NCT03676465

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.

Parents' or Guardians' Permission for Your Child to Be in a Research Study
Agreement of a Child to Be in a Research Study
(15-17 years of age)

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.
- ✓ If you are the child, you are being asked if you agree to be in this study.

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

In this form "you" means the person (your child) who is being asked to be in this study. As the parent or guardian, you are being asked to give permission for your child to be in this study.

Adult Participant's Name_____

Child Participant's Name_____

Principal Investigator: Mark DeBoer, MD
UVA Center for Diabetes Technology
Box 400888
Charlottesville, VA 22908 Telephone: (434) 924-5956

Sponsor: U.S. NIH Library of Medicine (NLM)

What is the purpose of this form?

This form will help you decide if you want to be part of the study portion of a research study. You need to be informed about this research procedure, before you can decide if you want to participate. You should have all your questions answered before you give your permission or consent to be in the 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 U.S. National Institute of Health (NIH) National Library of Medicine (NLM). All study equipment, which are commercially available products, have been purchased with study funding. The insulin pens have been purchased by Companion Medical. The Continuous Glucose Monitors have been purchased by Dexcom, Inc.

Why is this research being done?

The purpose of this study is to gain experience using a new diabetes self-management approach called CloudConnect, a self-help tool that will look at your blood sugars, when you take insulin, eat, and exercise and then determine if there are patterns. Based on these patterns, a report is created explaining things like when you might be at risk for low or high blood sugar and things like physical activity and how you are taking insulin at meal times might be affecting your blood sugar. We are looking to see if using CloudConnect is helpful in finding out why blood sugar levels are high or low and how using CloudConnect affects your ability to stabilize your blood sugar levels. Hopefully, from all of this information, we can tell you some ways that you might be able to fix some of problems you may be experiencing and provide some insight into why they are happening.

You are being asked to be in this study because you are between the ages of 12-17 and have been diagnosed with type 1 diabetes or you are a parent of a 12-17 year old who has been diagnosed with type 1 diabetes. You and a parent will be enrolled together to participate in this study.

Up to 210 (105 adolescent subjects with their parent or guardian (105)) will take part in this study at UVA.

How long will this study take?

Participation in the study is about 16 weeks (4 months). This study includes a screening appointment, a study equipment training visit, a 1-week run-in period using the study equipment (optional based on the investigator's discretion), and a 12-week data collection period. The run-in and the data collection periods may be repeated as needed.

What will happen if you are in the study?

STUDY PROCEDURES

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

SCREENING VISIT (up to 3 hours) (Clinical Research Unit [CRU])

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. This visit may be done in person or may be over the phone or video conference.

These include the following:

- Demographic information (date of birth, gender, race, and ethnicity)
- Diabetes History information
- A physical exam - including height, weight, and vital signs (this can be from a doctor's visit from during the past year)
- A urine pregnancy test if you are a young girl who can become pregnant. The pregnancy test must be negative in order for you to participate.. The results of the pregnancy test will be shared with you; however, it is required by law that the results be shown to your parents/legal guardian. If it is not possible to go to a laboratory or come to the clinic because of governmental restrictions such as Stay-at-Home orders a urine pregnancy test will be sent to you. Your parent/guardian will be responsible to report the results of the pregnancy test to the study team.
- You may have a Hemoglobin A1c using a point of care machine, at a local laboratory close to home, or at home using an A1c self-check test we provide you. The hemoglobin machine requires a small droplet of blood similar to a fingerstick. This can be omitted if it is not possible to go to a laboratory or come to the clinic because of governmental restrictions such as Stay-at-Home orders.

If you are eligible, you may continue with Visit 2.

Non-Blinded Randomization and Study Treatment

You will be randomly assigned (like the flip of a coin) to Control Group or an Experimental Group. You have an equal chance of being assigned to any one of the groups. Neither you nor your doctor can choose which treatment you are assigned. Non-blinded means that the study team will tell you if you have been randomized to the Control Group or the Experimental Group. You and your parent/guardian will decide if the study team should contact you or your parent by telephone, email, or text message.

CONTROL GROUP: Personal insulin pump (if pump user) or study insulin pen (if MDI user) for mealtime bolus treatment + study CGM + study activity tracker (i.e. Fitbit)

EXPERIMENTAL GROUP: Personal insulin pump (if pump user) or study insulin pen (if MDI user) for mealtime bolus treatment + study CGM + study activity tracker (i.e. Fitbit) + CloudConnect Report

Control Group

If you are assigned to the Control Group, you will use your personal insulin pump (if pump user) or study insulin pen (if MDI user) for mealtime bolus treatment, a study CGM, and a study activity tracker (i.e. Fitbit). You will use your own insulin. You will be provided a study CGM and a study exercise tracker (i.e. Fitbit). You and your parent/guardian will receive training on how to insert the CGM into your belly/abdomen. Dexcom Apps (i.e. Mobile App, Follow App, etc.…) will be permitted on personal devices to monitor CGM values. Use of the Dexcom alerts will be optional. You or your parent/guardian will be asked to download the data from the study devices as well as download your personal insulin pump or study insulin pen. You and your

parent/guardian will both receive weekly contact from the study team to discuss the communication that you and your parents/guardians had this week about your diabetes management (i.e. any low blood sugars that may have had).

Experimental Group

If you are assigned to the Experimental Group, you will be provided a study CGM, a study exercise tracker (i.e. Fitbit), and a study insulin pen if an MDI user. You will use your own insulin pump if a pump user. You will use your own insulin. You and your parent/guardian will receive training on how to insert the CGM into your belly/abdomen. Dexcom Apps (i.e. Mobile App, Follow App, etc.) will be permitted on personal devices to monitor CGM values. Use of the Dexcom alerts will be required. You or your parent/guardian will be asked to download the data from the study devices as well as download your personal insulin pump or study insulin pen. You and your parent will both receive a CloudConnect report by email. You and your parent should discuss this weekly report with each other. You and your parent/guardian will both receive weekly contact from the study team to discuss the communication that you and your parents had this week about this report and your diabetes management (i.e. any low blood sugars you may have had).

Questionnaires

During this study, you will be asked to complete the questionnaires by logging into a study account with the use of a computer or laptop. These questionnaires ask you about:

- the communication within your family about the information shared in this report
- how you feel when you blood sugar is high or low
- who takes responsibility of how your diabetes care is managed

These questionnaires will take about 90-120 minutes to complete. They may be completed at home but must be completed within a week of this appointment.

Study Training (Visit 2 – will last about 1 hour):

If you meet study eligibility, visit 2 may occur on the same day as visit 1. If visit 1 was performed over the phone or video conference, then the visits cannot be done on the same day. Visit 2 can also be performed over the phone or video conference. If this is the case, you will have to receive the study related supplies before the visit can occur.

If visit 1 and 2 are not performed on the same day,

- a urine pregnancy test for young girls who can become pregnant will be performed if it has been over 56 days since visit 1.
- a repeat hemoglobin A1c may be collected if visit 1 and visit 2 are greater than 28 days.

If you are randomized to the Control Group, you will:

- we will ask you to bring your laptop with you or have it available, if you are able, in order to download study-related software and help set up your study-related accounts for the devices. If you are unable to bring a laptop, we may give you a flash drive so you can download them at home
- you and your parent/guardian will be trained on how to use the study continuous glucose monitor (CGM); you will insert a CGM sensor into your belly/abdomen
- Dexcom Apps (i.e. Mobile App, Follow App, etc.…) will be permitted on personal devices to monitor CGM values
- you and your parent/guardian will be trained on how to use the study exercise tracking device (i.e. Fitbit)
- you will be given a study insulin pen and your own insulin if an MDI user
- you will use your own insulin pump and your own insulin if you are a pump user
- you and your parent/guardian will be trained on how to download the study equipment (i.e. CGM, Fitbit, study insulin pen if MDI user) you or your parent/guardian will be required to download the data stored on the diabetes devices and send the data to the study team once each week
- you and your parent/guardian will tell the study team how you want to be contacted each week (i.e. phone calls, emails, etc.) to answer some questions
- you *and* your parent/guardian will each communicate to the study team to discuss your diabetes management for that week

If you are randomized to the Experimental Group,

- we will ask you to bring your laptop with you or have it available, if you are able, in order to download study-related software and help set up your study-related accounts for the devices. If you are unable to bring a laptop, we may give you a flash drive so you can download them at home
- you and your parent/guardian will be trained on how to use a continuous glucose monitor (CGM) and an exercise tracking device (i.e. Fitbit)
- you will be given a study insulin pen and will use your own insulin if an MDI user
- you will use your own insulin pump and your own insulin if you are a pump user
- you and your parent/guardian will be trained on how to download the study equipment
- you or your parent/guardian will be required to download the data stored on the diabetes devices and send the data to the study team once each week
- you and your parent/guardian will receive a CloudConnect report from the study team. You and your parent/caregiver are encouraged to talk about the information contained in this report.
- you and your parent/guardian will tell the study team how you wanted to be contacted each week (i.e. phone calls, emails, etc.) to answer some questions
- you *and* your parent/guardian will each communicate to the study team to discuss your diabetes management for that week

Days 2-9 (week 1) – Run-In Period

Both the Control and Experimental Group subjects may complete a 1-week run-in period to make sure that you are comfortable the with use of the study equipment, all the study devices work properly, and to address issues related to transmission of the data to the study team. This run-in period may be repeated as necessary up to 3 times by you or the study team. This data collected during this week will not be included as part of the 12 week data collection. The run-in period may be skipped if you have experience with the study equipment and the study doctor believes you are comfortable using the equipment.

Days 10-94 (week 2-14)

If you are randomized to the Control Group, you will manage your diabetes as you normally do. You will use your personal insulin pump (if pump user) or study insulin pen (if MDI user) for mealtime bolus treatment + study CGM + study activity tracker (i.e. Fitbit) at home for up to 12 weeks. You will asked to download the study equipment once each week. You may be asked to repeat a week of data collection if the data is not good quality. The study team will contact you and your parent/guardian to discuss about how you and your parent talked about your diabetes management for that week.

If you are randomized to the Experimental Group, You will use your personal insulin pump (if pump user) or study insulin pen (if MDI user) for mealtime bolus treatment + study CGM + study activity tracker (i.e. Fitbit) at home for up to 12 weeks. You may be asked to repeat a week of data collection if the data is not enough or if the study team is able to create a CloudConnect report. You will asked to download the study equipment once each week. Study staff will call you to provide your CloudConnect report. You will receive your report by email, text, or phone. The study team will contact you and your parent/guardian to discuss about how you and your parent talked about your diabetes management for that week.

Visit 3 – Phone check-in (Week 8 / on-site, email, or phone call) (less than 15 minutes)

The study team will check in and see how you are doing during Week 8 of the study. The study team will answer any questions that you may have.

Visit 4 (Day 95): End of Study (Up to 3 hours) (CRU preferred)

At the completion of the study, you will return to using your personal diabetes equipment. Study equipment will be returned to the study team. You will have a repeat Hemoglobin A1c at the same location as the screening value. When this appointment is scheduled, you will be asked to electronically complete the questionnaires within a week of the visit 4/end of the study. If not completed prior to this appointment, the study team will provide you a laptop to complete at this appointment.

Study Schedule

	Visit 1	Visit 2	Visit 3	Visit 4
Location of Visit	**CRU/Home**	**CRU/Home**	**Home**	**CRU/Home**
Duration of Visit	**Up to 3 hours**	**~1 hour + ~1 week**	**12 weeks**	**Up to 3 hours**
Study Day	**1**	**2-9**	**~10-94**	**95**
Informed consent	X			
Review study eligibility	X			
Medical history	X			
Hemoglobin A1c (same lab or equipment)	X			X
Urine pregnancy test for adolescent females	X	X		
Study Equipment Training		X		
Use of Study Equipment		X (at home)	X (at home)	
Downloading Data		X (at home)	X (at home)	
Check-in			X (week 8)	
Return Study Equipment				X
Questionnaires	X			X

What are your/and your parent/legal guardian's responsibilities in the study?

You and your parent/legal guardian have certain responsibilities to help ensure your safety. While the study team encourages both parents to be involved with the study, the team will ask that one parent be identified as a *'family spokesperson'*. The responsibilities of this family spokesperson are listed below:

- Your parent/legal guardian must bring you to each study visit.
- You and your parent/legal guardian must be completely truthful about your health history.
- Follow all instructions given.
- Participate in weekly appointments (i.e. phone/email/text) with the study team.
- Complete questionnaires.
- Report any issues with the study equipment.
- You or your parent/legal guardian should tell the study doctor or study staff about any changes in your health or the way you feel.
- Ensure that the study equipment is only used by you.
- Answer all of the study-related questions completely.
- Inform the study doctor or study staff as soon as possible if you have to take any new medications, including anything prescribed by a doctor or those that you can buy without a prescription (over-the-counter), including herbal supplements and vitamins. The study doctor will let you know if you can take these medications.

If you want to know about the results of the study:

The purpose of the research is NOT to diagnose any disease or abnormality you may have. Because this study involves the use of investigational software there is no way for the study leader to understand if the results are "normal" or "abnormal". However, IF any results are concerning, your study leader will let you know. In addition, as the research moves forward, your study leader will keep you informed of any new findings about the research itself that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time, you can ask for more information about the study results.

What are the risks of being in this study?

Risks and side effects related to participate 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 / 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 (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 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.

Risk of using an Insulin Pen Use:

Likely**:**

- Inadequate mixing of insulin, leading to improper dosing

Less Likely:

- Leaving an insulin needle attached to the pen, contributing to air bubbles accumulating within the insulin and pen and leading to improper dosing of insulin or insulin contamination

Rarely:

- Sharing insulin pens may result in a bloodborne pathogen (a bacteria or a virus that can cause disease)

Risk of symptoms related to wearing an activity tracker (i.e. Fitbit):

Rarely:

- Skin irritation or redness

Performing a urine pregnancy tests for young girls who are able to become pregnant):

Less Likely:

- False positive or false negative results

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.

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 & CloudConnect Risks

The Questionnaires and the CloudConnect Reports may be upsetting, or you may feel uncomfortable. If you do not wish to answer a question on the questionnaire, 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. The CloudConnect Reports may result in either positive or negative feedback from your parents. You and your family may take a break if the CloudConnect Reports are uncomfortable to read or talk about.

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?

There are no expected benefits in this study. However, if you are in the Experimental Group, the CloudConnect report may improve the communication between you and your parent about how you manage your diabetes care. However, there is a risk that it could negatively impact your communication as well.

You may benefit for the use of the CGM which may improve your understanding of your blood glucose variability. For example, it may help you understand what happens before you have a hypoglycemic or hyperglycemic episode.

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.

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 (Adolescent subject) will be paid $300 when you complete the study. You will receive payment after the study equipment (i.e. study CGM, study Fitbit, study inPen if provided) 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.

- Payment of $25 per week will be provided for successfully completing the week's requirement of data downloading, talking with the study team each week, and completing the questionnaires.

Payment is not provided for Visit 1 (screening) appointment or the run-in phase.

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

- Study equipment and their associated supplies (e.g. CGM sensors, CGM transmitter, Fitbit, etc.…)
- Insulin pen for MDI study subjects only

You will be paid for the visits that you have completed successfully. You may be asked to repeat a week of data collection period if the team is not able to use the data provided.

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?

If you choose to participate in this study and use your personal cellular phone to transfer data from the devices to the online accounts, you will be responsible for the charges that are incurred as part of your participation. You have the option of using a study phone instead so you will not be billed for the data used during the study.

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, and study visits. You will use your own insulin.

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. The study equipment will 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?

- 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: Mark DeBoer, MD
UVA Center for Diabetes Technology
Box 400888
Charlottesville, VA 22908 Telephone: 434-924-5956

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

Assent from Child

Consent from the parent/guardian MUST be obtained before approaching the child for their assent.

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

Person Obtaining Assent of the Child (less than 18 years of age)

Consent from the parent/guardian MUST be obtained before approaching the child for their assent.

By signing below you confirm that the study has been explained to the child (less than 18 years of age), all questions have been answered and the child has voluntarily agreed to participate.

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

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

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 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.

____ 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.

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

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