Parents' or Guardians' Permission for Your Child to Be in a Research Study

In this form "you" means the child in the study *and* the parent or guardian.

- If you are the parent or guardian, you are being asked to give permission for your child to be in this study.

In this form "we" means the researchers and staff involved in running this study at the University of Virginia.

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.

Key Information About This Research Study

Principal Investigator:	Marc Breton, PhD UVA Center for Diabetes Technology Box 400888, Charlottesville, VA 22903 Telephone: (434) 982-6483
Sponsor:	Tandem Diabetes Care, Inc.

Your child is being asked to take part in a research study. Your child does not have to take part in this study. You and your child 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?

This study is trying to find out if it safe for preschool-aged children (ages 2 to less than 6 years of age to use the Artificial Pancreas System called Tandem t:slim X2 insulin pump with Control-IQ Technology. The system uses continuous glucose monitoring (CGM), an insulin pump, and a software algorithm (a complex mathematical formula) to automatically give insulin and control blood glucose. It is also sometimes called a "closed-loop" system.

Why would you want to take part in this study?
You might like to take part in this study because it may improve your understanding of your child's diabetes or may improve your ability to manage your child's diabetes. While there is no direct benefit to you or your child to participate in this study, the information gained from this study may help other children 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 you may not want your child to wear equipment that is not FDA approved. As you know, type 1 diabetes may cause your child's blood sugar to be high or low even when using the study pump and study CGM. The CGM sensor will need to be replaced during the study. Reinserting the sensor may cause your child pain. You and your child will need to agree to a Hotel Admission that will take about 48 hours

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, your child will:

- Meet with a study doctor to see if your child is healthy and meets the criteria to participate in the study
- Your child may need to change his/her insulin to lispro (Humalog) or aspart (Novolog) if not already using it
- Wear the study insulin pump and study CGM at home prior to the Hotel Admission
- Wear the study insulin pump and study CGM at a 48 hour Hotel Admission
- Wear the study insulin pump and study CGM at home for 72 hours after the Hotel Admission
- Complete one survey at the conclusion of the study asking about your use of the Tandem t:slim X2 insulin pump with Control-IQ Technology.

As a parent/guardian of a child enrolled in this study, you will have the following responsibilities:

- Participate in the study equipment training sessions
- You must remain with your child during all study visits including the 48 hour Hotel Admission
- Monitor your child and the Control-IQ System during the 72 hour At Home Use
- Follow the Glycemic Treatment Guidelines during home use of the study equipment
- Return the study equipment at the end of the study
- Notify the study team of any illness, hypoglycemic events or hyperglycemic events during the study

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

This is a research study is to test the Artificial Pancreas System called Control-IQ System. As a system, this is considered an experimental device that has not yet been proven to be safe or helpful. However, both the continuous glucose monitors (CGM) and the Tandem t:slim X2 insulin pump used in this study are approved by the U.S. Food and Drug Administration (FDA). The Dexcom G6 is approved to measure and monitor blood sugar. The insulin pump is approved by the FDA to administer insulin. However, these two devices working together with the control algorithm (a complex mathematical formula) creates the "artificial pancreas", and this device has not approved by the FDA. So far, the system has been used in over 1,200,000 hours of human use and in several centers in the U.S. and overseas.

This system is not available for use outside of a research study.

What other treatments may my child receive if we decide to not take part in this study?
Your child may continue their personal insulin pump and follow the insulin parameters developed by your child's physician.

Your child is being asked to take part in this study because they are between the age of 2 and less than 6 years old and have a diagnosis of type 1 diabetes mellitus.

Who is funding this study?

This study is being funded by Tandem Diabetes Care, Inc. Tandem is also providing the study devices (insulin pumps, continuous glucose monitors, infusion sets, and other supplies) for this study. Blood glucose meters and blood ketone meters will be purchased with study funds.

Is there a possible conflict of interest?

When a person or an organization has a financial or other interest large enough to seem as if it could affect their judgment, it is called a conflict of interest. Members of the Center for Diabetes Technology 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?

You and your child's participation in this study will require about 6 study visits, including phone check-ins over about 10 days.

The Screening Visit will take about 1 hour. The Study Equipment visit will take about 3 hours. These visits may occur on the same day.

The study team will contact you 48 hours before the Hotel Admission to remind you to insert the CGM sensor. The Hotel Admission will take about 48 hours. The Hotel Admission will occur one time with all parents and child participants attending at the same time.

At the conclusion of the Hotel Admission, your child will then continue to wear the Control-IQ System at home for 72 hours.

You and your child will be asked to return to the clinic to return the study equipment or return the study equipment via FedEx.

The study team will contact you about 48 after discontinuing the study equipment to see how your child is feeling.

What will happen if you are in the study?

SCREENING (visit will last about 1 hour)

Visit 1 (Day 1)

If you and your child 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. Your child will have tests and procedures during this time to make sure your child is eligible and it is safe for them to participate. These include the following:

- Review of your child's medical history
- A short physical examination and vital signs (heart, weight, blood pressure, heart rate, etc.)
- A blood test to obtain a hemoglobin A1c (blood test collected within the last 30 days may be used)
- Download of child's personal CGM to ensure eligibility requirement

If these tests show your child is eligible, you and your child may immediately participate in the Study Equipment Training session or may be delayed up to 14 days.

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

STUDY EQUIPMENT TRAINING SESSION (visit will last about 3 hours)

Visit 2 (Day 1) (may occur on same day of Screening Visit)

This visit provides training to introduce you and your child to the Tandem t:slim with Control-IQ Technology, the use of the blood glucose and ketone meters, and glycemic treatment guidelines. The Tandem t:slim with Control-IQ Technology is considered an investigational device because it has not been approved for use by the Food and Drug Administration (FDA).

Insulin Pump Training
You will be fully instructed on the study insulin pump. A qualified system trainer will conduct the training and, in particular, discuss differences between the study insulin pump and your child's current home pump. Topics include calculation of insulin on board and correction boluses, infusion site initiation, cartridge/priming procedures, setting up the pump, charging the pump, navigation through menus, bolus procedures including stopping a bolus, and others.

Your child will use the system in pump only (open loop) configuration where no algorithms are activated until the start of the Hotel Admission.

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

CGM Training
As you and your child are familiar with the use of the Dexcom G6, a brief review of the Control-IQ System with the Dexcom G6 will be provided by the study team. Sensor placement will occur about 48 hours before the start of the hotel admission. You will stop the use of your child's personal CGM when you start the study sensor.

You will remotely monitor your child in real-time using the DexCom G6 App capabilities provided by Dexcom® Inc. You may download the App on your personal phone or a study phone will be provided for you.

You will be asked to get your child's fingerstick blood glucose measurement before a meal on the first day of using the study equipment. You will be asked to perform fingerstick blood glucose measurements (if needed) according to the Dexcom User Manual.

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

The use of Dexcom Apps on personal devices to monitor CGM values and alerts in real-time may be used. Data and text charges may apply.

Blood Glucose and Ketone Meter Training
You will be provided with a study blood glucose and ketone meter and test strips to be used at home. You will be provided instructions on how to treat your child when s/he experiences a low or high blood glucose value while wearing the study equipment.

Your child will use the Tandem t:slim X2 insulin pump and Dexcom G6 CGM at home before the Hotel Admission. The Closed Loop will not be activated. This is called using the system in Open Loop.

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

Pre-Admission Check-In Visit (about 15 minutes)

Visit 3 (Day 2)

You will be contacted by the study team approximately 48-72 hours prior to the hotel admission to:

- Inquire about any changes to about your child's health (e.g. illness, medications, etc…)
- Answer questions about current use of the equipment
- Verify that the subject has downloaded their insulin pump, CGM, and verify that that data is of sufficient quality
- Determine what pump profile(s) the subject uses on certain days
- Verify that a new CGM sensor was placed approximately 48 hours prior to the admission for proper warm up
- Verify that the goal CGM reading at time of arrival is less than 250 mg/dL
- Remind you to bring your child's insulin and the study supplies provided at the Study Equipment Training Session
- Should any concerns regarding child's health, pump information, or unforeseen issues arise, the admission may be cancelled at the discretion of the investigator

HOTEL ADMISSION (visit will last about 48 hours)

Visit 4 (Day 3-5)

This admission may occur at a hotel or a research house. You and your child will be asked to arrive at the hotel between 3-4 p.m. The child's insulin will be used throughout the study. A short physical (e.g. vital signs, illness, medications, etc…) will be performed. The study team will start your child on the Control-IQ System. You will be responsible for monitoring your child's blood glucose values, bolus treatments, and respond to system alarms. The study team will be assist you during this admission.

Group meals and activities will occur during the weekend at the direction of the study team. Quiet activities are also scheduled during the admission.

Hotel Admission Study Timeline (estimated)

	Day 1	Day 2	Day 3
7 – 8 a.m.		Breakfast	Breakfast
9 – 11 a.m.		Group Activities	Group Activities
10 a.m.		Snack (Optional)	Snack (Optional)
11:30 – 12:30 p.m.		Lunch	Lunch
12:30 p.m. – 3 p.m.		In room activities with parent/guardian(s) (including sleep)	Discharge
3 p.m.	Arrival	Snack (Optional)	
3:30 – 5:30 p.m.	Check in	Group Activities	
6 – 7 p.m.	Dinner	Dinner	
7 – 7 a.m.	Snack (Optional) / In room activities with parent/guardian(s) (including sleep)	Snack (Optional) / In room activities with parent/guardian(s) (including sleep)	

Procedures Related to Discharge

1. At approximately 3:00 PM, your child will be discharged if the fingerstick value is 70-300 mg/dL and ketone concentration is ≤ 0.6 mmol/L. If the fingerstick value is not in range, appropriate treatment will be given and the fingerstick will be rechecked.
2. Your child will continue to wear the study equipment for the next 72 hours.
3. You and your child will be offered dinner or a snack prior to discharge.
4. The study team will verify that you have study team's contact information.

HOME USE (visit will last about 72 hours)

Visit 5 (Day 6-9)

Child participants will continue to use the Control-IQ System (closed loop) for another 72 hours at home under parental/guardian(s) supervision. You will remotely monitor your child in real-time using the DexCom G6 App capabilities provided by Dexcom® Inc. The study team will also monitor the system remotely. Study staff will be available 24/7 by phone to answer any questions, concerns or to help resolve any technical problems.

We will ask that your child avoid physical activity (e.g. sports) if the CGM reading is below 90 mg/dL.

A fingerstick blood glucose value should be obtained prior to your child's bedtime each night of At-Home Use.

If you child will have a caretaker during the At-Home Use visit, we will require that they are trained on the use of the study equipment and glycemic treatment guidelines. Caretakers are defined as someone who cares for your child more than one time per week for longer than one month.

At the conclusion of 72 hours, you will return your child to their standard diabetes care under the supervision of a study physician. You and your child may either visit the clinic or switch the child back to their personal insulin pump and CGM at home. If you discontinue the study devices at home, you may return these study devices by shipping (e.g. FedEx) provided by the research team.

You will be asked to download your child's personal pump to ensure that pump parameters are correct.

POST-ADMISSION CHECK-IN (about 15 minutes)

Visit 5 (Day 10)

Study staff will contact you within 24-48 hours after stopping the study equipment to see how your child is feeling and if any new medical events have occurred since discharge.

Questionnaire

At the conclusion of the hotel admission, parent/guardian(s) will be asked to complete a questionnaire about your experience with the t:slim X2 with Control-IQ Technology equipment.

Study Schedule

	SCREENING	OPEN LOOP AT-HOME USE	PRE-ADMISSION CHECK-IN	HOTEL ADMISSION	CLOSED LOOP AT-HOME USE	POST-ADMISSION CHECK-IN
DURATION	**ABOUT 3 HOURS**		**ABOUT 30 MINUTES**	**ABOUT 48 HOURS**	**ABOUT 72 HOURS**	**ABOUT 30 MINUTES**
COMMENT	**SCREEN / ENROLL**		**PHONE, EMAIL, TEXT**	**HOTEL**	**HOME**	**PHONE, EMAIL, TEXT**
Informed Consent	**X**					
Eligibility Assessment	**X**					
Medical History	**X**					
HbA1c	**X**					
Physical Exam	**X**			**X**		
Vital Signs	**X**			**X**		
Equipment Training	**X**			**X**		
Use of Study Equipment		**X**	**X**	**X**	**X**	
Blood Glucose & Ketone Measurement				**X**		
CGM Placement			**X**			
Review diabetes management and AEs				**X**	**X**	**X**
Review Medical Changes			**X**	**X**		
Questionnaire						**X**
Return study equipment						**X**

What are your responsibilities in the study?

As parent/guardian(s) of the child participant, you have certain responsibilities to help ensure their safety. These responsibilities include:

- You must bring your child to each study visit.
- You must stay with your child during each visit.
- You must be completely truthful about your child's health history.
- Follow all instructions given.
- You should report any issues with the study equipment.
- Ensure that the study equipment is only used by your child.
- You should tell the study doctor or study staff about any changes in your child's health or the way they feel.
- Answer all of the study-related questions completely.
- Inform the study doctor or study staff as soon as possible if your child has 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 your child can take these medications.

You will be asked to sign this consent to confirm you are aware of your parental/guardian responsibilities.

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

During the study you are using an investigational device. The purpose of the test is NOT to diagnose any disease or abnormality you may have. Because the test is investigational there is no way for the study leader to understand if the results are "normal" or "abnormal". However, if any test results are concerning, your study leader will let you know.

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

What are the risks of being in this study?

Risks and side effects related to participating in this study:

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.

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
- Finger stick for calibration of the continuous glucose monitor
- Discomfort from insertion of sensor into the skin

Less Likely:

- Bruising less than ½ inch
- Bleeding less than ¼ teaspoon
- Sensitivity to adhesives with use of continuous glucose monitor resulting in skin irritation, redness, blistering, scarring, systemic allergic reaction (shock with breathing problems, heart failure)

Rarely:

- Swelling or redness at insertion site
- Psychological reaction to viewing the continuous glucose monitor information or attending to continuous glucose monitor alarms or finger stick blood glucose values.
- Breakage of the continuous glucose monitor sensor under the skin with possible symptoms of skin irritation and inflammation. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Please call the study team or seek immediate medical assistance. Seek professional medical help if you have symptoms of infection or inflammation – redness, swelling or pain – at the insertion site.

Risk 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 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.

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.
- The Hotel Admission will have other parents and child participants also in attendance..
- Taking pictures of participants other than your own child is not allowed unless there is a mutual agreement between all members involved. If you agree to allow other participants to include you or your child in a picture, you place you and your child at risks of having your picture appear in social media sites. UVA will not be responsible participants taking personal photos and sharing them on social media.
- Photographs and videotapes taken by the study team will be used in presentations at conferences, potential study subjects, and potential research donors. The study team keeps these photos and videotapes indefinitely.

Questionnaire Risks

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

Neither you or your child will directly 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 $600 when your child completes the study. You should get your payment by check about 4 weeks after finishing the study. The income may be reported to the IRS as income.

- ❖ Screening Visit: $50
- ❖ Hotel Admission: $250
- ❖ Home Use: $300

Payment is provided after the all study equipment has been returned to the study team and study downloads have been completed.

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

- Study equipment and their associated supplies (e.g. CGM supplies, glucometer, ketone meter, etc.…)

Should you withdraw from the study, you will be paid for the visits that you have completed once all the study equipment and downloads are returned to the study team.

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, food, hotel room, recreational activities at the hotel.

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.

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) The study physician is concerned about your child's health
b) Your child's condition gets worse
c) The side effects of the study procedures are too dangerous for your child
d) New information shows the study procedures will not work or is not safe for your child
e) You or your child do not follow your study doctor's instructions
f) The study sponsor (Tandem Diabetes Care) 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 the property of the CDT and will need to be returned.

Any data collected about you or your child up until the time you and your child 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 and your child for this study. If you decide not to give your permission, you and your child cannot be in this study, but you and your child 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 and your child:

- 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 child's health information if required for this study. This may include a review of your child's medical records and test results from before, during and after the study from any of your child's doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your child's private information?

- Outside researchers from suppliers and potential funding agencies may observe the trial.
- Study collaborators at Barbara Davis Center, University of Colorado, Colorado and Stanford University, California
- 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 child's medical bills or other costs of your child's 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 devices 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 your child, 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 will be present during the study to both observe and support the Hotel Admission's recreational activities.
- Other participants will likely take photos of this event. Your and your child's face may be in these photos. Others participants may post these photos on social media without your permission.

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

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

Data obtained from you and your child during this study may be used in future research. Your or your child's data may be shared with other researchers inside or outside of the University of Virginia. They will not be sent with information that could identify you or your child 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 or your child. 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 or your child's 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 and your child will no longer be in the study. The researchers will still use information about you and your child that was collected before you ended your and your child's participation.

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

Please contact the Principal Investigator listed earlier in this form to:

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

Principal Investigator:
Marc Breton, PhD
UVA Center for Diabetes Technology
Box 400888
Charlottesville, VA 22903 Telephone: 434-982-6484

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your and your child's 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 or your child's 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.

Parental/ Guardian Permission for your Child's participation

By signing below, you confirm you have the legal authority to sign for this child.

_____	_____	_____
PARENT/GUARDIAN (SIGNATURE)	PARENT/GUARDIAN (PRINT NAME)	DATE

_____	_____	_____
PARENT/GUARDIAN (SIGNATURE)	PARENT/GUARDIAN (PRINT NAME)	DATE

If you are unable to obtain parental permission from both parents/guardians, explain why not:

_____

Person Obtaining Parental/Guardian Permission

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

_____	_____	_____
PERSON OBTAINING PARENTAL/ GUARDIAN PERMISSION (SIGNATURE)	PERSON OBTAINING PARENTAL/GUARDIAN PERMISSION (PRINT NAME)	DATE

Consent from Parent/Guardian

By signing below, you understand your responsibilities in this study while you support your child. These include:

- Participate in the study equipment training sessions
- Remain with your child during all study visits including the 48-hour Hotel Admission
- Monitor your child and the Control-IQ System during the 72-hour At Home Use
- Follow the Glycemic Treatment Guidelines during home use of the study equipment
- Return the study equipment at the end of the study
- Notify the study team of any illness, hypoglycemic events or hyperglycemic events during the study
- Completion of one survey at the conclusion of the study regarding use of the Tandem t:slim X2 insulin pump with Control-IQ Technology.

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

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

Person Obtaining Consent of Parent/Guardian

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 decide that your child should leave the study early, the study leader will keep the data collected about you up until the time you leave the study to help determine the results of the study.

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

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

- Obtaining information from my medical records
- Phone call or email

____ 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 Parent/Guardian of Child

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

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

Person Obtaining Consent from Parent/Guardian of Child

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