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
(Children 6-10 years old)

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.

Participant's Name _____

Principal Investigator: Sue Brown, MD
Department of Medicine/Endocrinology
UVA Center for Diabetes Technology
Box 400888
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Sponsor: Virginia Research Investment Fund (VRIF)
University of Virginia Office of the Vice President for Research (VPR)

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.

For the purpose of this study, the term "you" defines the older adults, the child, and the child's parent participant. Parents will be asked to attend all training sessions and to complete questionnaires.

Who is funding this study?

This study is paid for by a grant from the Virginia Research Investment Fund (VRIF) and University of Virginia Office of the Vice President for Research (VPR). The study insulin pump will be provided by Tandem Diabetes Care. The other study supplies will be purchased with grant funding. Dexcom, Inc. will provide the continuous glucose monitor equipment and supplies.

Why is this research being done?

The purpose of this study is to test the use of an investigational device: the Tandem t-slim X2 with Control-IQ Technology and to see if improved glycemic control can positively influence cognitive function and Quality of Life (QOL).

You are being asked to be in this study because you are between the ages of 6-10 and 65 years old or older and have been diagnosed with type 1 diabetes. Participants between the ages of 6-10 will have at least one parent participate in this study.

Up to 68 people (including children, parents, and older adults) will take part in this study at UVA.

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

How long will this study take?

Participation in the study is about 10 weeks (2 months). If unfamiliar with the Dexcom Continuous Glucose Monitor (CGM), you will use the CGM up to 14 days so you can become familiar with the equipment. The Screening and Equipment Training Visits (visit 2 & 3) will occur in the UVA's Clinical Research Unit (CRU) at Fontaine Research Park (Charlottesville, VA).

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 at 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.

These include the following:

- Demographic information (date of birth, gender, race, and ethnicity)
- Medical history information including your diabetes history
- A physical examination or a copy of medical history performed within the last 3 months. The study physician may ask you to obtain laboratory testing if necessary. The laboratory testing would be to measure your diabetes control, your thyroid function, how well your kidneys/liver work, and the amount of certain salts and sugars.
- You will have a Hemoglobin A1c collected using a point of care machine. This machine requires a small droplet of blood similar to a finger stick.
- A blood or urine pregnancy test if you are an adolescent woman 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. Also, Virginia law requires release of the test results to your parent(s)/legal guardian if they request the results or request a copy of your medical records.
- Your personal insulin pump may be downloaded by the study team.
- You must be willing to use a regular insulin pump during the study. You will not be allowed to use functionality that automatically regulates your blood sugar, such as the Medtronic 670G in auto mode. The use of predictive low blood glucose suspend, such as a Tandem insulin pump with Basal-IQ, will be permitted.

If you are eligible, you may complete the questionnaires during this appointment. These questionnaires ask about:

- how you are feeling
- how you sleep
- how you feel about your diabetes
- how you feel about hypoglycemia

These questionnaires will take about 90-120 minutes to complete and will be completed on a computer. You will be asked to complete these questionnaires at three different times during the study.

There are questionnaires for adult subjects, child subjects, and parents to complete. Parents will be encouraged to have their child to complete their questionnaires without their direct oversight. If you chose to complete the questionnaires at home, we will ask that you complete them within a week of this appointment.

You are welcome to contact the study team at any time during the study if you have any questions or problems that you would like to discuss. The study team will contact you periodically as well to check on you

and discuss any issues that you may have during the study.

Visit 2: Study Equipment Training (will last about 90 minutes at CRU):

(Day 2-15)

If you meet study eligibility, visit 2 may occur on the same day as visit 1

- You will receive a study continuous glucose monitor (CGM) to use each day during the study; if currently using a CGM, you will be asked to discontinue its use.
- If you are not familiar with the study CGM, you will be trained on how to use it during the study.
  - You will be trained on how to insert the CGM sensor into your abdomen.
  - You will use the study CGM for up to approximately 14 days.
- You will receive a study glucometer and trained on its use.
- You will receive a study ketone meter and trained on its use.
- You will receive guidelines for treatment of low and high blood glucose values.
- You will receive study insulin pump, study CGM, study glucometer, and study ketone meter supplies.
- You ***and*** your parents may use the Dexcom Apps on your personal devices to monitor CGM values and alerts in real-time during the SAP phase.
- You and your parent will each receive an actigraphy watch to collect sleep data.
- You will receive a study cell phone (functionality of phone is inactive) or iTouch or similar device to respond to the Daily Diary assessments.
- You will be required to have a home glucagon emergency kit; a prescription may be provided to you.

The equipment given to you during this study should be returned to the Investigators when your involvement with the study ends.

Sensor Augmented Pump (SAP) Period (about 28 days)

(Day 15-43)

- During the SAP period, you will use your personal insulin pump and the study CGM for about 4 weeks.
- You will be asked to complete a Daily Diary on a study cell phone or iTouch during the last 14 days of this period. There will be about 4 entries each day during a 14 hour time period. You will be prompted randomly. Answers will take less than 5 minutes to complete. You will be able to "skip" Diary entries when prompted at inconvenient times.
- Daily diary questions will ask you to answer math problems, identify your mood, etc...
- You ***and*** parents will be asked to wear an actigraphy watch during the last 14 days of this period. (Sleep actigraphs are generally worn on the wrist of the non-dominant arm. They are useful for determining sleep patterns and circadian rhythms and may be worn for several weeks at a time.)
- You ***and*** parents will be asked to complete the same questionnaires at the end of this period.
- You will have a Hemoglobin A1c collected using a point of care machine at the completion of this period.

Visit 3: Closed Loop Control (CLC) Training (about 4 hours at CRU)

(Days 44)

You (and your parent) will be trained to use the study system. System parts include the Tandem t:slim X2 insulin pump with Control-IQ technology and the study CGM system. You will be taught how to use the study system in all modes of operation. Using the study system in closed-loop mode will automatically adjust your insulin delivery based on the CGM glucose readings. You can always stop closed-loop mode at any time and take over control of your insulin delivery. You will be trained on how to download your study pump.

Parent(s)/guardian(s) of child participants will be required to use the Dexcom App on your personal devices to monitor CGM values and alerts in real-time during the CLC phase.

By the end of training, you will be expected to perform certain tasks without help from the study team. You will use the study system at home, day and night, for a 4-week period. You will be given a User Guide as a reference.

Closed Loop Control (CLC) Period (about 28 days)

(Day 44--71)

- You will be asked to complete a Daily Diary on a study cell phone or iTouch during the last 14 days of this period. There will be about 4 entries each day during a 14 hour time period. You will be prompted randomly. Answers will take less than 5 minutes to complete. You will be able to "skip" Diary entries when prompted at inconvenient times.
- Questions will ask you to complete answer math problems, identify your mood, etc...
- You ***and*** parents will be asked to wear an actigraphy watch during the last 14 days of this period. (Sleep actigraphs are generally worn on the wrist of the non-dominant arm. They are useful for determining sleep patterns and circadian rhythms and may be worn for several weeks at a time.)
- You ***and*** parents will be asked to complete the questionnaires again at the end of this period.
- You will be asked to download your study pump approximately once per week throughout the study.

Visit 4: Study Completion (about 3-4 hours at CRU)

(Day 72)

At the completion of the study, you will:

- Return to the CRU to return the study equipment to the study team.
- You will return to using your personal equipment.
- The study team may download the glucometer and ketone meter. This equipment can then be returned to you.
- You ***and*** parents will be asked to complete the questionnaires electronically within a week of completing the CLC phase. If not completed prior to this appointment, the study team will provide you a computer to complete at this appointment.
- You will have a Hemoglobin A1c collected using a point of care machine at the completion of this period.

- You will complete a semi-structured interview to talk about your thoughts and attitudes related to your or your child's diabetes and the use of technology in diabetes care. This may happen in-person at this visit or may be completed on the phone. This interview will take approximately 30 minutes.

Study Schedule

	Visit 1	Visit 2	Visit 3	Visit 4
Location of Visit	**CRU**	**CRU/Home**	**CRU/Home**	**CRU**
Duration of Visit	**About 3 hours**	**~90 min + ~28 days SAP**	**~4 Hours & ~28 days CLC**	**About 3 hours**
Study Day	**1**	**2-43**	**44-71**	**72**
Informed consent	X			
Review study eligibility	X			
Medical history	X			
Hemoglobin A1c	X	X		X
Pregnancy test for females	X	X		
Questionnaires	X	X (end of visit)		X (end of visit)
Diabetes & Technology Interview				X (at visit or remotely via phone)
Weekly Study Pump **Downloads**			X----------X	
Daily Diary Assessments		X (last 14 days)		X (last 14 days)
Actigraphy Watch (Adult, Child, Parent)		X (last 14 days)		X (last 14 days)
Study Equipment Training (CGM, Glucometer, Ketone Meter, Actigraphy Watch)		X		
Tandem Equipment Training & use during study			X	
Use of Study Equipment (CGM, Glucometer, Ketone Meter, Actigraphy Watch)		X	X	
Return Study Equipment (CGM, Glucometer, Ketone Meter, Actigraphy Watch, Tandem Insulin Pump)				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 the Parental Questionnaires and Daily Diary Assessments.
- Report any issues with the study equipment.
- Wear the Actigraphy watch during the last 14 days of each study phase
- 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.

As an adult participant in this 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.
- Participate in weekly appointments (i.e. phone/email/text) with the study team.
- Complete the questionnaires and Daily Diary Assessments.
- Report any issues with the study equipment.
- Wear the Actigraphy watch during the last 14 days of each study phase
- You 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 device, 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 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 symptoms related to wearing an actigraphy watch

Rarely:

- Skin irritation or redness

Performing a serum (blood) or urine pregnancy tests (females 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 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 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.

Risks of Recording Audio

As part of the study, you will complete a structured in-person or phone interview that will be audio recorded. Your voice will be stored on a recording device. To protect your privacy, the recording will not contain any specific identifiers – you will be referred to by your subject number and will be instructed to not discuss any personally identifying information during the interview.

Risks for women:

Pregnancy and Contraception

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

Other unexpected risks:

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

Could you be helped by being in this study?

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

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

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

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 $250 when you complete the study. You will receive payment after the study equipment has been returned to the study team. You should get your payment by check about 4 weeks after finishing the study. The income may be reported to the IRS as income.

- After SAP Visit: $100
- After CLC: $100
- Three questionnaires and assessment completed: $50

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

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

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

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

Should you withdraw from the study, you will be paid for the visits that you have completed.

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

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

Will being in this study cost you any money?

Being in this study will not cost you any money. Your insurance company will also not be billed. If you don't have an emergency glucagon kit, the study physician will provide you a prescription to obtain one. The cost of this glucagon kit will be your or your insurance company's responsibility.

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 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 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 appointments may be cancelled. The study insulin pump and study CGM remain property of the CDT and will need to be returned.

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

How will your personal information be shared?

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

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

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

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- The sponsor(s) of this study, and the people or groups it hires to help perform or review this research
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study
- Tax reporting offices (if you are paid for being in the study)
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may

require us to let people in authority know so they can protect you and others.

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

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

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

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

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

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

Please contact the researchers listed below to:

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

Principal Investigator: Sue Brown, MD
UVA Center for Diabetes Technology
Box 400888
Charlottesville, VA 22904 Telephone: 434-982-0602

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research

PO Box 800483
Charlottesville, Virginia 22908 Telephone: 434-924-9634

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

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form, it means that you agree to join the study. You will receive a copy of this signed document.

Consent from Adult

PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

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

Person Obtaining Consent

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

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

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
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

Notification of My Health Care Provider

Your health care provider will be notified of your participation in this study if you are a UVA patient.

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.

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

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 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