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Medical Record # _____

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 (Age 15 to less than 18)

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

What is the purpose of this form?

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

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

Why is this research being done?

The purpose of this study is to assess the use of a new feature of the Control-IQ system, ***MyTDI.*** The insulin pump will take your total daily insulin (TDI) into account when making decisions on how much insulin to give you to treat your blood glucose.

This is a study for an experimental device that has not yet been proven to be safe or helpful. The continuous glucose monitors (CGM) used in this study are approved by the U.S. Food and Drug Administration (FDA) to measure and monitor your blood sugar. The insulin pumps used in this study are approved by the FDA to administer insulin to you. However, these two devices working together with the control algorithm (a complex mathematical formula) creates an "artificial pancreas", and this device has not approved by the FDA. So far, the system has been used for over 350,000 patient hours.

You are being asked to be in this study because you are between the ages of 12-18, you live with type 1 diabetes and are using an insulin pump.

Up to 25 people will be in this study at UVA.

Is there a possible conflict of interest?

Technologies tested in this trial are patented or have a patent pending by the University of Virginia. The UVA Licensing and Ventures Group handles all 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?

Note: All procedures, assessments, and tests performed in this consent are done for research purposes only.

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Your participation in this study will require 5 study visits over about 2 weeks. The length of each visit varies and is outlined in the next section.

What will happen if you are in the study?

SCREENING

Visit 1 (Day 1):

The screening appointment and the study equipment training may take up to 6 hours to complete.

If you agree to participate, you will sign this consent form before any study-related procedures take place. Before you can start in the study, there will be a screening visit. You will have tests and procedures during this time to make sure you are eligible, and it is safe for you to participate. These include the following:

- Demographic information (address, date of birth, gender, race, ethnicity, and your parent(s) contact information)
- Collection of information about you: your diabetes history, past and current medical conditions, surgical procedures, menstrual history (females), allergies, medications and supplements.
- Review your current insulin pump information over the past 2 weeks
- Willingness to switch to lispro (Humalog) or aspart (Novolog) if using glulisine (Apidra).
- A physical exam (including height, weight, and vital signs)
- HbA1c blood test (results collected within the last two weeks are also acceptable)
- A 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.

Study Equipment Training

If you meet study eligibility, you will participate in the study equipment training session. This training will occur on the same day as visit 1. Your parent(s) or legal guardian will participate in this training session as well.

- You will be trained to use the study system by a qualified trainer. 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. The insulin pump will be programmed with your current home insulin parameters. 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 receive a study continuous glucose monitor (CGM) to use each day during the study; if currently using a CGM, you will be asked to stop using it.
- 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 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 wear an activity tracker (i.e. 'Fitbit') on your wrist during the entire study to collect information about your activity and your heart rate. You may take it off before bathing.
- You will receive study insulin pump, study CGM, study glucometer, and study ketone meter supplies.
- You will be required to have a home glucagon emergency kit; a prescription may be provided to you.
- Your parent(s)/guardian(s) will be required to use the mobile app on personal devices to monitor CGM values and alerts in real-time while using the system at home.

You will begin using the Control-IQ AP system at the end of this training session for about 5 days at home. The study team will download the data from the study equipment during the ski admission.

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

Post-Training Data Collection Period (about 5 days)

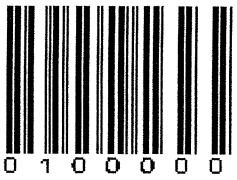
Visit 2 (Day 1-5):

You will use the Control-IQ system at home for about 5 days before the start of the ski admission. This will begin your first 5 days of at-home data collection period. The study team will check in with you (by phone, email or text) about 48-72 hours after the training visit to:

- See if you have questions about the study devices
- Check to see if you have had any new medical issues
- Remind you about the Ski Admission and what to bring

Ski Admission (about 72 hours)

Visit 3 (Day 6-10)



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The supervised study visit will occur at a local ski resort (i.e. Wintergreen Resort), where you will stay for 72 hours. When you get to the resort, the study team will do the following to make sure it is still safe for you to be in the study:

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

If these tests show that it is okay for you to be in the study, you will be randomized into a study group.

Randomization

GROUP 1: EXPERIMENTAL GROUP – CONTROL-IQ WITH MYTDI
GROUP 2: CONTROL GROUP – CONTROL-IQ USING YOUR USUAL PARAMETERS

Note: All of the study procedures will be the same for both of the groups except for which version of the AP system being used.

You will be randomly assigned (like the flip of a coin) to 1 of 2 study treatment groups. You have an equal chance of being assigned to either one of the groups. Neither you nor your doctor can choose which treatment you are assigned. The study team will tell you which group you have been assigned.

During the Ski Admission,

- You will be provided meals.
- You will be offered and provided snacks.
- You will participate in structured supervised exercise (e.g. skiing/snowboarding – 3 hours in the morning and 3 hours in the afternoon). Study staff will be with you when you are skiing/snowboarding.
- You will be asked to notify staff of any alerts/alarms by the study device.
- You will interact with the other study participants and study staff.

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- You will be continually monitored by study staff (i.e. physicians, nurses, technicians, and other study staff)

After the Ski Admission is over, you will return home using the AP system used during the admission (i.e. you will continue using the assigned AP system after you leave the resort). You will wear and use the system at home for about 5 days after the admission ends. You will be given CGM and pump supplies needed for this period of time. You will take the study glucometer and study ketone meter to use at home. You will be given instructions on how to manage your blood sugar and diabetes care. You will be monitored by at least one of your parents/guardians using a mobile app. In addition, study team members will be available 24 hours a day to address questions or concerns.

Post Admission Data Collection Period (about 5 days)

Visit 4 (Day 10-15)

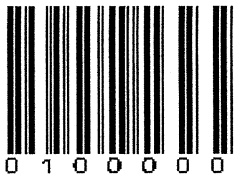
You will continue to use the Control-IQ system at home for about 5 days after the ski admission. This will begin your second 5 days of at-home data collection period. The study team will check in with you (by phone, email or text) about 48-72 hours after the ski admission to:

- See if you have questions about the study devices
- Check to see if you have had any new medical issues

End of Study (about 15-60 minutes)

Visit 5 (Day 16)

You will stop using the study equipment and you will start your regular diabetes care (personal insulin pump, CGM, personal insulin parameters, etc.) at this time. You will return the study devices and supplies (CGM, insulin pump, activity tracker) to the study team. You may be allowed to keep the study glucometer and/or study ketone meter if they are not labeled for investigational use only. If this visit is performed via phone, you will be given instructions on mailing the devices and supplies back to the study team.



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Study Schedule

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
Visit	**Screening**	**Post-Training Data Collection**	**Ski Admission**	**Post-Admission Data Collection**	**End of Study**
Study Day	**1**	**1-5**	**6-10**	**10-15**	**16**
Informed Consent	X				
Review study eligibility	X		X		
Medical History	X		X		
Vital signs	X		X		
Physical Exam	X		X		
Blood draw (for HbA1c)	X				
Urine Pregnancy Test	X		X		
Check in		48-72h post		48-72h post	
Assigned AP System			X		
Review health related problems		X	X	X	X

*Physical exam report will be accepted if it was done <12 months before screening visit
**HbA1c lab result will be accepted if it was done <2 weeks before screening visit

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. These responsibilities 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.
- 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.
- Answer all of the study-related questions completely and accurately.
- 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.

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Blood Testing

We will take (or "draw") up to 1 teaspoon of blood at the Screening Visit. The total amount of blood we will take will be 1 teaspoon. The blood we take will be tested to measure what your average blood sugar over the last 3 months has been.

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

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

What are the risks of being in this study?

Risks and side effects related to treating type 1 diabetes (with or without using study equipment/devices) include:

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 (DKA), hospitalization, and coma. DKA can lead to kidney failure, cardiac arrhythmia (irregular heartbeat), myocardial infarction (heart attack), rhabdomyolysis (muscle breakdown), and even death.

Risks and side effects related to performing fingersticks include:

Likely

- Pain at site of lancet (finger-pricking needle) use
- Bleeding at site of lancet use

Less Likely

- Incorrect information from a false low or a false high fingerstick value

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Rarely

- Infection at site of lancet use

Risks and side effects related to continuous glucose monitor sensor use include:

Likely

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

Less Likely

- Bruising less than ½ inch
- Bleeding less than ¼ teaspoon
- Sensitivity to adhesives with use of the CGM resulting in skin irritation, redness, blistering, scarring, systemic allergic reaction, or secondary skin infection

Rarely

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

Performing a urine pregnancy tests females who are able to become pregnant):

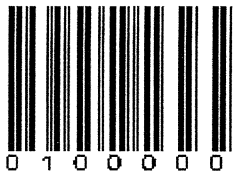
Less Likely

- False positive or false negative results

Risks and side effects related to the study system include:

Even though the study algorithm has been tested prior to this study, there is still a risk that parts of the system may malfunction. As a result, you could receive less or more insulin than you need and be at risk for hyper- or hypoglycemia. The following are common cases of system malfunction:

- CGM sensor reads higher or lower than your actual blood glucose level



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- CGM sensor stops working or cannot communicate with the system. If this occurs, the insulin pump will start delivering its preset basal rates within 30-60 minutes
- Infusion set failures

Risk of injury while skiing/snowboarding:

A wide range of injuries may occur when skiing/snowboarding. Bruising, dislocations, sprains, and fractures of the leg and shoulders are very common.

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 hospital approved cleaning method. The FDA approved the continuous glucose monitor as a 'single use device'. This means that they recommend that only one person use this device as there is a rare risk that a blood borne pathogen, such as Hepatitis B, may be spread if used with multiple patients.

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

The FDA approved these meters for 'single-patient use'. This means that they recommend that only one person use this device as there is a rare risk that a blood borne pathogen, such as Hepatitis B, may be spread if used with multiple patients. All parts of the meters are considered biohazardous and can potentially transmit infectious diseases.

Risk of Sharing the Insulin Pump

The FDA typically approves an insulin pump for 'single-patient use'. This means that they recommend that only one person use this device as there is a rare risk that a blood borne pathogen, such as Hepatitis B, may be spread if used with multiple patients. The insulin pump handheld device may be reused after cleaning thoroughly with a diluted mixture of bleach or another hospital approved cleaning methods.

Risks of Videotaping/Audio taping:

- Photographs and videotapes will be used in presentations at conferences, potential study subjects, and potential research donors. Your picture can be blacked out in photographs that we maintain.
- The study team can keep a participant's identity anonymous.
- The study team will keep these photos and videotapes indefinitely.

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- The study team is not able to restrict other participants from sharing photographs that include you (i.e. social media).

Unknown Risks

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

Loss of Privacy

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

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

Risks of having your blood drawn:

Having blood drawn may cause:

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

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

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

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

Risks for women:

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.

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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 may benefit from being in this study by having better glycemic control while using the Control-IQ system. 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 even if you choose not to be in this study. The usual treatment would include:

- Continuing your diabetes care as you normally do at home

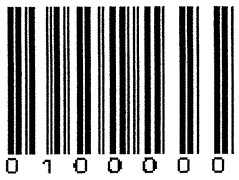
If you are an employee of UVa, your job will not be affected if you decide not to participate in this study. If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will 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 health insurance: lab tests, urine pregnancy testing, study visits (including Ski Admission, ski equipment, lodging & meals/snacks), use of the study devices.

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. Parking will be provided at no costs.



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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 lost wages, disability, or discomfort. The sponsor will reimburse the reasonable cost of necessary and appropriate emergency and/or acute medical care for injury or illness that is determined by the principal investigator and sponsor to be directly related to the study. Injury related to the study does not include the normal progression of any disease or any underlying pre-existing medical conditions.

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 or the sponsor of this study can take you out of the study.

If you decide to stop being in the study, we will ask you to tell us that decision in writing. We will ask you to return all study equipment.

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.

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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.

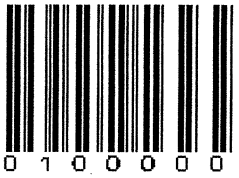
Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

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



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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 if you have a UVA medical chart. (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: Marc Breton, Ph.D.
P.O. Box 400888
Charlottesville, VA 22903 Telephone: (434) 982-6484

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your 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

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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:

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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

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.

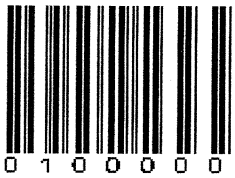
_____	_____	_____
PERSON OBTAINING ASSENT (SIGNATURE)	PERSON OBTAINING ASSENT (PRINT)	DATE

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: _____

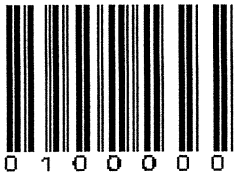


Medical Record # _____

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.



Medical Record # _____

Leaving the Study Early

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

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

Check one option below:

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

- Obtaining information from my medical records
- Phone call (48-72h after stopping study equipment)

____ 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 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

Medical Record # _____

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