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 # _____

Principal Investigator:	Sue Brown, MD UVA Center for Diabetes Technology Box 400888 Charlottesville, VA 22908 Telephone: (434) 982-0602
Sponsor:	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

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 signed copy of this form.

Who is funding this study?

This study is paid for by a grant from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The insulin pump will be provided by Tandem Diabetes Care, Inc. The Continuous Glucose Monitors will be provided by Dexcom, Inc.

Why is this research being done?

The purpose of this study is to gain experience using an experimental insulin management system ("study system") before starting a larger study. The proposed artificial pancreas system is named *Control-IQ*. This Artificial Pancreas (AP) system is designed to help control blood sugar in people with type 1 diabetes mellitus who are on insulin pump therapy and can successfully be used and supervised in a non-hospital (research house) setting. This study will test an insulin pump and continuous glucose monitoring (CGM) to automatically give insulin and control blood sugar.

The study system is an experimental device that has not been proven to be safe or helpful. This device is not approved by the U.S. Food and Drug Administration (FDA). The algorithm (the complex mathematical formula that calculates your insulin dosage) has been tested in more than 280,000 patient hours using laptops and cell phones. Using the algorithm in this insulin pump with this CGM is new research and has not been tested in people living with type 1 diabetes before this study.

You are being asked to be in this study because you live with type 1 diabetes and are using an insulin pump.

Up to 20 people will be in this study at UVA.

When a person or an organization has a financial or other interest large enough to seem as if it could affect their judgment, it is called a conflict of interest. Members of University of Virginia's Center for Diabetes Technology (CDT) have a conflict of interest with this study. Technologies tested in this trial are patented or have a patent pending by investigators who work at UVA Center for Diabetes Technology. However, the investigators have assigned all patent rights to the University of Virginia. The UVA Licensing and Ventures Group handles all further transactions, licensing, and other issues related to these technologies. If this technology leads to marketable products, UVa may receive compensation. UVa has a financial interest in the outcome of this study.

How long will this study take?

Your participation in this study will require up to 3 study visits over 2 weeks. Visit 1 is a screening visit to determine your eligibility. This visit may take about 2 hours to complete. Visit 2 is a 36-48 hour supervised hotel visit. Visit 1 and 2 may occur on the same day if you meet study eligibility. Visit 3 is a follow up check-in up to 36 hours after the Visit 2 to see if you are feeling well after the completion of the study.

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

What will happen if you are in the study?

SCREENING (visit will last about 2 hours)

Visit 1 (Day 1)

If you agree to participate, you will sign this consent form before any study-related procedures take place. You will have tests and procedures to make sure you are eligible, and verify that it is safe for you to participate.

These include the following:

- Collection of information about you: your diabetes history, past and current medical conditions, surgical procedures, menstrual history (females), allergies, medications and supplements, social history (including drinking, smoking and drug habits), and whether or not you have various symptoms.
- Your pump settings and average daily insulin use over the past seven days.
- Collection of your contact information
- Physical exam
- HbA1c test (results collected within the last two weeks is also acceptable)
- Additional blood tests if your study doctor has any concerns about medical conditions that might affect your participation in the study

- A urine pregnancy test if you are a woman who can become pregnant. The pregnancy test must be negative in order for you to participate and will be repeated at each follow-up clinic visit during the study.

If these tests show you are eligible, you will participate in the supervised hotel study admission.

SUPERVISED STUDY (visit will last about 36-48 hours)

Visit 2 (Day 2-4)

The supervised study visit will occur in an outpatient setting (i.e. local hotel) and will require two overnight periods. This visit will last about 36-48 hours. Visit 2 may immediately follow Visit 1.

- You will have your vital signs measured.
- You will not be allowed to start the study if you have a fever or had a significant illness within 24-hours of admission.
- A fingerstick blood glucose and fingerstick ketone measurement will be obtained.
- Female subjects of childbearing potential will be required to complete a urine pregnancy test. If positive, you will be discontinued from the study. You will be asked to seek confirmation of this test result and seek appropriate medical care by your physician.

You will receive training on the study system by a qualified trainer. You will be fully instructed on how to use the study insulin pump. You will wear two CGM sensors. The study team will train you on the use of the CGMs. You will be asked to perform a fingerstick blood glucose measurement per the CGM labeling.

You will also be trained on the use of the study glucometer and ketone meter.

You will use your personal insulin during the study.

During the study,

- You will be provided restaurant meals.
- You will be offered snacks per your usual routine.
- You will participate in a structured exercise (e.g. walking 30-45 minutes).
- You will simulate an infusion site change and sensor change.
- You will be asked to perform fingersticks prior to meals and any correction boluses.
- You will be asked to perform fingersticks in the event that the study system alarms.
- You will be asked to notify staff of any alerts/alarms.
- You will be asked to challenge the AP system by physically disconnecting it from the infusion site which will result in you being without insulin for a short period of time (less than an hour).
- You will be asked to change a cartridge during this admission and therefore would require an additional cartridge fill during the admission (approximately 120 additional units of insulin).

You will return the study insulin pump and CGMs at the end of the trial; you may keep the study glucometer and ketone meter.

You are encouraged to bring quiet activities for you to do during your stay in the hotel. You will interact with the other study participants and study staff during the study admission.

At the completion of the study, you will return to using your personal equipment. Study equipment will be returned to the study team.

FOLLOW UP:

Visit 3 – Day 4

A member of the study team will contact you within 36 hours after completing Visit 2. You will be asked you how you are feeling, and if you have experienced any hypoglycemic or hyperglycemic symptoms.

Study Schedule

	Visit 1 (Screening)	Visit 2 (Baseline)	Visit 3 Follow-up
Location of Visit	**CRU**	**Hotel**	**Phone**
Duration of Visit	**~2 hours**	**36-48 hours**	**~15 minutes**
Study Day	**1**	**2-4**	**5**
Informed Consent	x		
Review study eligibility	x	x	
Medical History	x		
Vital signs	x	x	
Physical Exam	x		
Pregnancy test for females in childbearing years	x	x	
Blood Draw (for laboratory testing)	x	x	x
Study Equipment Training		x	
Assess hypoglycemia/hyperglycemia post hotel study			x
Questionnaire		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 as advised by the study staff.
- You must be completely truthful about your health history.
- Follow all instructions given.
- You should tell the study doctor or study staff about any changes in your health or the way you feel.

- Answer all of the study-related questions completely.
- Inform the study doctor or study staff as soon as possible if you have to take any new medications, including anything prescribed by a doctor or those that you can buy without a prescription (over-the-counter), including herbal supplements and vitamins. The study doctor will let you know if you can take these medications.

Blood Testing

We will take (or "draw") up to 2 tablespoons of blood during the screening visit. The blood we taken at the screening appointment will be tested to measure your diabetes control, your thyroid function, how well your kidneys/liver work, the amount of certain salts and sugars, and to see if you are pregnant (females).

You will take fingersticks during the trial to measure your blood glucose levels. The physician may ask that you take more fingersticks to help monitor your glucose levels. Please note that if you access LabCorp, more blood will be taken than the UVa laboratory. No other blood sampling will be completed during the trial.

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

What are the risks of being in this study?

Risks and side effects related to the devices include:

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

Likely**:**

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

Rare but serious

- Risk of severe temporary low blood sugar (hypoglycemia) that can lead to unconsciousness, hypoglycemic seizure, hospitalization or even death.
- Risk of prolonged high blood sugar leading to diabetic ketoacidosis, 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.

Fingerstick Risks

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

Rarely:

- Infection at site of lancet use

Continuous Glucose Monitoring Sensor Risk

Likely:

- Failure or lack of sensitivity of the continuous glucose monitor sensor that requires replacement / insertion of new sensor
- Fingerstick for calibration of the continuous glucose monitor
- Discomfort from insertion of sensor

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 or secondary skin infection

Rarely:

- Swelling or redness at insertion site
- Psychological reaction to viewing the continuous glucose monitor information or attending to continuous glucose monitor alarms or fingerstick 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.

Performing a serum (blood) or urine pregnancy tests females who are able to become pregnant):

Less Likely:

- False positive or false negative results

Study System Risks

Even though the study algorithm has been tested prior to this 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 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

Risk of Sharing the Continuous Glucose Monitor

We may use the continuous glucose monitor equipment with other study subjects. The sensors will not be shared. The transmitter wirelessly sends your glucose information from the sensor to the receiver. The transmitter, which snaps into the sensor, will be cleaned thoroughly with a diluted mixture of bleach or another appropriate cleaner after use per hospital approved cleaning procedure. The FDA approved the continuous glucose monitor as a 'single use device'. 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.

Risk of Re-using the Blood Glucose Meter or Ketone Meter

The FDA approved these meters for 'single-patient use'. 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 parts of the meters are considered biohazardous and can potentially transmit infectious diseases. In the study, we do not plan to reuse these meters.

Risk of Sharing the Insulin Pump

This pump is not approved by the FDA. The FDA typically approves an insulin pump for 'single-patient use'. 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. The insulin pump handheld device may be reused after cleaning thoroughly with a diluted mixture of bleach or another appropriate cleaner after use per hospital approved cleaning procedure.

Unknown Risks

In any study, there is the possibility something could happen that we did not foresee. This is not likely but is always a possibility.

Loss of Privacy

The study team will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. All identifiable information about you will be replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data.

We encourage you to discuss the risks with your study doctor or any other health care professional who may understand our process.

Questionnaire Risks

Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and to the next question. Also, you can decide to take a break or stop taking part in the study at any time. The questionnaire will not cause any physical or emotional risks. The questionnaires are de-identified, meaning your name is not associated with your answers.

Risks of having your blood drawn:

Having blood drawn may cause:

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

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

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

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

Risks for women:

Pregnancy and Contraception

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

Other unexpected risks:

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

Could you be helped by being in this study?

You will not benefit from being in this study. However, the information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment for your T1DM even if you choose not to be in this study. The usual treatment would include continuing your home insulin regimen.

However, in order to do this study we must change the equipment that you use in usual treatment. This would be wearing the study insulin pump and study CGM. We must change your insulin dosing and allow the algorithm (complex mathematical formula) to calculate your insulin dosages.

If you are a patient at UVa, your usual care will not be affected if you decide not to participate in this study.
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 $150 when you complete the MAIN STUDY. **You will receive payment after the study equipment has been returned to the study team.** You should get your payment by check about 4 weeks after finishing the study. The income may be reported to the IRS as income.

- Completion of Visit 2 and Visit 3– $150

Payment is not provided for Visit 1 (screening) appointment.

The study will provide you with the following to use during the study:

- Study equipment and their associated supplies (e.g. infusion sets, CGM sensors, etc.…)
- Blood Ketone Meter and Test Strips (may keep at the end of the study)

Should you withdraw from 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.

If you owe money to any Virginia state agency, the state can use the money you earn in this study to pay those debts. These state agencies include the UVa Medical Center, VCU Medical Center or a college or university. The money may be withheld to pay back debt for such things as unpaid medical bills, taxes, fines, child support. Even if this happens, the money you earn may be reported to the IRS as taxable income.

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

Will being in this study cost you any money?

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

The following procedures/tests, which are being done for research purposes, will be provided at no cost to you or your health insurance: lab tests, study equipment, study visits, food, hotel shuttle service (if used), and hotel room charges.

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

You will be responsible for the cost of travel to come to any study visit and for any parking costs. All of the research facilities have an appropriate parking lot where free parking is available.

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) New information shows the study procedures will not work or is not safe for you
e) You do not follow your doctor's instructions
f) The study sponsor (i.e. NIH) 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 admissions may be cancelled. The study insulin pump and study CGM 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 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?

- Tandem Diabetes Care employees will be present during the structured admission (Visit 2)
- 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.

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.

Please contact the researchers 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
UVA Center for Diabetes Technology
Box 400888
Charlottesville, VA 22904 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.

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

Signatures should be obtained in this section if the subject decides to leave the study early.

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

Check one option below:

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

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

- Phone call within 36 hours after the hotel admission discharge.

____ 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 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