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.

Permission for You and 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 _____

What is the purpose of this form?

This form will provide you with information about this research study. Your child does not have to be in the study if you or your child do not want to. You and your child should have all your questions answered before you and your child agree to be in this study.

Please read this form carefully. If you and your child 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 Health (NIH). The study insulin pump and its associated supplies (infusion sets, cartridges) will be provided by Tandem Diabetes Care, Inc. The study continuous glucose monitors (CGMs) and its supplies (sensors, transmitters) will be provided by Dexcom, Inc. The ketone meter and activity tracker (e.g. Fitbit) will be purchased with grant funding.

Key Information About This Research Study

Principal Investigator:	Mark DeBoer, MD University of Virginia Center for Diabetes Technology (CDT) Box 400888, Charlottesville, VA 22903 Telephone: 434-924-5956
Sponsor:	National Institute of Health (NIH)

You and your child are being asked to take part in a research study. You and your child do 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 and your child 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 teenagers going through puberty with Type 1 Diabetes can control their diabetes better by using an Artificial Pancreas (AP) system as compared to performing their usual diabetes care. This AP system is designed keep a blood glucose level between 70-180 mg/dL. The insulin pump uses the Dexcom G6 CGM values to predict what your child's glucose levels will be in 30 minutes and then adjust the insulin delivery to fall within between 70-180 mg/dL range.

The Artificial Pancreas System used in this research study is the Tandem t:slim X2 Insulin Pump with Control-IQ Technology. This device is approved by the U.S. Food and Drug Administration (FDA) for persons 6 years and older. So far, the device has been used by about 100 adolescent subjects in other clinical trials performed at the Center for Diabetes Technology.

Your child is being asked to take part in this study because your child is between 11 and less than 13 years old, is going through puberty, and has received the diagnosis of Type 1 Diabetes. You and your child will be enrolled together to participate in this study.

Why would you and your child want to take part in this study?

There is scientific evidence that wearing a CGM regularly improves glucose control so your child will benefit from wearing the CGM during this study. Your child will further benefit if he/she is randomized to the AP Group as the devices helps reduce the large changes in his/her blood glucose values. You, as a parent, may benefit from a better understanding and better management of your child's diabetes. Participants from both groups may help researchers gain more knowledge about children with type 1 diabetes mellitus.

If your child is assigned to the AP system during the study, your child must change the equipment that he/she uses in the usual treatment of his/her diabetes. This means wearing the study insulin pump and study CGM. It may mean changing your child's fast acting insulin to Humalog or Novolog which are the only two insulins that are used in this insulin pump. The study team must change your child's insulin dosing and allow the algorithm (complex mathematical formula) to calculate your child's insulin dosages.

Why would you NOT want to take part in this study?

You and your child might not want to take part in this study because:

- Study participation lasts for about 2 years.
- Your child will need to use study devices for 2 years (CGM, Ketone meter, activity tracker, and possibly an AP system).
- Neither you nor your child can choose whether your child receives the AP system.
- Your child will have 3 study-related procedures that will require an IV placed in your child's arm and one in your child's his/her hand. An IV is a small flexible tube that is inserted into a vein guided by a needle. Once the tube is in place, the needle is removed and replaced with cap that allows blood to be withdrawn or fluids or medications to be given.
- For this study, glucose will be given to your child in your child's IV's and blood samples will be taken from the other IV.
- You and your child may not want to complete questionnaires about what it is like to live with type 1 diabetes.

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 your child takes part in this study:

- You and your child will be required to attend a screening visit. There will be about 15 clinic, or phone visits. About 10 of these visits can be done from your home, but there are about 4-5 visits that will require you to come to the Clinical Research Unit (CRU) at UVA.
- You and your child will be trained on how to use the study devices, including a CGM and an insulin pump.
- If your child currently uses multiple daily injections (MDI) to treat his/her insulin, your child may need to use a study pump during this study.
- Your child will be required to give blood and urine samples.
- Your child will be required to have his/her body composition measured three times. This test will measure the percentages of fat, bone, water and muscle in your child's body.
- You and your child will be required to complete questionnaires about living with diabetes.

As a parent/guardian participating in this study, you will need to:

- bring child to study visits
- attend training sessions with subject
- download data to study team as needed
- participate in check-in visits
- complete the questionnaires

Diabetes can affect your child's mood and behavior. Contact his or her physician if you see increases in the following symptoms: Outburst and irritability, sadness, feelings of worthlessness, social withdrawal, or frequent crying.

What is the difference between being in this study and your child performing his/her usual diabetes care?

If you and your child take part in this study, the following things will be done differently than if you and your child do not take part in this study.

- You and your child will answer questions about your child's health.
- Your child will use study devices and technology that will give information about their diabetes care.
- You and your child will need to come to UVA for 4-5 visits. The other 10 visits may occur from your home.
- Your child will be required to give blood and urine samples.
- Your child will have their body composition measured before each clinic visit to see how much of their body is lean and how much is fat. This measurement is used to help set up for the clinic visit.

Your child will continue regular appointments and remain under the care of your child's diabetes physician. The study physician will be available to talk with your child's physician if you would like them to talk about your child's diabetes treatment.

What other treatments may my child receive if I decide to not take part in this study? Your child may continue his/her diabetes care (personal insulin pump or MDI) developed by your child's physician during the study.

How long will this study take?

Your and your child's participation in this study will require about 15 check-ins and study visits at the CRU over 2 years. Each CRU visit will last about 1 day because you and your child will stay overnight in a hotel the night before. The study team will contact you and your child every 3 months.

All procedures discussed in this study are completed for research purposes only.

What will happen if you and your child are in the study?

Visit 1: SCREENING (visit will last about 3 hours)

(Day 1):

If you and your child agree to take part in this study, you will sign this consent form before any study related procedures take place. Before your child can start in the study, there will be a screening period. Your child will have tests and procedures during this time to make sure he/she is eligible, and it is safe for him/her to participate. These include the following:

- A review of your child's 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 pediatrician or endocrinologist dated with the last 52 weeks may be substituted.
- Your child will also have an assessment to see how his/her puberty is changing. This is called a puberty assessment. While it is preferred that the study doctor perform this examination, you may do this evaluation on behalf of your child.
- A blood test to measure your child's hemoglobin A1c.
- A blood/urine pregnancy test if your child has started her period; this pregnancy test must be negative for your child to participate. Virginia law requires release of the test results to you as the child's parent/legal guardian if you request the results or request a copy of the medical record.
- A body composition measurement that will measure the percentages of fat, bone, water, and muscle in your child's body. These measurements will be obtained from a machine called a Bod Pod or a DEXA Scan. A Bod Pod is an egg-shaped machine that calculates these measurement by displacing the air around your child. A tight-fitting clothing like a bathing suit and a swimming cap is required while sitting inside the pod. A DEXA scan uses very weak x-ray beams to measure body composition. Each test takes less than 10 minutes.
- Your child's demographic information, such as race, gender, and date of birth will be collected.

If these tests show your child is eligible, you and your child will return to the clinic (within 60 days) to begin study treatment.

VISIT 2: Triple Tracer Study #1, Baseline (test will last about 7 hours; visit will last 24 hours if remain in overnight)

(Month 1 or 2)

A repeat urine pregnancy test will be performed if this visit is not performed immediately after Visit 1.

Insulin resistance (IR) is a condition in which the body's cells become resistant to the effects of insulin. That is, the normal response to a given amount of insulin is reduced. As a result, higher levels of insulin are needed in order for insulin to have its proper effects, and normally the pancreas compensates by trying to produce more insulin. This test is to assess the amount of insulin action required in the liver and muscle as it is unknown where in the body that IR that occurs during adolescence.

During this visit:

- You and your child will stay at a nearby hotel overnight or at your home if you live nearby.
- Your child will be encouraged to drink extra water during the day and evening.
- At about 5:00 PM, your child will eat a meal that is provided by the study team. Your child will bolus his/her regular pre-meal insulin bolus treatment.
- Your child will not be allowed to snack after dinner except to treat hypoglycemia.
- You will take your child's blood glucose level at 2 or 3 AM with your child's personal glucometer. If your child's blood glucose level is above 230 mg/dL, you will give a partial correction insulin dose. We want your child to have stable insulin levels at the time of the Triple Tracer Study.
- The next morning you and your child will come to the clinic at about 6:00 AM without having eaten since the night before.
- Your child will have an IV's put into both of your child's arms. A heating pad will be used to warm your child's arm which makes it easier to draw blood from your child's IV. Numbing medicine will be placed over the skin to minimize pain.
- Your child will get a meal at this time provided by the study team. This meal will include Jell-O that has a "tracer" which allows the study team to "trace" the glucose as it is used by the body. None of these "tracers" have any radioactive material.
- With this meal, your child will receive his/her regular insulin bolus.
- Other "tracers" will be given through the arm IV which are also NOT radioactive.
- The study team will take no more than one teaspoon for every 5 pounds of body weight. This visit will last until mid-afternoon.

Questionnaires

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

- Diabetes Responsibilities
- Family Conflict
- Peer Influence
- Problem Areas in Diabetes
- Being Scared of Hypoglycemia
- Depression
- How you feel about Technology
- How you feel about having Diabetes
- Demographic Data Survey (at the screening appointment only)

Visit 3: Randomization and Equipment Training (will last 3-4 hours)

(Month 1 or 2)

A repeat urine pregnancy test will be performed if this visit is not performed immediately after Visit 2.

Randomization

Your child will be randomly assigned (like the flip of a coin) to 1 of 2 study treatment groups. Your child has a 7 out of 15 chance to being assigned to the Artificial Pancreas group and an 8 out of 15 chance of being assigned to the Usual Care+CGM group. Usual care means how your child normally manages their diabetes at home. Neither you, nor your child, nor your doctor can choose which treatment you are assigned.

Equipment Training

This training is to introduce you and your child to the insulin pump (if applicable), CGM, ketone meters, and glycemic treatment guidelines.

Artificial Pancreas Group:

If you child is randomized to this group, he/she will wear the AP system during the study. You and your child will receive training on the following:

- Insulin Pump and supplies
- CGM and supplies
- Blood Ketone Meter and supplies
- Activity Tracker (e.g. Fitbit)
- Glycemic Treatment Guidelines

Usual Care+CGM Group:

If you child is randomized to this group, he/she will continue their usual care during the study.

You and your child will receive training on the following:

- CGM and supplies
- Blood Ketone Meter and supplies
- Activity Tracker (e.g. Fitbit)
- Glycemic Treatment Guidelines

Insulin Pump (Artificial Pancreas Group Only)

A qualified system trainer will train you and your child on the use of the insulin pump. The trainer will

discuss differences between the study insulin pump and your child's home pump. Topics include the calculation of insulin on board, correction boluses, infusion site initiation, cartridge/priming procedures, setting up the pump, charging the pump, navigation through menus, and bolus procedures including stopping a bolus, among others.

You will be instructed to how to download the insulin pump and the CGM. The study team will ask that you provide a download of this equipment during the first two weeks of the study. The study physician will review this data to review your initial pump settings.

Your child will use insulin parameters such as carbohydrate ratio and correction factors consistently on their pump to dose insulin for meals or corrections.

The study team will send your Endocrinologist a letter telling him/her that you received a study insulin pump. Your child will remain under the care of his/her treating Endocrinologist. However, the study team may make recommendations during the study, especially if your child has reoccurring hypoglycemic and hypoglycemic events. The study team will be available to answer any questions that the treating endocrinologist may have while using the study equipment.

CGM Training (Both Groups)

You and your child will receive training on the use of the study CGM. The study team may have you and your child watch the Dexcom training video (https://www.dexcom.com/training- videos). Your child will stop using their personal CGM during this visit and will start the study CGM. You or your child will download Dexcom Apps onto a phone to watch your child's CGM values and alerts in real-time. This App may be downloaded to a phone provided to you and your child by the study team, or you/your child may use your personal phone or your child's personal phone. The use of the Dexcom Apps on a personal phone may result in data and text charges.

If the CGM requires calibration, your child will be asked to perform fingerstick blood glucose measurements according to the Dexcom User Manual.

You and your child will be provided the CGM supplies to use during the study.

Dexcom Share is a feature within the G6 app that allows for remote monitoring. You will be encouraged to watch your child with the use of the Dexcom Share App for the duration of the study.

Ketone Meter and Strips Training (Both Groups)

Ketones are caused by the breakdown of fat when there isn't enough insulin to allow the glucose (sugar)

into the cells for energy. When ketones build up, the result is acidosis (too much acid in the blood). Your child will use a ketone meter to test their ketones when their blood glucose values are high.

Your child will be provided with a study ketone meter to be used at home. Instructions will be provided on how to test for ketones and under what conditions your child's ketone levels should be tested.

Activity Tracker

Your child will be supplied an activity tracker (e.g. Fitbit) to wear during the study It will be recommended to wear the activity tracker throughout the study, but the study team will remind you and your child that it should be worn the 2 weeks prior to Triple Tracer Study

Glycemic Treatment Guidelines

You and your child will be taught what to do if your child has high or low blood sugar or develops ketones. All participants will need to have a Glucagon Emergency Kit during this study.

You and your child will be asked to be in different rooms when you complete these questionnaires. These questionnaires will take about 30-45 minutes to complete. You and your child may have a break during this time or complete the questionnaires in two different sessions.

Visit 4: Study Pump and CGM Run-In Period (Optional) (about 14 days)

(Month 1 or 2)

There will be a mandatory period to practice using the study CGM at home for about 14 days before the main part of the study begins for children who have no CGM experience or Multiple Daily Injection (MDI) users who have never used an insulin pump. After about 14 days, you will be asked to download the study equipment so the study physician can check your adjustment to the study equipment. The study physician may adjust your basal rates, correction factor, insulin-to-carbohydrate ratio, etc.

Children with experience using an insulin pump and a CGM may skip this visit.

Visit 5, 7, 10, 12: Tri-Monthly Check-In Visits (about 15 minutes)

(Months 3, 9, 15, and 21)

The study team will contact you and your child every three months (by phone or using an APP such as a HIPAA compliant WebEx) to assess how they are progressing with the study. The study team will ask you and your child about any safety issues that might have come up from using the study devices, and any illnesses, injury or medication changes that may have happened. This may also be a time to discuss

changes in your child's pump settings. If needed, a download of study equipment will be requested.

Visit 6 and 11: 6-Month and 18 -Month Follow-Up (about 15 minutes)

(Months 6 and 18) (Day 182 and Day 547)

The study team will contact you and your child (by phone or using an APP such as WebEx) to assess how they are progressing with the study. The study team will ask you and your child about any safety issues that might have come up from using the study devices, any illnesses, injury or medication changes that may have happened. This may also be a time to discuss changes in your child's pump settings. If needed, a download of study equipment will be requested.

Your child will also have an HbA1c blood glucose test (at a local lab or clinic) and provide current insulin parameters if an MDI user.

Visits 8 and 13: 1 Week before Check-In Visit (about 20 minutes)

(Months 12 and 24)

You will be asked to download your child's study equipment and send it to the study team for review within 30 days of the Triple Tracer Study.

About 7-14 days before the Triple Tracer Study you and your child will be contacted (by phone or using an APP such as WebEx) to talk about the Triple Tracer Study. Your child will be encouraged to drink plenty of water for the 24-48 hours before the test and to place a new CGM sensor about 36 hours before the test. Your child will also be reminded to wear the activity tracker and collect an HbA1c at a local lab. HbA1c may also be collected during the Triple Tracer Study rather than at a local lab. If your child is an MDI user, we will ask for your child's current parameters.

Visits 9 and 14: Triple Tracer Study (12 Month and 24 Month) (test will last about 7 hours; visit will last 24 hours if remain in overnight)

(Months 12, and 24)

During this visit you and your child will stay at a nearby hotel overnight, or at your home if you live nearby. Your child will have his/her body composition measured. At about 5:00PM your child will eat a meal that is provided by the study team and get his/her regular dose of bolus or pre-meal insulin. A Body Composition Measurement will be taken. At approximately 2 AM you will test your child's blood sugar and give a partial correction dose if they are >230 ml/dL. It is important to have stable glucose values for the test.

The next morning you and your child will come to the clinic at about 6:00AM where your child will get carbohydrates, but no food. The study team will obtain your child's vital signs, height, and weight,

obtain a urine pregnancy testing if appropriate, review of insulin parameters, and discuss any health or equipment issues that your child may be having, Your child will have an IV put into their forearm and another IV put into their hand. Your child's hand will also be placed on a heated pad. This will help make the blood draws easier. Your child will get a meal at this time that is provided for him/her. With this meal, your child will give his/her regular bolus. The study team will take no more than4 tablespoons of blood during this test.

Your child will also have a puberty assessment completed.

You and your child will be asked to electronically complete the questionnaires.

Transition back to Usual Care

After your child completes the study procedures at Visit 14, your child will return to his/her standard diabetes care. The study team will be available to answer questions about your child's insulin parameters. You and your child will also need to return of all the study equipment (e.g. study insulin pump, study CGM, remaining supplies, etc…).

You and your child will be asked to return all investigational study devices either via mail or at an office visit.

Visit 15: Post Study Check-In Visit (about 15 minutes)

(Month 24)

The study team will contact you/your child by phone, email, or text about 24-48 hours after completing the final Triple Tracer Study (visit 14) to ask you/your child:

- How your child is feeling
- If your child has had any blood glucose values less than 60 mg/dL and more than 300 mg/dL
- Discuss insulin parameters

Repeating Visits and Unscheduled Visits

You and your child may have unscheduled phone or virtual visits if additional training or other needs arise. You and your child will also be contacted for guidance if your child has not been using the CGM or pump enough of the time

IRB-HSR#190088: Artificial Pancreas - Adolescent Physiology & Psychology Longitudinal Evaluation (A.P. APPLE)

Randomized Sub-Study

Study Schedule

	Screening	Triple Tracer Study	Equipment Training	Study Pump &CGM Run-In	Check-In Visit	Check-In Visit	Check-In Visit	1 week before Check-In Visit	Triple Tracer Study	Post-Study Visit
		(Baseline)		(Optional)	(3 & 15 mos)	(6 & 18 mos)	(9 & 21 mos)	(12 & 24 mos)	(12 & 24 mos)	
Visit - Year 1	1	2	3	4	5	6	7	8	9	
Visit - Year 2					10	11	12	13	14	15
Location	Clinic	CRU	CRU/Clinic	Home/Phone	Phone	Phone	Phone	Phone	CRU	Phone
Informed Consent	X									
Eligibility Assessment	X									
Medical History	X								X	
HbA1c	X					X			X	
Pregnancy test (if applicable)	X	X	X						X	
Physical Exam	X									
Vital Signs (including height/weight)	X	X							X	
Body Composition Testing	X								X	
Blood draws		X							X	
Randomization			X							
Pubertal assessment	X								X	
Questionnaires		X							X	
Review parameters & AEs	X	X		X	X	X	X	X	X	X
Equipment downloads				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.
- 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 or 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 and your child know if your child can take these medications.

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

During the study, your child is having an investigational test done. The purpose of the test is NOT to diagnose any disease or abnormality your child 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 child’s study leader will let you and your child know. In addition, as the research moves forward, your child’s study leader will keep you and your child informed of any new findings about the research itself that may be important for your child’s health or may help you and your child decide if you want to continue in the

study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time you may ask for more information about the study results.

Blood Testing

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). When these tests are done, any remaining sample will be thrown away. It will not be stored for any future testing.

During the yearly Triple Tracer Study (baseline, 12- months and 24 months), 4 tablespoons of blood will be taken during each test.

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

What are the risks of being in this study?

Risks and side effects related to treating type 1 diabetes (with or without 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 symptoms of high blood sugars such as thirst and frequent urination. You may have a higher level of sugar in your urine.

Rare but serious

- Risk of severe temporary low blood sugar (hypoglycemia) that can lead to unconsciousness, hypoglycemic seizure, hospitalization or even death.
- Risk of prolonged high blood sugar leading to diabetic ketoacidosis (DKA), hospitalization, and coma. DKA can lead to renal failure (kidney failure), cardiac arrhythmia (irregular heartbeat), myocardial infarction (heart attack), rhabdomyolysis (muscle breakdown), and even death.

Risks related to using the Artificial Pancreas System:
Likely

- Infusion set failures that may cause hyperglycemia and/or DKA.

Rare

- 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

Risk of Changing Insulin Therapy Rare

- Mild allergic reaction including developing a rash after injection

Risks related to using a Continuous Glucose Monitoring Equipment:
Likely

- Failure or lack of sensitivity of the continuous glucose monitor sensor that requires replacement and or insertion of new sensor in your abdomen
- Discomfort from insertion of sensor into the skin

Less Likely

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

Rare but serious

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

- Discomfort or pain from insertion of the needle
- Sometimes the catheter stops working. In order to get the blood we need, we may have to stick you with another needle.
- Low red blood cell counts (i.e. may make you feel more tired)

Less Likely

- Fainting at or about the time of the blood draw
- Bruising at the site of the blood draw

Rarely

- Infection at the site of the blood draw

Risk of Sharing the Insulin Pump, Continuous Glucose Monitor, and Ketone Meter:

The FDA approved the insulin pump, continuous glucose monitor, and ketone meter as ‘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 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 discarded after use.

Risk of the Heating Pad:

The temperature inside the pad where your hand will be placed is kept at about 55°C which is 107° Fahrenheit. With prolonged exposure to continuous heat, there is a potential risk of local skin irritation/redness. If this occurs, it will be treated appropriately.

Risks from Stable (non-radioactive) glucose (sugar):

There is no known risk of stable isotopes of glucose as these are naturally occurring substances and are present in the body.

Risks from Completing Questionnaires:

Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and to the next question. You can decide to take a break or stop answering the questions 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. Rather, the questionnaires are assigned a study subject number only.

During the research, if we learn you are having thoughts about suicide or hurting yourself or others, the research staff will ask you more questions about your thoughts. Based on your response, the staff may provide you with help to get treatment. This may include: working with you to contact your doctor or therapist, referral to a therapist to discuss your thoughts, contact a trusted family member, significant other or clergy or work with you on a plan that may include getting you to a hospital for safety and treatment.

Risk of Radiation Exposure:

This study involves radiation exposure from up to 3 DEXA scans of your body. As part of everyday living, everyone is exposed to a small amount of background radiation. Background radiation comes from space and naturally occurring radioactive minerals. The radiation dose you will receive in this study will give your body the equivalent of about 3 days' of this natural radiation. This radiation dose is what you will receive from this study only and does not include any exposure you may have received or will receive from other tests. The risk from this dose is considered small. This radiation exposure is not necessary for your medical care but is necessary to obtain the research information desired.

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.

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 or your child be helped by being in this study?

Prior research studies have shown that glucose control improves from wearing a CGM on a regular basis. Therefore, you child's blood glucose will benefit from wearing a study CGM. Your child will further benefit if he/she is randomized to the AP Group as the devices helps reduce the large changes in his/her blood glucose levels. You and your child may improve your understanding of your child's diabetes or may improve your ability to help your child manage his/her diabetes from being in this study. Information researchers get from this study is intended to help other children in the future. This study is expected to help researchers learn more about managing diabetes during puberty with the use of an AP system.

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

You and your child do not have to be in this study in order for your child to be treated for his/her diabetes. Your child can get the usual treatment for his/her T1DM even if you/your child choose not to be in this study. The usual treatment would include continuing your child's home insulin regimen. In addition, the artificial pancreas and/or CGM are FDA approved and available for treatment of T1DM without participating in this study.

- 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 $800.00 by check for finishing this study. You should get the payment about 4 weeks after finishing the study. The compensation payment may be reported to the IRS as income.

- Triple Tracer 1 (baseline): $100
- 6-month data upload: $100
- Triple Tracer 2 (12 months): $200
- 18-month data upload: $100
- Triple Tracer 3 (24 months): $300

Payment for study visits completed will be provided after all study equipment has been returned to the study team and study downloads have been completed.

If you/your child do not finish the study, you will be paid for the study visits that you/your child have/has completed. If the study leader says you/your child cannot continue, you will be paid for the study visits that you/your child have completed.

By agreeing to be in this study, your child is donating their blood samples for research and giving up any property rights he/she may have in them. The results of this research using his/her donated materials may have commercial value. However, he/she will not receive any payments.

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 child's health insurance: lab tests, study equipment and their associated supplies (e.g. Insulin pump, CGM supplies, , etc.…).

You will be responsible for the cost of your child's insulin that is used during the study.

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

The study team will pay for the cost of the hotel the evening before the Triple Tracer Study.

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

What if you or your child are hurt in this study?

You and your child do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you/your child feel you/your child 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/your child is hurt as a result of being in this study, there are no plans to pay you/your child for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you/your child receive will be billed to your/your child's insurance. You will be responsible for any amount your/your child's insurance does not cover.

What happens if you/your child leave the study early?

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

Even if you or your child do not change your minds, the study can take your child out of the study. Some of the reasons for doing so may include

a) Your child's study physician is concerned about your child's health
b) Your child's condition gets worse
c) The side effects of the treatment are too dangerous for your child
d) New information shows the treatment will not work or is not safe for your child
e) You or your child do not follow your doctor's instructions
f) The study sponsor closes the study for safety, administrative or other reasons

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

Any data collected about you and your child up until the time you leave the study must be kept in order to determine the results of the study.

How will you/your child's personal information be shared?

The UVA researchers are asking for you and your child's permission to gather, use and share information about your child for this study. If you or your child decide not to give your permissions, 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/your child is 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/your child's private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- The sponsor(s) of this study, and the people or groups it hires to help perform or review this research
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your child's participation in the study
- Tax reporting offices (if you/your child is 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/your child tells us that someone is hurting you or your child, or that you/your child might hurt yourselves or someone else, the law may require us to let people in authority know so they can protect you/your child and others.

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

Information obtained from you and your child during this study may be used in future research. You and your child's 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 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/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/your child's private information shared?

You and your child can change your minds at any time. You and your child's 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/ your child will no longer be in the study. The researchers will still use information about you/your child that was collected before you and your child ended participation.

You/your child's 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 or your child, 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/your child may harm yourselves or others, or if there is evidence of probable child or elder abuse or neglect.

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

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

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

Your personal email or phone provider may also share or release your information because they do not have to follow the privacy laws that UVA follows. Sometimes email and phone providers release

information to marketing companies for use in direct advertising. If you choose to communicate by email or text messaging, UVA cannot control this potential loss of privacy, but we want to tell you about this possible risk.

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

Please contact the Principal Investigator 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/your child's regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Mark DeBoer, MD, MSc

University of Virginia Center for Diabetes Technology (CDT) Box 400888, Charlottesville, VA 22903

Telephone: 434-924-9833

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your/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 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 IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

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

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form, it means that you agree for you and your child 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.

If an interpreter is involved in the consent process because the potential subject does not speak English well or at all, the participant should NOT sign on the line above – leave this line blank. Instead, the participant should sign the IRB approved Short Form or full consent written in the language they can understand.

Parental/ Guardian Permission to Permit Your Child to Participate in this Study

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

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

Consent From Parental/Guardian

By signing below, you confirm that you will be the responsible parent/guardian to complete the study procedures for the parent-child dyad in this trial.

_____	_____	_____
Participant (SIGNATURE)	Participant (PRINT NAME)	DATE

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

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

Notification of My Child's Health Care Provider

Please indicate below whether you want us to notify your child's health care provider that you have agreed for your child to take part in this study.

_____ Yes, I want the study doctor to notify my child's health care provider that I have agreed to allow my child 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 child's health care provider that I have agreed to allow my child to take part in this study or I do not have a health care provider for my child.

Leaving the Study Early

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

Consent From Adult

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

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

If an interpreter is involved in the consent process because the potential subject does not speak English well or at all, the participant should NOT sign on the line above – leave this line blank. Instead, the participant should sign the IRB approved Short Form or full consent written in the language they can understand.

Parental/ Guardian Permission

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

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

Consent From Parental/Guardian

By signing below, you confirm that you are the responsible parent/guardian for the parent-child dyad in this trial.

_____	_____	_____
Participant (SIGNATURE)	Participant (PRINT NAME)	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