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.

Participant's Name_____ Medical Record # _____

Principal Investigator: Patricio Colmegna, PhD
Center for Diabetes Technology
University of Virginia
P.O. Box 400888
Charlottesville, VA 22908

Sponsor: JDRF

What is the purpose of this form?

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

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a copy of this form.

Who is funding this study?

This study is being funded by the JDRF and the University of Virginia's Strategic Investment Fund (SIV). The continuous glucose monitoring (CGM) sensors and transmitters will be purchased with grant funding.

Key information about this research study

You are being asked to take part in a research study. You do not have to take part in this study. You should only agree to take part in this study after reading this consent form and discussing it with the study team. You may also discuss this with your family, friends, health care providers or others before you make a decision.

You will interact with a web-based simulation tool (WST) that will allow you to:

1) see information about your diabetes;
2) see what would have happened to your glucose levels if you had changed some of your diabetes treatment decisions;
3) get results shown in numbers and in graphs.

This is an educational tool. For this system to work, the study team will collect insulin, glucose, and meal data from your insulin pump. The system will require you to move scroll bars, click on check boxes or make selections from drop-down lists. This information will show you what would happen if you made changes to your insulin therapy parameters or your meals.

You should talk with your Primary care Physician before making any changes to your treatment based on your interaction with this tool. This tool is not approved for changing insulin dosing or management of diabetes. This web-based simulation app does not make changes to how your insulin pump dispenses insulin.

What problem is this study trying to solve?

This study is trying to find out if the web-based simulation tool (WST) is easy and comfortable to use when caring for yourself and your diabetes.

Why would you want to take part in this study?

You will not benefit from being in this study. You might like to take part in this study because the interaction with the web-based simulation tool might give you additional information about your blood glucose control and insulin treatment.

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

You might not want to take part in this study if:

- you do not want to interact with a web-based program
- if you do not want to think about possible changes to your current insulin treatment
- you don't want to use a Dexcom CGM
- you don't want to participate in study visits
- you do not want to complete questionnaires
- you do not want to use your personal insulin pump
- You do not want to use your account(s) associated with Tandem t:connect or create one for use during the study
- you do not want to send (transmit) your CGM or personal insulin pump data to Tandem via the Tandem Mobile Application

What will I have to do if I take part in this study?

If you take part in this study,

- you will use Dexcom CGM transmitter and sensors
- you will be asked to use this CGM on a daily basis and in accordance with manufacturer recommendations
- you will be asked to use your personal Tandem insulin pump and connect it to a personal or study smart phone running the t:connect app

- you will be asked to provide the study team access to an existing t:connect account or create a personal or study account and associate it with your personal insulin pump for about 5 weeks
- you will be asked to use this insulin pump for about 5 weeks
- you will interact with a software program for about 5 weeks
- you will electronically complete questionnaires
- you will participate in a follow-up interview which will be recorded to tell us about your experience with the software program
- you will use the bolus calculator feature of your insulin pump and record the carbohydrate information at each meal.
- you may be asked to download the data from your insulin pump and CGM each week

Diabetes can affect your mood and is associated with increased risk of depression. Please be vigilant for changes in your mood and behavior and contact your physician if you notice any of the following symptoms: Increased irritability, continuous sadness, feelings of worthlessness, social withdrawal, or frequent crying.

What is the difference between being in this study and getting usual care?

There is no change to your usual care other than that you will get a new CGM transmitter and sensors to use for 5 weeks (35 days).

How long will this study take?

Your participation in this study will require 4 study visits within about 35 days. You will have a screening visit (Visit 1) which may take about 2 hours. You will also have a training visit (Visit 2) that will take about 2 hours. Visit 1 and 2 may be done on the same day. For approximately the first 7 days, the study team will collect your diabetes data, but you will not use the web-based simulation tool. You will use the WST for about 28 days (4 weeks) at home. At study end, you will be asked to complete questionnaires (Visit 3) and participate in a follow up interview (Visit 4). These visits may be completed at the Clinical Research Unit (CRU) or may be completed via a secure web-based video conferencing tool.

You may be asked to repeat some or all of the study period if the web-based simulation tool is not used like it was meant to be used. You may also be asked to repeat some or all of the study period if there are not enough data.

What will happen if you are in the study?

<u>Visit 1: Study Screening (Day 1) (about 2 hours to complete)</u>

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

These tests and procedures include the following:

- Information about you such as your date of birth, gender, race and ethnicity, socioeconomic status, education, etc.
- A review of your medical and surgical history, allergies, and current medications
- A review of your current diabetes treatment.
- A physical exam and vital signs (height, weight, blood pressure, temperature, heart rate) or a copy of your medical history performed within the last 6 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 liver/kidneys work, and the amount of certain salts and sugars. Your Hemoglobin A1c may be collected using a point of care machine. This machine requires a small droplet of blood similar to a fingerstick. If you have had these tests done within the last 3-6 months, you may not need to have these tests repeated. You may have the blood/urine drawn at a local laboratory (i.e. LabCorp).
- Standard blood or urine pregnancy test will be performed. If you are a woman who can become pregnant. A negative urine pregnancy test will be required for all premenopausal women who are not surgically sterile prior to each visit. If female and sexually active, must agree to use a form of contraception to prevent pregnancy while a participant in the study. Subjects who become pregnant will be discontinued from the study.

If these tests show that you are eligible to participate in the study, you may immediately begin Study Training Session (Visit 2).

Visit 2: Training Session (Day 2) (about 2 hours to complete)

Questionnaires:

During this study, you will be asked to electronically fill out some questionnaires. These questionnaires ask about how you manage your diabetes and about your expectations with the web-based simulation tool.

These questionnaires will take about 30 minutes to complete.

This part of the study might occur on the same day as your screening visit or at home.

Web-Based Simulation Tool (WST):

Study staff will instruct you on how to use the WST. During this session, you will learn how to: 1) gain access to the web-based simulation tool; 2) visualize your data; 3) simulate new scenarios; and 4) obtain comparison results expressed by numbers and graphs. Figure 1 shows an example of what kind of information you will obtain from WST. As you can see, original data (light blue) and simulated or replay data (orange) will be displayed together to facilitate the comparison between these two data sets. WST will show you the amount of available data, time in range, glucose traces and other metrics related to your diabetes control.

Continuous glucose monitoring (CGM) system:

You will use your personal Tandem t:slim X2 insulin pump and Dexcom G6 CGM during the study. If you are not currently using a Dexcom G6 CGM, this will be provided to you. All subjects will receive Dexcom G6 CGM transmitters and sensors to use during this study. Study staff will instruct you on how to use this CGM system. Juvenile Diabetes Research Foundation (JDRF). CGM training may include review of study CGM in real-time to make management decisions and how to review the data. Study staff will specifically identify how alarms are set and the frequency that these alarms will repeat when enabled. You will be asked to use the CGM on a daily basis and in accordance with manufacturer recommendations, the bolus calculator feature of your insulin pump, and to record the carbohydrate information at each meal. You may be asked to download the data from your insulin pump and CGM each week.

Participation Period (approximately Day 3-38):

In the first week of the participation period we will collect your diabetes data, but you will not use the web-based simulation tool. You will use the system during the following 4 weeks. You will be asked to use your diabetes data with the web-based simulation tool at least once a week. You must run at least one simulation in the WST application for it to count. If you only log in to the application, it will not count. The study team will monitor your interaction with the application. The study team will be available if you have questions during the study.

You must talk with your Endocrinologist before changing your insulin parameters, or any other part of your diabetes treatment based on information that you may learn during this study.

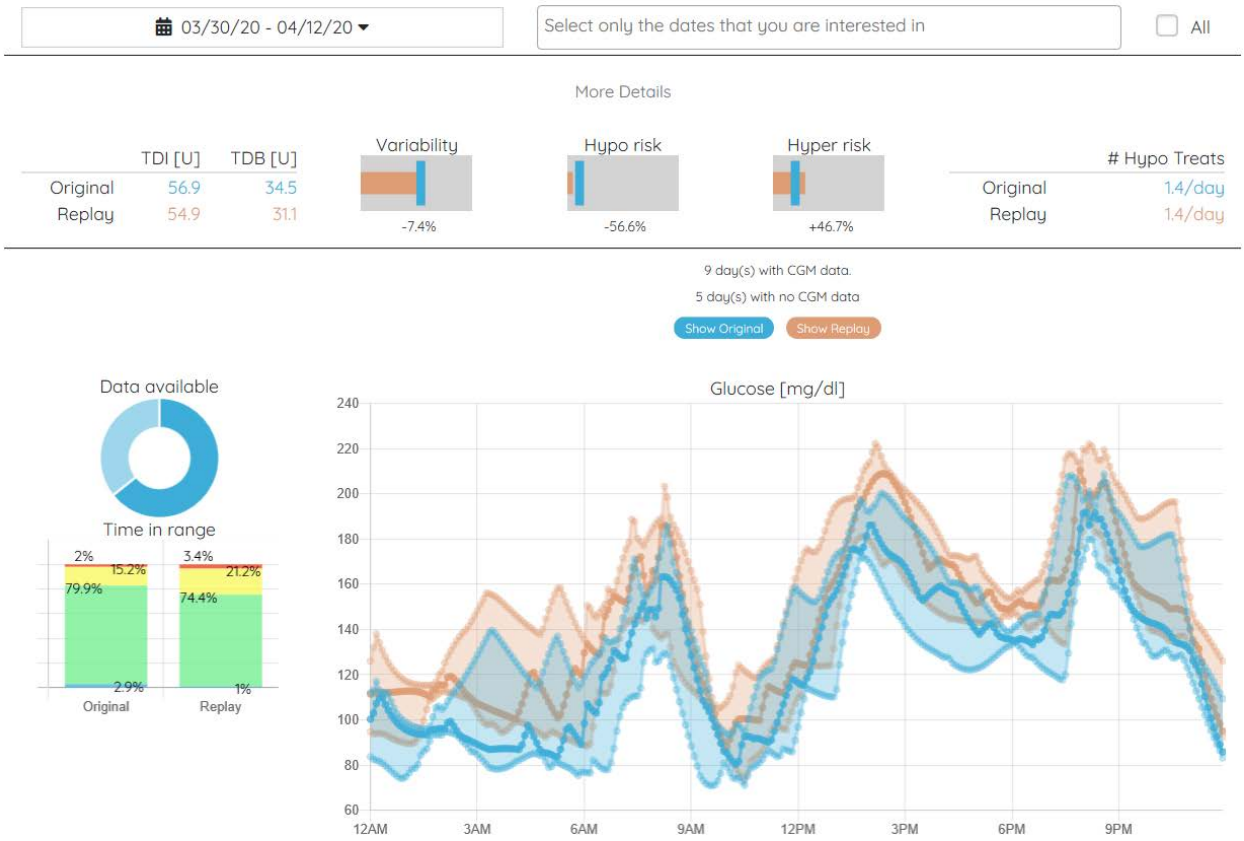

Figure 1: Example of data displayed on the dashboard page of WST

Visit 3: Questionnaires (about Day 39)

At the completion of the trial, we will ask you to complete questionnaires about your perceived treatment satisfaction and the use of the web-based simulation tool.

These questionnaires will take about 30 minutes to complete.

Visit 4: Follow-up Interview (about Day 40-69)

A follow up interview with a study team member will be scheduled within 30 days of completing the study. These questions will ask you to describe your experience with the web-based simulation tool, and what things you liked most and least about it. This interview will be recorded to assist staff with documenting your responses. We will not refer to you by name during the audio recording. You will be asked not to say another that may identify you (i.e. your name, your occupation, etc.) The recording of the session will be identified using your study subject ID number. The recording will be saved with all study documents. This interview will take about 30 minutes to complete.

STUDY SCHEDULE

Study Procedures	Screening	Training	Data Collection Period	Participation Period	Questionnaires	Follow-up Interview
Visit	1	2	-	-	3	4
Days	1	2	3-9	10-38	39	40-69
Duration (approximate times)	2 hours	2 hours	about 7 days	about 28 days	about 30 min	about 30 min
Location	CRU*	CRU*	Home	Home	Home	Home/CRU*
Informed Consent	X					
Medical History	X					
Inclusion/Exclusion Criteria	X					
Screening Labs	X					
Urine pregnancy test (women able to become pregnant)	X	X				
Questionnaires		X			X	
WST training		X				
CGM training		X				
WST use				X		
Software Interaction				At least 1x weekly		
Data Collection from Insulin Pump and CGM			X	X		
Interview						X

*CRU = Clinical Research Unit

What are your responsibilities in the study?

You have certain responsibilities to help ensure your safety. These responsibilities are listed below:

- Follow all instructions given.
- You must attend each study visit as advised by the study staff.
- You must be completely truthful about your health history.
- You should tell the study doctor or study staff about any changes in your health or the way you feel.
- Answer all of the study-related questions completely.
- Inform the study doctor or study staff as soon as possible, if you 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 before the study is done:

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

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

What are the risks of being in this study?

Risks related to treating type 1 diabetes (with or without using the web-based simulation tool):
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.
-

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 even death.

Risk associated with using a web-based simulation tool:
Unknown:

- You using the insulin parameters provided during simulation without consulting your endocrinologist first.

Risks associated with continuous glucose monitor insertion:
Likely:

- Failure or lack of sensitivity of the continuous glucose monitor sensor that requires replacement / insertion of new sensor.
- 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 or secondary skin infection.

Rarely:

- Swelling or redness at insertion site
- Psychological reaction to viewing the continuous glucose monitor information or attending to continuous glucose monitor alarms.
- 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 insulin pump use:
Likely:

- Risk of pump site failure and need to re-establish a functional pump site for insulin administration.

Rarely:

- Risk of symptoms related to the continuous subcutaneous insulin infusion (CSII) insertion: sensitivities to adhesives associated resulting in skin irritation, bruising, and bleeding. Risk of developing subcutaneous hypertrophy or atrophy of tissues related to insulin infusion.

Risks associated with performing a serum (blood) or urine pregnancy tests (women who are able to become pregnant):
Less Likely:

- False positive or false negative results.

Risk of fingersticks:
Likely:

- Pain at site of fingerstick
- Bleeding at site of fingerstick

Less Likely:

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

Rarely:

- Infection at site of fingerstick

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:
You must use an approved form of birth control during this study. You will be told to ask your doctor for more details about the proper birth control method. If you become pregnant during this study, you are told to inform your study doctor right away. Your study doctor will discuss her treatment and the effect of the study on your pregnancy.

Risks of Videotaping/Audiotaping:
The structured interview will be audiotaped. We will not refer to you by name in the audiotape and the taped record will be stored and labeled with your unique study ID number, the visit number, and the date of this visit.

Risks from Completing Questionnaires:
Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and move on to the next question.

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 even if you choose not to be in this study. The usual treatment would include the treatment recommendations provided by your treating endocrinologist.

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 for completing the study. Payments will be processed after you complete each part. You should receive your payment by check about 4 weeks after finishing the study. The income may be reported to the IRS as income.

- Participation Period (Visit 2): $100
- Questionnaires (Visit 2 and Visit 3): $25 per session ($50 total)
- Follow-up Interview (Visit 4): $100

Any study supplies provided to you during the study must be returned to the study team prior to receiving study payment.

There is no payment for completing the screening visit (visit 1). There is no study compensation if the study physician finds that you are ineligible to participate in the study. You will not be paid at all if **you** decide not to finish this study. If the study leader says you cannot continue, you will be paid the full amount for the study.

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. Lab tests at the screening, which are being done for research purposes, will be provided at no cost to you or your health insurance.

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

- The WST tool
- Continuous Glucose Monitor Transmitter and Sensors, if needed

You will use your own insulin, insulin pump, and its associated supplies.

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.

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 at 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) New information shows the treatment will not work or is not safe for you.
c) You do not follow your doctor's instructions.
d) The study sponsor closes the study for safety, administrative or other reasons.

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.
- 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.

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

- Obtain more information about the study.
- Ask a question about the study procedures or treatments.
- Report an illness, injury, or other problem (you may also need to tell your regular doctors).

- Leave the study before it is finished.
- Express a concern about the study.

Patricio Colmegna, PhD
University of Virginia, Center for Diabetes Technology
Box 400888 Charlottesville, VA 22908
Phone: 434-982-6483

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

Notification of My Health Care Provider

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

_____ Yes, I want the study doctor to notify my health care provider that I have agreed to take part in this study.

Health Care Provider Name:
Health Care Provider Address:

Study team will send a copy of the consent form to the health care provider.

_____ No, I do not want the study doctor to notify my health care provider that I have agreed to take part in this study or I do not have a health care provider.

Leaving the Study Early

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

Check one option below:

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

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

- Obtaining information from my medical records
- Phone call or email
- Sending me questionnaires at the end of the study
- A Follow-Up Interview

____ 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