Please check one of the following:

_____ You are an adult participant in this study.

_____ You are the parent or guardian granting permission for a child in this study.

Print child's name here: _____

The following information applies to the adult participant or to the child or ward. If the participant is a child or ward, the use of "you" refers to "your child" or "your ward."

**********

Are you participating in any other research studies? _____ Yes _____No

## PURPOSE OF RESEARCH

You are being asked to take part in this research study because you are at increased risk of developing type 1 diabetes. Type 1 diabetes is an autoimmune disease. This means that the immune system, the part of your body which helps fight infections, mistakenly attacks cells that produce insulin in your body. The cells that produce insulin are called beta cells and are found in the pancreas. As the immune system destroys these cells, the body's ability to produce insulin decreases and diabetes develops.

The investigators carrying out this study are part of an international research group called TrialNet that is studying type 1 diabetes. These investigators are testing a medication called abatacept, which is approved by the U.S. Food and Drug Administration as a treatment for rheumatoid arthritis. In a previous TrialNet study abatacept was shown to have some effect on preserving insulin secretion after diagnosis.

We know that development of diabetes occurs over time as the immune system destroys insulin producing cells. As you know from the TrialNet Natural History-Pathway to Prevention Study, individuals like yourself with multiple autoantibodies have a risk of getting diabetes. As the immune system starts to destroy insulin producing cells, blood glucose values increase. First the blood glucose values may increase enough to be called "abnormal". Later, blood glucose values may increase more and diabetes is diagnosed.

The goal of this study is to learn if abatacept can help prevent or delay these abnormal glucose levels or diabetes.

This consent form tells you about the study and what people in the study will be asked to do. The study will be explained to you and you will be given the chance to ask questions. You will be given a patient handbook that explains the overall study. Taking part in this study is your decision.

If you agree to take part in the study, you will be asked to sign this consent form. You will be given a copy of the consent form to keep for your records.

If you decide to terminate your participation in this study, you should notify Darrell Wilson, MD, at 650-723-5791.

This research study is looking for 206 people throughout the United States at risk for developing type 1 diabetes. Stanford University expects to enroll approximately 25 research study participants.

## VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

## DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 5-6 years. If you develop diabetes, you will no longer be in this study. However, we will let you know if there are other TrialNet studies available to you.

This study will have two phases, a treatment phase for the first year and then a monitoring phase for an additional two years. During the treatment phase, you will receive the study medication 14 times over the first year. During the monitoring phase you will have clinic visits every six months, and a blood work only visit at Stanford or your local lab halfway between the clinic visits.

## PROCEDURES

### *All study visits:*

During study visits we will ask questions about your health, diet and activity, and experience as a research participant. We will periodically perform a physical examination and take blood for testing. Females will also give regular urine samples to be checked for pregnancy.

The blood tests will help us check for diabetes, your immune system, and your general health. They will also be used to better understand what causes type 1 diabetes, to look for new ways to identify people at risk for disease, and to get ideas about new treatments in the future. While TrialNet is ongoing, these samples will be used only by TrialNet-approved researchers. As such, we will be collecting blood samples, including genetic samples, for these studies at most of your visits. You will not routinely be provided with test results from these studies.

The total amount of blood drawn for tests done at each visit will not exceed the amount that is safe for your age and weight. For most visits, it will not be more than 3-4 Tablespoons; and not more than 5 Tablespoons for visits which include an Oral Glucose Tolerance Test. More information about the specific blood tests can be found in the research volunteer handbook.

### *Treatment phase*

At the first study visit, you will be placed into one of two groups. One group will receive abatacept through a vein. The other group will receive placebo instead of abatacept. A placebo looks like medicine, but has no medicine in it so that people in the study will not know whether they are receiving the drug or placebo. You will be placed into one of these groups by chance (similar to drawing straws). You will have a 1 out of 2 chance of getting abatacept or placebo. Neither you nor your doctor will be able to choose the group in which you will be placed. Neither you nor your doctor will know who is getting abatacept and who is getting placebo.

After you are assigned to a study group, you will receive three doses during the first month and then monthly doses of either the abatacept or the placebo through a vein in your arm. The first dose will be given as part of your first visit; the second dose will be given 2 weeks later, and the third dose will be given two weeks later. Other doses will be every 4 weeks. You will have a total of 14- infusions over a period of one year. Administering the study medication will take about one-half hour. In addition, you will need to remain at the study site to be observed for one hour following the infusion.

During the treatment study phase, in addition to monthly visits to receive the study infusion, every six months you will undergo an Oral Glucose Tolerance Test or OGTT (described below). At visits requiring an OGTT you will be there an extra 2 hours. Even if you do develop abnormal glucose levels, you will still come in for treatment visits monthly.

We will ask you about your experience as a research participant at the end of the treatment phase of the study. This information will be used to help us plan future studies.

### *Monitoring Phase*

At the end of one year, you will come in every six months for OGTT visits. Even if you do develop abnormal glucose levels, you will still come in for visits every six months.

After the first year, in addition to study visits every six months, we will monitor you for risk of diabetes at three month intervals by phone contact. We will ask you about possible symptoms of diabetes such as blurry vision, unintended weight loss, increased hunger, thirst, or frequent urination. In addition we will ask you to have a blood test every three months. If you have any of these symptoms or abnormal blood tests, we may ask you to come to the study site for additional testing including an interim OGTT.

We will ask you about your experience as a research participant again at the two-year time point of the study.

### *Other Study Procedures:*

#### Oral Glucose Tolerance Test (OGTT)

You underwent OGTT studies as part of the TrialNet Natural History- Pathway to Prevention Study. An OGTT is done in the morning after an overnight fast (not eating during the night). Your blood glucose (sugar) will be measured after you drink a sweet liquid that contains glucose over a 5-minute period. To make the blood sampling easier, we will place an intravenous needle and plastic tube (IV) in a vein in your arm. This IV will stay in your arm until the end of the test. Blood samples will be drawn through the IV before you drink the liquid and then four more times after you have finished drinking it. A total of about 1 tablespoon of blood will be drawn for the OGTT. The visit for the OGTT takes about 3 hours.

In some cases you will be asked to repeat the OGTT within one month to confirm the results.

#### Immunizations

During the treatment phase you will receive a flu shot (given at the appropriate time of the year). Children less than 9 will need two flu shots (to be given one month apart) if they have not received a flu shot before. By testing your blood after the flu shot we can learn about how abatacept affects the response to vaccines.

#### Women of Childbearing Potential

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk.

To confirm to the extent medically possible that you are not pregnant, you agree to have a pregnancy test done before beginning this research study. You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

**Tissue Sampling for Research**

Research using tissues is an important way to try to understand human disease. You have been given this information because the investigators want to include your tissues in a research project and because they want to save the samples for future research. There are several things you should know before allowing your tissues to be studied.

Any of your samples which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, Stanford University and/or others. However, donors of samples do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

Your samples will be sent outside of Stanford for analysis.

**Storage of Samples in NIDDK Repository**

When TrialNet is over, we intend to put any remaining samples including genetic samples into the National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK) repository for future studies related to type 1 diabetes and its complications. They will be stored there indefinitely without your name or any other identifying information on them, as such, once in the repository you will not be able to have them removed. Researchers must first get permission from the National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK) to use samples from the repository.

The following checkbox gives you the choice of allowing us to put any remaining blood samples in the NIDDK repository. Even if you decide not to have your remaining blood samples stored, you can still participate in this study.

Are you willing to allow us to put any remaining blood samples in the NIDDK repository **(please initial yes or no)?**

_____YES _____NO

## Tissue Sampling for Genetic Testing

As part of the analysis on your samples, the investigators may do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

The results of the study of your samples from this project will be used for research purposes only, and you will not be told the results of the tests.

## PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Take the study drug as instructed.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Keep the study drug in a safe place, away from children and for your use only.
- Keep your diaries as instructed.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.

- Tell the Protocol Director or research staff if you change your mind about staying in the study.

## WITHDRAWAL FROM STUDY

Your choice to be in this study is completely voluntary. You may choose not to be in this study or to stop being in this study at any time, and your doctor will still take care of you. Your current or future medical care will not be changed if you decide not to be in this study or to stop being in this study at any time. Your study doctor may also choose to discontinue your study treatment at any time if it is felt that continuing treatment may hurt you. This may happen if the side effects are too great, or if you do not follow the study instructions. You will be told of any new findings that affect your being in this study.

If you decide to withdraw your consent to participate in this study, you should notify Darrell Wilson, MD at 650-723-5791.

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

## POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

The treatment and tests involved in this research project have the known risks listed below. There may be other risks that are not possible to predict.

**Common Side Effects:**
Abatacept can cause side effects that occur while it is being given. They are called infusion-related reactions. Possible reactions include nausea, dizziness, and high blood pressure, or low blood pressure. Other possible reactions include flushing, itching, coughing, wheezing, difficulty breathing, and fatigue. For your safety, the research staff will watch you closely for these effects. For example, you will have your blood pressure,

heart rate, and temperature taken regularly while you are receiving abatacept and during the observation period following the infusion.

**Uncommon Side Effects:**

Abatacept affects your immune system. Although unlikely, it is possible you could be at increased risk of certain types of infections including respiratory, urinary and skin infections. We will carefully check you for signs of infection during the study. If we see signs that you developed a new infection we will temporarily discontinue giving you monthly infusions until the infection has resolved. You should contact your doctor if you develop any infections, any flu-like symptoms, or are not feeling well at any time. You will not receive an infusion if you have an infection. Other uncommon, but possible, side effects include gastrointestinal irritation, diarrhea, abdominal pain, blurred vision, dizziness, rashes, hair loss, depression and anxiety.

**Rare Side Effects:**

Medications like abatacept that alter responses by the immune system can possibly lead to an increased risk of certain types of cancer. This has not been seen in previous studies of abatacept. In very rare instances, anaphylaxis (a severe allergic reaction) can occur which could be life-threatening. There may be increased infections or reappearance of previous infections. Very rarely these infections could be severe or even fatal.

**Birth control and pregnancy**

It is not known whether abatacept can damagefetuses. Women must not become pregnant for at least 3 months after completing the treatment phase of the study. If you could become pregnant, you must agree to use a reliable and effective form of birth-control while you are having monthly infusions during the study. You will need to provide a urine sample for pregnancy testing regularly during this study. If you become pregnant, you must tell the study doctor right away. We will stop your study medicine.

**Intravenous Needle (IV) and Blood Drawing**

While on the study you may have side effects from having your blood taken or IV placed. The risks of side effects from these procedures are very small. There is sometimes soreness and/or a bruise at the site where the needle goes through the skin. Once in a while, people faint. It is rare, but some people may get an infection, a small blood clot, swelling of the vein and the area around it or bleeding where the needle goes through the skin.

**Oral Glucose Tolerance Test (OGTT)**

Some people may feel nauseous when they have the OGTT.

**Immunizations**

Like all immunizations flu vaccines have a small risk of allergic reactions that can be severe. If you had a severe reaction to flu vaccine before, you will not be given that

immunization during this study. You will also not get the flu shot if you are allergic to eggs. If you have an illness with a fever, you will not get the vaccinations until you recover. The injections of vaccines may cause redness, swelling, and pain or soreness in the muscle where the injection is given. Immunizations may also cause a slight fever. Rarely, a mild flu-like illness and muscle aches may occur. All effects are usually mild and go away without treatment.

It is not known what effect abatacept may have on other vaccines. If you need any routine vaccinations, you should not get them during the first 15 months of the study (during the treatment phase and 3 months following). After that time, be sure you let us know if you have received any vaccines as part of your usual medical care.

## POTENTIAL BENEFITS

Abatacept may help the body to delay abnormal glucose or diabetes, but there is no guarantee.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

## ALTERNATIVES

Before you decide to take part in this study, we will talk with you about the other options available to you. You may choose not to participate in this study. At present, there is no approved medical treatment that will delay or prevent abnormal glucose or diabetes. There may be other research studies that you can choose to be in.

## PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

## ClinicalTrials.gov

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.

## CONFIDENTIALITY

Your consent to be in this study gives the TrialNet researchers permission to collect personal information about you and to use it for research purposes. This information may be shared with other TrialNet centers as needed to help with the study. Your consent also includes permission for the sponsor of this study (NIDDK) and the Food and Drug Administration (FDA) to review your records.

Personal information is information such as your name that directly identifies you. This personal information will be kept in a database at the central TrialNet Coordinating Center at the University of South Florida.

If you participate in this study, you will be given a unique study code number. It will identify the information and samples collected from you from study examinations and procedures. It will be sent to the central TrialNet Coordinating Center under the supervision of the NIDDK.

When TrialNet is completed, your data (but not your personal identifying information) will be moved to another location that will be under the supervision of the NIDDK. Once this happens, it will no longer be possible to link your code to your name or other personal identifying information.

A Certificate of Confidentiality has been obtained from the National Institutes of Health (NIH). This is intended to further protect the confidentiality of information that we obtain about you. By having a Certificate of Confidentiality, TrialNet researchers are not required to give information that can be used to identify you. For example, we cannot be forced to give information about you to insurance companies. Also, we cannot be forced to give information about you for any civil, criminal, administrative, or legislative proceedings whether at the federal, state or local level. However, the Certificate of Confidentiality does not prevent you from giving this information to others. Please understand that we will maintain the confidentiality of your research record. We cannot guarantee the confidentiality of test results provided to you if you wish to share them.

There are some rare exceptions to the protection offered by the Certificate of Confidentiality. TrialNet researchers are not prevented from telling about matters such as child abuse, certain infectious diseases, or threatened violence to yourself or others.

TrialNet researchers will consider your records private. Rarely, representatives of the United States Department of Health and Human Services (DHHS) or TrialNet may review or ask for a copy of your study records. If this happens, we will provide your records. Also, for auditing purposes, employees of Stanford University or its agents

could be allowed to see your study records to make sure that the study is being done properly.

The results of this study may be published for scientific purposes. By signing this form, you are agreeing to this. Your records and results will not be identified as belonging to you in any publication.

Your identity will be kept as confidential as possible as required by law. Your personal health information related to this study may be disclosed as authorized by you. Your research records may be disclosed outside of Stanford, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed**.**

The purpose of this research study is to obtain data or information on the safety and effectiveness of abatacept; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

# Authorization To Use Your Health Information

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

## What is the purpose of this research study and how will my health information be utilized in the study?

The goal of this study is to learn if abatacept can help people at high risk of developing type 1 diabetes by delaying or preventing the destruction of insulin-producing beta cells in the pancreas. Blood tests will be performed

to monitor the effects of abatacept and to learn how it may work in people who are at risk for developing diabetes.

### Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study, including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

### If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Darrell Wilson, MD, at Stanford University Medical Center, Dept. of Pediatric Endocrinology, 300 Pasteur Drive, Room G-313, Stanford, CA 94305-5208.

### What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to your name, age, e-mail address, phone number, and information relating to a particular medical condition, specific blood tests, and specific physical examination measures.

### Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director , Darrell Wilson, MD
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

- Other members of the TrialNet study team at Stanford University

## Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The National Institutes of Health
- The Food and Drug Administration
- Other federal and state agencies as required by law
- TrialNet Data Safety Monitoring Board
- Other members of the TrialNet team at the other study sites and the data collection centers.

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

## When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on December 1, 2120 or when the research project ends, whichever is earlier.

## Will access to my medical record be limited during the study?

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

_____ _____

Signature of Participant Date

------OR---------

_____ _____
Signature of Legally Authorized Representative Date

_____
Description of Representative's Authority to Act for Subject

## FINANCIAL CONSIDERATIONS

**Payment**
You will get $50 for visits with infusions or OGTTs, and $25 for visits to have your PPD read and to get blood drawn for a glucose check. In addition to this, we will pay for your minor travel or parking costs.

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive payment.

**Costs**
There is no cost to you for participating in this study, but you should consider other potential costs. These include the personal time it will take to come to all of the study visits.

The study will pay for those services, supplies, procedures, and care associated with this study that are not a part of your routine medical care. If you would like to review the list of such covered services, supplies, procedures and care, please tell us now or at any time during the study.

Participation in this study is not a substitute for health insurance. You and/or your health insurance must pay for those services, supplies, procedures, and care that you require during this study for routine medical care. **You will be responsible for any co-payments and/or deductibles as required by your insurance.**

**Sponsor**
This study is sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), with additional sponsorship of the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Child Health and Human Development (NICHD), and the National Center for Research Resources (NCRR). Other support is from the Juvenile Diabetes Research Foundation and the American Diabetes

Association. Bristol Myers Squibb will donate the abatacept being used in the study and may pay for some of the study's costs.
The National Institutes of Health are providing some financial support for the facility and staff where part or all of the study is taking place.

## COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

## CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Darrell Wilson, MD, at 650-723-5791. You should also contact him any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, MC 5579, Palo Alto, CA 94304.

Appointment Contact: If you need to change your appointment, please contact Trudy Esrey, RD, at 650-498-4450.

Alternate Contact: If you cannot reach the Protocol Director, please contact the research team at 650-725-6577.

## EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

Signing your name means you agree to be in this study and that you were given a copy of this consent form.

_____ _____
Signature of Adult Participant Date

------OR-------

_____ _____
Signature of LAR (Parent, Guardian or Conservator) Date

_____
Authority to act for participant

_____ _____
(If available) Signature of Other Parent or Guardian Date

_____
Authority to act for participant

*The IRB determined that the permission of one parent is sufficient for research to be conducted under 21 CFR 50.52, in accordance with 21 CFR 50.55.*

_____ _____
Signature of Person Obtaining Consent Date

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

_____ _____
Signature of witness Date

(e.g., staff, translator/interpreter, family member, or other person who speaks both English and the participant's language)

- Translated short form must be signed and dated by both the participant (or their LAR) and the witness.
- The English consent form (summary form) must be signed by the witness and the POC. The non-English speaking participant does not sign the English consent.
- The non-English speaking participant should not sign the HIPAA participant line