developed. The Neural Net Artificial Pancreas (NAP) and UMPC are automated insulin delivery algorithms designed to result in similar insulin dosing decisions but use different mathematical approaches to dose insulin. Neither NAP nor UMPC have been approved by the Food and Drug Administration (FDA) and are therefore considered investigational for the purpose of this study.

The NAP system has not been used with human subjects before this study. The NAP 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 UMPC has been tested in simulation as well as with 49 people in supervised hotel settings.

Your Tandem Control-IQ (CIQ) insulin pump, the CGM, and the algorithms will be connected to the study-provided Android cellphone. The study team calls this closed-loop control system the Diabetes Assistant (DiAs) system. DiAs will automatically manage insulin infusion to keep your blood glucose within a desired range. It will also allow for remote monitoring of your pump and CGM. This system will be referred to as the "**study system**" throughout this consent document.

You will be studied at a local hotel for approximately 20 hours per session. Prior to each hotel session, you will collect insulin pump data from your CIQ insulin pump for a week. The two hotel sessions can be performed back-to-back during the same hotel stay or in two hotel stays separated by up to 28 days.

You are being asked to take part in this study because you are 18 years old or older and have been diagnosed with type 1 diabetes mellitus.

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. You may not be helped by being in this study, but the information gained by doing this study may help other people 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:

- This study is using the NAP and UMPC systems which are not approved by the FDA.
- The study requires two 20 hour hotel sessions with other study participants.
- You will need to use these systems during the hotel session.
- You must use the NAP and UMPC systems during the study. The study team will change insulin dosing and allow the algorithm to calculate your insulin dosages.
- You may not use tobacco or alcohol during the hotel session.
- You will need to be using Humalog (lispro) or Novolog (insulin aspart) during the supervised study hotel session(s), if not, you will be asked to contact your healthcare provider to change your prescribed insulin to one of these insulins for that portion of the trial as they are the FDA approved insulins for use in the CIQ device. Your healthcare/insurance will have to pay for this insulin.

What will I have to do if I take part in this study?
Full details of all the procedures are found later in this form. If you agree to take part in this study, you will:

- You will use the Neural Net Implementation algorithm or the UVA Model Predictive Control Algorithm (UMPC) algorithm.
- You will need to give a finger stick blood sample to measure your hemoglobin A1c.
- If needed based on your medical history, the study physician may request a thyroid function or kidney/electrolyte blood test. Lab results within one year of your screening appointment may be used.
- You will need to share insulin pump data with the study team.
- You will need to stay at a hotel for about 20 hours. If you complete the study sessions back-to-back, you will stay at the hotel for about 40 hours.
- You will eat the same dinner and breakfast during the sessions, with the same amount of carbohydrate, protein, and fat for each hotel session.
- Snacks with carbohydrates will not be allowed unless for the treatment of low blood sugars.

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 study visits and have access to internet and willingness to upload data during the study.
- You will use study systems during the study.

What other treatments may I receive if I decide to not take part in this study?
If you do not participate, you will continue your diabetes care (using your personal insulin pump) as you normally do.

How many people will take part in this study?
Up to 20 people will be in this study at UVA.

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. As owner of the intellectual property rights in UMPC, the University of Virginia may make money in the future if this UMPC has good results.

How long will this study take?

Your participation in this study will require 7 study visits over 5 weeks. Visit 1 is the screening visit to determine if you are eligible to participate in this study and will take about 1-2 hours. Visit 1 and visit 3 hotel session may be up to 3 months apart. Visit 2 and visit 5 are check-in visits about 1-3 days before the start of the hotel session and will take about 15-30 minutes each to complete. Visit 3 and visit 6 are hotel sessions that will take about 20 hours each to complete. These sessions can be completed back-to-back or up to 28 days apart. If you choose to do the hotel sessions back-to-back, you will be at the hotel for about 40 hours. Visit 4 and visit 7 are check-in visits 1-2 days after the hotel session and will take about 15 minutes to complete.

What will happen if you are in the study?

NOTE: All procedures/assessments and tests described in this consent are completed for research purposes only.

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

(Day 1/Remote or Clinical Research Unit (CRU) Visit)

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

- A review of your medical and surgical history, allergies, and current medications.
- A physical examination and vital signs (height, weight, blood pressure, heart rate, temperature). A physical history from your endocrinologist or another physician dated within the last 9 months may be substituted.
- Blood may be taken from your finger to obtain a hemoglobin A1c test. This is the same test that you may have done at your endocrinologist's office every 3 months. A hemoglobin A1c value that was obtained within the last two weeks prior to screening and up until the start of the hotel sessions may

be used for this test.

- If needed based on your medical history, the study physician may request a thyroid function or kidney/electrolyte blood test for laboratory testing. Lab results within one year of your screening appointment may be used.
- If you are a female of childbearing potential will be asked if you are currently pregnant or may be pregnant. You are not able to participate in this study if you are pregnant or plan to get pregnant during the study period. Before you start the hotel sessions, a urine pregnancy test will be performed, if applicable, before starting the study system. This pregnancy test must be negative for you to participate.

Note: Potential eligibility may be assessed as part of a routine-care examination. A physical exam documented in the prior 9 months can suffice for the physical exam but will not serve as an exclusionary criterion if not available. Any labs required may be obtained at a local laboratory (e.g., LabCorp) convenient to the participant.

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

Data Collection

One week of data will be downloaded from your insulin pump or from your t:connect account to establish your baseline values and initialize the control algorithms. Up to 3 months of historical data from your Control-IQ (CIQ) system may be downloaded or recorded. This data may be obtained through the commercially available applications (e.g. t:connect).

Randomization

You will be randomly assigned (like the flip of a coin) to determine the order of the system approach during your hotel sessions. There are two approaches to be used for different 20-hour periods during the study (NAP or UMPC).The study team will know whether you are using NAP or UMPC system during the session.

GROUP 1: NAP Session then UMPC Session
GROUP 2: UMPC Session then NAP Session

Visit 2: Pre-Session Check-In Visit at Hotel (about 15-30 minutes)

(Day 2/Telephone call)

You will be contacted by the study team approximately 1-3 days prior to the hotel session by phone to verify the following:

- Inquire about any changes to your health (e.g. illness, changes in medications)
- Verify that your Dexcom CGM sensor was placed approximately 24-72 hours prior to the study session for proper warm up.
- Remind you that the CGM reading should be 80-250 mg/dL at the start of the study at the hotel.
- Remind you to bring your insulin and other medications.
- You will be reminded to bring quiet activities for yourself to enjoy during the hotel session.
- Should any concerns regarding your health, pump information, or unforeseen issues arise, the session may be cancelled at the discretion of the investigator.

Visit 3: Hotel Study Session (will last up to 20 hours)

(Day 3-4/Hotel)

Hotel Session Arrival (Day 0):

- You will come to a hotel for the hotel session. This session will last up to approximately 20 hours**.** The actual testing session is 18 hours in duration.
- The study team will confirm that you brought your insulin, insulin pump supplies, and regular medications to the hotel sessions.
- A urine pregnancy test will be performed, if applicable, before starting the study system. This pregnancy test must be negative for you to participate.
- You may change your CGM sensor if your current sensor was inserted more than 24-72 hours before your arrival.
- The study team will provide dinner.
- The content of the meals will be the same between the two hotel sessions.
- Carbohydrates, protein, and fat will be approximately the same between the two hotel sessions.
- Snacks with carbohydrates will not be allowed unless for the treatment of low blood sugars.

Hotel Session:

- Your home insulin pump will be discontinued, and the study research insulin pump will be set and inserted on your abdomen.
- You may be asked to use a Tandem infusion set. This infusion set will be replaced with a new infusion set in 2-3 days.
- Your CGM value and your ketone value will be tested by the study team. The study physician may provide treatment if these values are too high. This treatment may include asking you to drink fluids, walk, etc. to reduce your ketones prior to the start of the study.
- You will have dinner and breakfast during the hotel session.
- You will eat meals at the times designated by the study team.
- You will follow your usual daily routine as closely as possible. Some types of exercise will be permitted if it is your usual routine and is feasible for the study team to monitor you (e.g. walking, yoga, treadmill).
- You will go to bed no later than 11 pm.
- At least two study team members (e.g. technician, nurse, physician, nurse practitioner or physician assistant) will be present during the day and overnight hours of the hotel session.
- Any adjustments to your current insulin parameters during the hotel study session will be done with the assistance of the study physician.

NOTE: You may choose to complete two hotel sessions back-to-back (Visit 6 immediately after Visit 3). The hotel session will then be a 40-hour session.

Hotel Discharge:

- Your CGM value will need to be stable and between 80-250 mg/dL with ketone levels less than or equal to 0.6 mmol/L.
- You will return the study system.
- You will return to using your personal insulin pump.
- You will be asked to monitor your ketone levels for up to 24-48 hours after discharge from the hotel

session if ketones were elevated within 12 hours prior to discharge. Urine ketone strips may be provided to you if needed.

Visit 4: Post-Session Check-In Visit (about 15 minutes)

(Day 5/Phone, Text, or Email)

The study team will contact you about 24-48 hours after completing the Hotel Study Session 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

You can talk with the study physician or physician's assistant if you have questions related to adjusting back to your usual insulin parameters.

Post-Session Check-In Visit will not occur if you complete the hotel sessions back-to-back.

Visit 5: Pre-Session Check-In Visit at Hotel (about 15-30 minutes)

(Day 6/Telephone call)

Same as visit 2. You will have up to 28 days to complete this hotel session.

Pre-Session Check-In Visit will not occur if you complete the hotel sessions back-to-back.

Visit 6: Hotel Study Session (will last up to 20 hours)

(Day 7-8/Hotel)

Same as visit 3.

Visit 7: Post-Session Check-In Visit (about 15 minutes)

(Day 9/Phone, Text, or Email)

Same as visit 4.

End of Study Participation:

At the conclusion of the Post-Session Check-In Visit7, your participation in the study is complete.

Study Schedule

	Screening	Hotel Session 1			Hotel Session 2		
		Pre-Session Check-In	Hotel Session 1	Post-Session Check-In	Pre-Session Check-In	Hotel Session 2	Post-Session Check-In
Location	In person or Remote	Phone/ Email/ Text	Hotel/ Rental House	Phone/ Email/ Text	Phone/ Email/ Text	Hotel/ Rental House	Phone/ Email/ Text
Visit	1	2	3	4	5	6	7
Informed Consent	X						
Eligibility Assessment	X						
Medical History	X						
HbA1c	X						
Laboratory Testing (if required)	X						
Urine Pregnancy test (if applicable)			X			X	
Physical Exam	X						
Vital Signs (height/weight)	X		X			X	
Demographic Survey	X						
Baseline data download (1 week of data)	X						
Randomization	X						
NAP / UMPC use Review diabetes management and AEs		X	X	X	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 attend each study visit.
- You must be completely truthful about your health history.
- Follow all instructions given.
- Answer all the study-related questions completely.
- You should tell the study doctor or study staff about any changes in your health or the way you feel.
- You should report any issues with the study equipment.
- Inform the study doctor or study staff as soon as possible if you have to take any new medications, including anything prescribed by a doctor or those that you can buy without a prescription (over-the-counter), including herbal supplements and vitamins. The study team will let you know if you can take these medications.

Blood Testing

The blood we take will be tested to measure your hemoglobin A1c which is a blood test used to monitor how well you're managing your diabetes. This blood we will take less than a ½ teaspoon of blood.

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

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

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

During your study participation, you will be undergoing research assessments using two investigational systems The purpose of these investigational systems is NOT to diagnose any disease or abnormality you may have. Because the testing is investigational there is no way for the study leader to understand if the results are “normal” or “abnormal”. However, if any test results are concerning, your study leader will let you know.

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

What are the risks of being in this study?

Loss of Privacy:

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

The study team will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible but participating in research may involve a loss of privacy and the potential for a breach 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.
- The hotel session will have other participants also in attendance.
- The study team is not able to restrict other participants from sharing photographs that include you (i.e. social media).

Risks and side effects related to treating type 1 diabetes (with or without using study equipment):

Likely

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

Rare but serious

- Risk of severe temporary low blood sugar (hypoglycemia) that can lead to unconsciousness, hypoglycemic seizure, hospitalization or even death. One of the ways this could happen is if the system delivers too much insulin when a meal was not eaten but the system detected what looked like a meal based on the CGM increasing.
- Risk of prolonged high blood sugar leading to DKA, hospitalization, and coma. DKA can lead to renal failure (kidney failure), cardiac arrhythmia (irregular heartbeat), myocardial infarction (heart attack), rhabdomyolysis (muscle breakdown), and even death.

Risks related to using a 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 associated with performing a urine pregnancy tests (women who can become pregnant):
Less Likely
- False positive or false negative results.

Risks associated with staying at the hotel for research purposes:
Likely
- Loss of privacy
- Disruption of daily routine similar to staying at a bed and breakfast

Risks and side effects related to the study system include:
Even though the study algorithm has been tested in a computer simulation or in another clinical study, there is still a risk that parts of the system may malfunction. As a result, you could receive less or more insulin than you need and be at risk for hyper- or hypoglycemia. The following are common cases of system malfunction:
- CGM sensor reads higher or lower than your actual blood glucose level
- CGM sensor stops working or cannot communicate with the system. If this occurs, the insulin pump will start delivering its preset basal rates within 30-60 minutes
- Infusion set failures

Risks associated with having your blood drawn:
Having blood drawn may cause:
- ✓ pain (common),
- ✓ a bruise (sometimes),
- ✓ fainting or passing out (not very often), and
- ✓ infection (rare).

If the people doing the study are exposed to your blood or body fluids in a way that could give them a disease, your blood may be tested. The tests might check for:
- ✓ hepatitis,
- ✓ HIV (Human Immunodeficiency Virus), or
- ✓ other infections.

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

Risk of Sharing the Insulin Pump, Continuous Glucose Monitor, and Ketone Meter:
Insulin pump, continuous glucose monitor, and ketone meter are 'single use devices'. This means that they recommend that only one person use this device as there is a rare risk that a blood borne pathogen, such as Hepatitis B, may be spread if used with multiple patients. All devices will be cleaned thoroughly with a diluted mixture of bleach or another appropriate cleaner after use per approved cleaning procedure.

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

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

Risks for women:
Being in this study might hurt your unborn baby, so you will not be able to join or stay in the study if you become pregnant. You must use an effective method of birth control during the study if you are a female of child-bearing potential. 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 might like to take part in this study because this study may improve your understanding of diabetes. You may or may not be helped by being in this study, but the information gained by doing this study may help other people with type 1 diabetes mellitus at some future time.

What are your other choices if you do not join this study?
You do not have to be in this study to be treated for your illness. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include:

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

If you are an employee of UVA, your job will not be affected if you decide not to participate in this study.
If you are a student at UVA, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?
You will be paid up to $500.00 by check for finishing this study. You should get your payment about 6 weeks after your participation in the study is complete. The compensation payment may be reported to the IRS as income.

- Travel Stipend: $200 (unless the study team organizes your airfare or rail ticket)
- Completion of the Visit 3: Hotel Session #1: $150
- Completion of the Visit 5: Hotel Session #2: $150

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

Payment for study visits completed will be provided after all study pump has been returned to the study team.

Will being in this study cost you any money?
The following procedures/tests, which are being done for research purposes, will be provided at no cost to you or

your health insurance: hemoglobin A1c test, pregnancy test, study systems, infusion set, and CGM supplies. Any additional laboratory tests the study physician request from you to participate in this study will not cost you additional money nor will your insurance be billed. The study team will pay for the cost of the hotel and the meals during the study sessions.

You will be responsible for the cost of your insulin, glucometer, and test strips that you use during the study.

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

What if you are hurt in this study?

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

What happens if you leave the study early?

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

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

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

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

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

How will your personal information be shared?

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

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

- Personal information such as name, address and date of birth

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

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- 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 provide supplies, and government agencies that provide oversight such as the Food and Drug Administration (FDA) as the study is regulated by the FDA.
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.
- Members of the Center for Diabetes Technology, researchers from outside of UVA and other non-medical staff may be present during the study to both observe and support the hotel session.
- Other participants may take photos of this event. Your face may be in these photos. Other participants may post these photos on social media without your permission.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

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

Information obtained from you during this study may be used in future research. Your information may be shared with other researchers inside or outside of the University of Virginia. They will not be sent with information that could identify you such as name, address or phone number.

A description of this clinical trial will be available on *http:// www.ClinicalTrials.gov*, as required by U.S. Law. This web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this web site at any time.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form or complete the "Leaving the Study Early" part of this form and return it to the researchers. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

A copy of this consent form will be put in your medical record. (This is not the same as the record of this research study.) This means that everyone who is allowed to see your medical records will be able to find out that you are in this study. This is done so your regular doctors will know what you receive as part of this study. If you have other health problems during the study, they will be able to treat you properly.

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.
- Reports to authorities if you have an infectious disease that health care providers are required to report by law.

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

Please contact the Principal Investigator listed BELOW to:

- Obtain more information about the study
- 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:
Sue 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 22903 Telephone: 434-924-2620

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

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

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

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

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

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

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

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

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

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

Check one option below:

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

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

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

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

Consent From Adult

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

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

Person Obtaining Consent

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

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