Please check one of the following:

_____ You are an adult subject in this study.

_____ You are the parent or guardian granting consent for a minor in this study.

Print minor's name here:

_____

The following information applies to the individual or to his/her minor child. If the subject is a minor, use of "you" refers to "your child".

Are you participating in any other research studies? _____ yes _____no

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a human subject you have the following rights. These rights include but are not limited to the subject'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 rise;
- 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- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;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.

PURPOSE OF RESEARCH

You are being asked to take part in this research study because you have developed type 1 diabetes within the last 3 months. 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 a research group called TrialNet that is studying type I diabetes. These investigators are testing a medication, rituximab (Rituxan), as a possible treatment for people with newly diagnosed type 1 diabetes. Rituximab is approved by the U.S. Food and Drug Administration for the treatment of a blood condition called lymphoma. The use of rituximab for treating Type 1 diabetes is experimental (not an FDA approved indication).

The goal of this study is to learn if rituximab could also help people with newly diagnosed type 1 diabetes by delaying or stopping further destruction of beta cells. We will follow people in the study by performing blood tests and will collect information about their diabetes management to learn whether rituximab works when given to people with newly diagnosed type 1 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.

Your participation in this study is entirely voluntary.

Your decision whether or not to participate will not prejudice you or your medical care. If you decide to participate, you are **free to withdraw** your consent, and to discontinue participation at any time without prejudice to you or effect on your medical care. If you decide to terminate your participation in this study, you should notify Darrell Wilson, MD at (650) 723-5791.

This international research study is looking for 66 people with newly diagnosed Type 1 Diabetes. Stanford University expects to enroll 10 to 15 research study subjects.

DURATION OF STUDY INVOLVEMENT

For this study, you will have four treatment visits and twelve additional visits over the next two years. At the end of two years, you may be asked to come in every six months for an additional two years. These four additional visits are to help us understand how long the effects of the rituximab will last. Thus the entire study will take approximately 4 years.

PROCEDURES

If you chose to participate, Dr. Wilson and his research study staff will ask questions about your health, periodically perform a physical exam and take blood for testing. Females will also give regular urine samples to be checked for pregnancy. The tests will help us learn about your diabetes control, your immune system, and your general health. In some cases, we will take additional blood (up to 2 tablespoons) to make sure that test results performed by TrialNet laboratories are accurate. The total amount of blood drawn for tests done at each visit will not exceed 13 tablespoons and will be safe for your age and weight. More information about the specific blood tests can be found in the research volunteer handbook.

At the first treatment visit, you will be randomly assigned (like drawing straws) into either a group that gets the rituximab or a placebo group. A placebo looks like medicine, but has no medicine in it so that people in the study will not know whether they are receiving rituximab or not. You will have a 2 out of 3 chance of getting the medicine and a 1 out of 3 chance of getting the placebo. Neither you nor the researchers will know who is getting rituximab and who is getting the placebo.

After you are assigned to a study group, you will receive four separate doses of either the rituximab or the placebo through a vein in your arm. You will need to come to the study site to receive each dose once a week for four weeks. Each visit will take 3-8 hours. While you are receiving the rituximab or placebo, we will frequently check your temperature, heart rate, and blood pressure.

Other study procedures:

- Mixed Meal Tolerance Test (MMTT)

You will have an MMTT 5 times during the study to find out how much insulin your pancreas is still making. Before each MMTT, you will get special instructions about diet and insulin dosing. To make the blood sampling easier for the test, an intravenous needle and plastic tube (called an IV) will be placed in your vein. The IV will be kept in place during the test. Two blood samples taken ten minutes apart (one teaspoon of blood for each sample) will be drawn through

the IV. You will then be given a drink called Boost, the "mixed meal". This drink will raise your blood sugar and cause your body to produce insulin. After drinking Boost, one-half teaspoon of blood will be taken through the IV at regular intervals for 2 hours for most of the visits, or 4 hours for the visits at the end of 1 and 2 years. The total amount of blood taken for the MMTT will not be greater than 2 tablespoons for the two-hour test and 3 tablespoons for the 4-hour test.

- Immunizations

The following immunizations are part of the study so that we can learn about how rituximab could affect the response to vaccines.

- **Tetanus/diphtheria vaccine:** If you have previously had a tetanus immunization, you will receive a tetanus/diphtheria booster immunization at least one year after you receive rituximab or placebo. It is an injection into a muscle of your arm or leg.

- **Hepatitis A vaccine:** If you have never had a hepatitis A vaccine before, you will receive two hepatitis A immunizations. The first immunization will be at least a year after you receive rituximab or placebo and the second will be at least six months later. It is given as an injection beneath your skin.

- **PhiX174 vaccine:** This part of the study is optional. The purpose is to see how your immune system responds after being treated with rituximab. Your body has never been immunized to this protein before. With your permission the phiX174 will be given through a plastic tube (IV) in your vein on two occasions during the first year, and on two occasions during the second year. In addition, there will be up to six additional visits for blood tests during the first year and again during the second year (some of these visits can be done locally if you prefer).

- Other Medications You Will Receive

You will get two commonly used medicines, acetaminophen (*Tylenol*) and diphenhydramine *(Benadryl*) before each dose of the rituximab or placebo. These are given to lower the risk of any side effects that rituximab could cause. (see list below)

- Diabetes Care

If you decide to be in this study, you will receive what is called "intensive management" of your diabetes. The goal of this type of treatment is to keep your blood sugar as close to normal as possible. This will require you to take enough daily insulin injections to meet this goal. You could also be on an insulin pump instead of injections. During the study you will need to check your blood sugar levels frequently, and report them as often as once every two weeks to the study team. Your research study team will work with your personal diabetes health care team to keep your diabetes under good control.

OPTIONAL BLOOD SAMPLES FOR STORAGE

With your permission, we would like to store remaining samples of your blood. Your blood samples will be stored indefinitely. Your blood samples will be used to help us learn more about what causes type 1 diabetes and how to treat it better. They also could help us learn more about type 1 diabetes, its complications (such as eye, nerve, and kidney damage) and other conditions for which people with diabetes are at increased risk. With your permission, your blood samples will be stored at a TrialNet laboratory or a place that is maintained for research purposes by the National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK). Your samples will not have your name or any other identifying information that could link them with you. You will not get any test results from tests that are done on the stored samples.

As long as TrialNet continues, your stored blood samples could be used by TrialNet researchers and researchers from outside of TrialNet. However, if researchers from outside of TrialNet want to use your samples, they must first get permission from TrialNet researchers and the study sponsor, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). As long as TrialNet continues, you can have your stored blood samples destroyed at any time if you wish. However, once TrialNet is over, your samples cannot be destroyed because they will no longer be identified as belonging to you.

When TrialNet is over, your blood samples will continue to be stored under the control and protection of the NIDDK. Researchers will not be able to use your samples without the permission of the NIDDK. You should understand that you can still be in this study without allowing us to store your blood for further testing.

Any tissues you have donated 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 tissues do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests, or discoveries.

SUBJECT'S RESPONSIBILITIES

You should:

- 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.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

While participating in this research study, you should not take part in any other research project without approval from all of the Protocol Directors. This is to protect you from possible injury arising from such things as extra blood drawing, extra x-rays, the possible interaction(s) of research drugs, or other similar hazards.

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. You will be told of any new findings that affect your being in this study.

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

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

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

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.

Rituximab

There can be risks from drugs like rituximab because they lower the activity of the immune system. In addition, there can be other risks from these kinds of drugs that are not related to their immune effects.

Risks of rituximab from its effects on the immune system:

There may be increased infections or reappearance of previous infections. Very rarely these infections could be severe or even fatal. Even though the drug is given only during the first month of the study, the effects on the immune system may last approximately one year. Because you could be at risk for an infection from taking rituximab, you should take certain safety measures. You should contact your physician as soon as possible if you get a fever, nausea/vomiting, sore throat, swollen glands, cold sores, or experience major changes in vision, loss of balance, or have feelings of disorientation or confusion. We will also check for infections during your visits.

There can also be an increased risk of cancer, especially if the immune system is heavily suppressed for many years. In this study, you will take a medication that will suppress the immune system for approximately 1 year. There are no reports of increased cases of cancer in people treated in this way. However, we recommend that women in the study who could become pregnant have a regular exam and Pap smear each year as part of their regular medical care.

You should also know that rituximab can cause vaccines to not work as well anymore. You may need to have these vaccines again to make sure you do not get sick. We will test the level of your body's response to immunizations during the study.

Other effects of Rituximab:

Common Side Effects: Rituximab can commonly cause side effects that occur while it is being given. These side effects can be severe and are called infusion-related reactions. These reactions can include fever and chills, a change in blood pressure, skin rash and itching. Other side effects that have been seen when rituximab is given include flushing, nausea, vomiting, tiredness, and headache, cold-like symptoms, the feeling of tongue or throat swelling, and trouble breathing, including shortness of breath. If these side effects occur, they usually happen between 30 minutes to 2 hours after the start of the rituximab being given.

For your safety, we will watch you closely for these events. For example, you will have your blood pressure, heart rate, and temperature taken regularly while you are receiving the rituximab. If you have any of these problems, we may slow down, pause, or even stop the

infusion. Your study doctor may also give you additional medicines to treat these symptoms (Tylenol and Benadryl).

Rare Side Effects: In some rare cases (about 1 in 1,000), very serious side effects such as chest pain or abnormal heartbeat may occur. Even less commonly (1 out of 10,000), the infusion related reactions can cause severe or fatal side effects such as disorders of blood vessels, severe shortness of breath, eye inflammation, skin rashes, and fluid build up or swelling.

Other side effects that you may have after the visit include decreased red blood cells (anemia) or decreased blood cells that help blood to clot (platelets), flu-like symptoms, joint pain, decreased appetite and a general feeling of tiredness.

Birth control and pregnancy

It is not known whether rituximab can damage fetuses. If you are pregnant, you cannot be in the study because we do not know the risks to the fetus . For this reason it is important that you do not become pregnant for at least 1 year after receiving rituximab. If you could become pregnant, you must agree to use a reliable form of effective birth control for the two years of the study. Women will need to provide a urine sample for pregnancy testing regularly during the study. If you do become pregnant during the study, you must tell the study doctor right away.

Immunizations

All immunizations have a small risk of allergic reactions that can be severe. If you had a severe reaction to tetanus/diphtheria vaccine before, you will not be given that immunization during this study. 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 with the phiX vaccine. All effects are usually mild and go away without treatment. It is not known what effect rituximab may have on vaccines. We are studying this possible interaction as part of this protocol. Therefore, if you need any vaccinations, you should get them at least one month before, or one year after, receiving the study medication.

Intravenous Needle (IV) and Blood Drawing

While in the study, you may be at risk for side effects from having your blood taken or an 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. Rarely, 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.

Mixed Meal Tolerance Test (MMTT)
The use of Boost during this test has no known side effects, but you may not like the taste of Boost.

POTENTIAL BENEFITS

If you decide to take part in this study, there is no guarantee that your health will improve. It is hoped that the rituximab will help the body to continue to make insulin, but there is no guarantee that this will happen. Studies have shown that people who continue to make insulin have less trouble with low blood sugar and less complications from their diabetes than people who no longer make their own insulin. Even if these medicines can protect the insulin producing cells that are left, you will still need to take insulin shots. Since there are no current treatments that preserve the body's ability to make insulin, we don't know if this benefit will occur.

The vaccinations you could receive may improve your immune system's protection against tetanus/diphtheria and hepatitis A.

We will follow your health and diabetes closely.

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 preserve beta cells and the ability to make insulin for people with type 1 diabetes. There may be other research studies that you can choose to be in.

SUBJECT'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 still receive care for your disease and will not lose any benefits to which you would otherwise be entitled.

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.

CONFIDENTIALITY

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. TrialNet researchers may review all your health records and collect study information (data) as needed for the purposes of this research study. The sponsor of this study (NIDDK) and the Food and Drug Administration (FDA) may also review your study and medical records as necessary.

Information from your research records will be sent to our central coordinating center at The George Washington University for statistical analysis. No personal information that directly identifies you will be included with this data. Personal information is information such as your name that directly identifies you. Instead you will be assigned a unique study code. The key to the code, linking your personal information to you, will be kept in a locked file here at Stanford University. Only Darrell Wilson, MD, and his study staff at Stanford University, will have access to the key to the code. After the study is completed, the study data may be placed in a government information bank and may become available to researchers under the supervision of the NIDDK/NIH. Your privacy will be protected whenever this information is used.

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, if you wish.

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 U.S. 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, employees of the

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.

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

Authorization To Use Your Health Information For Research Purposes

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 rituximab could help people with newly diagnosed type 1 diabetes by delaying or stopping further destruction of beta cells. Information from your research records will be sent to our central coordinating center at The George Washington University for statistical analysis. After the study is completed, the study data may be placed in a government information bank and may become available to researchers under the supervision of the NIDDK/NIH.

Do I have sign to 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, please contact: Darrell Wilson, MD, at (650) 723-5791.

What Personal Information will be 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 all information in a medical record, certain information indicating or relating to a particular medical condition, blood and other tissue samples and related records, physical examinations, x-rays, MRI's, etc.

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.

- Other members of the TrialNet Study team at Stanford University

Who May Receive / 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, as well as 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 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 expire December 31, 2105.

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

medical or billing decision about you (e.g., if included in your official medical record).

_____
Signature of Subject

_____
Signature of Legally Authorized Representative

_____
Date

_____
Description of Representative's Authority to Act for Subject

FINANCIAL CONSIDERATIONS

PAYMENT

If you decide to be in this study you will receive $25 or $50 for each study visit that you complete ($50 for MMTT or Rituximab injection visits, and $25 for all other visits). Also, you will be paid for minor travel and/or parking costs. Legally, you can be paid only if you are a US citizen, a legal resident alien (e.g., possess a "green" card), or have a work eligible visa sponsored by the paying institution.

COSTS

There is no cost to you for participating in this research study. There will be no charge for the visits, tests, or drugs required by the study. You and/or your insurance company will be responsible for all other costs related to your usual medical care (eg. insulin, needles, monitoring equipment, etc.).

SPONSOR

The National Institutes of Diabetes and Digestive and Kidney Diseases (NIDDK) is providing major support for this study. The study is also paid for by National Institute for Allergy and Infectious Diseases (NIAID), the National Institute for Child Health and Human Development

(NICHD), the National Center for Research Resources (NCRR), the Juvenile Diabetes Research Foundation (JDRF), and the American Diabetes Association (ADA). Genentech will donate the rituximab and the placebo for this study and arrange for performance of study related tests on coded samples. Roche Diagnostics will provide the blood glucose meters and monitoring strips for the study.

CONTACT INFORMATION

- Appointment Contact: If you need to change your appointment, please contact Alison Rigby toll free at (877) 232-5182.

- 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. You may contact him/her now or later, Darrell Wilson, MD, at (650) 723-5791.

- Emergency Contact: If you feel you have been **hurt by being a part of this study**, or need immediate assistance please contact the page operator at (650) 497-8000 and ask for the "Pediatric Endocrinologist on Call".

- Alternate Contact: If you cannot reach the Protocol Director, please page the research team at (650) 723-8222, pager # 1-8187.

- Independent of the Research Team Contact: If you are not satisfied with the manner in which this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a research study subject, please contact the Stanford Institutional Review Board (IRB) to speak to an informed individual who is independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. Or write the Stanford IRB, Administrative Panels Office, Stanford University, Stanford, CA 94305-5401. In addition, please call the Stanford IRB at (650)-723-5244 or toll free at 1-866-680-2906 if you wish to speak to someone other than the research team or if you cannot reach the research team.

COMPENSATION

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 but this study does not provide financial assistance for additional medical or other costs. Additionally, Stanford is not responsible for research and medical care by other institutions or personnel participating in this study. You do not waive any liability rights for personal injury by signing this form.

Stored Samples:

Please indicate whether you are willing to provide blood samples for blood storage. These blood samples could be used to help us learn more about what causes type 1 diabetes and how to treat it better. These samples could also be used to help us learn more about type 1 diabetes, its complications (such as eye, nerve and kidney problems) and other conditions for which people with type 1 diabetes are at higher risk. Even if you decide not to have blood samples stored, you can still be in this study.

I give permission to have my blood stored: (check one below and initial)

☐ *Yes, store all samples including the genetic samples ____ Initials*

☐ *Yes, store all samples but <u>not</u> the genetic samples ____ Initials*

☐ *No, I do not give permission to have any samples stored ____ Initials*

PhiX immunization course:

Please mark whether you agree to get the PhiX immunization shots and tests. These tests will help us learn about the effects of Rituximab on vaccines. As explained above, this will require two doses of this protein given through an IV during the first year, and another two doses given again during the second year. You will have to come to the study center for these treatments. In addition, there will be up to six additional visits for blood tests during the first year and again during the second year. You can come to the study site for these blood tests or you can have this done locally at a place that is easier for you. Because it is more work for you to have these tests done, you will get paid an extra $50 for every extra shot and $25 every time extra blood is taken for these PhiX immunization studies. Even if you decide not to get the PhiX immunization you can still be in this study.

☐ *YES, I agree to get the PhiX immunization course _____ initials*

☐ *NO, I do not want the PhiX immunization course _____ initials*

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

_____ _____
Signature of Subject Date

_____
Social Security #

_____ _____
Signature of Legally Authorized Representative Date

_____
Description of Representative's Authority to Act for Subject

Person Obtaining Consent

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the subject has been provided with the Experimental Subject's Bill of Rights, if appropriate, that I have discussed the research project with the subject and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the subject to ask questions and that all questions asked were answered.

_____ _____
Signature of Person Obtaining Consent Date