

STANFORD UNIVERSITY Research Consent Form

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Approval Date: May 7, 2013

Expiration Date: May 7, 2014

Protocol Director: Darrell Wilson, MD

Protocol Title: Type 1 Diabetes TrialNet Protocol TN-10, Anti-CD3 mAb (Teplizumab) for Prevention of Diabetes in Relatives At-Risk for Type 1 Diabetes Mellitus (Follow-up Consent)

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

INTRODUCTION TO RESEARCH STUDIES

A research study is designed to answer specific questions, sometimes about a drug's or device's safety and effectiveness. Being in a research study is different from being a patient. When you are a patient, you and your doctor have a great deal of freedom in making decisions about your health care. When you are a research participant, the Protocol Director and the research staff will follow the rules of the research study (protocol) as closely as possible, without compromising your health.

PURPOSE OF RESEARCH

You (you means you or your child) are being asked to take part in the follow-up phase of the TrialNet Anti CD3 (Teplizumab) trial for prevention of diabetes in relatives at-risk for Type 1 Diabetes Mellitus. You have already been assigned to a treatment group and have completed the initial two week treatment phase of the study. This phase of the study is being done to monitor you for possible development of type 1 diabetes and to find out if the study treatment helps to delay or prevent onset of the disease.

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

Participant ID:



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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 1 diabetes. These investigators are testing a medication called teplizumab to see if this treatment will delay or prevent the onset of type 1 diabetes. Teplizumab is an investigational drug. It has been tested in clinical trials for 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 this part of 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 your medical care. 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 internationally for 140 to 170 participants with increased risk of developing type 1 diabetes. Stanford University expects to enroll 15-25 research study participants.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 4 - 6 years, depending upon rate of enrollment and number of subjects who develop diabetes.

PROCEDURES

There will be follow-up visits at 1 week, 6 weeks, 3 months, 6 months and then every six months thereafter. Starting with the 3 month visit, all visits will include an Oral Glucose Tolerance Test (OGTT). There will also be additional blood tests to check for the possible development of type 1 diabetes and to monitor your overall health. Even if you develop type 1 diabetes, we may continue to follow you to learn more about how the study drug works, to see if it helps to maintain insulin, and to look for possible side-effects of the study drug.



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During study visits we will ask questions about your health, diet and activity, and experience as a research participant in the follow-up phase of the study. We will periodically perform a physical examination and take blood for testing. Females will also give regular urine samples to be checked for pregnancy. We will draw some blood for testing autoantibodies (proteins that attack your insulin-producing cells) and HbA1c (a test that measures a person's average blood glucose level for the last 2-3 months). The tests will help us check for diabetes, your immune system, and your general health. 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. More information about the specific blood tests can be found in the research volunteer handbook.

The exact duration of the study is not known. We anticipate that your participation will be no longer than 5-6 years.

Other study procedures:**• Oral Glucose Tolerance Test (OGTT):**

The OGTT test is done after an overnight fast (not eating during the night). This test is done to measure the level of glucose (sugar) in the blood after you drink a sweet liquid that contains glucose over a 5-minute period. To make taking the blood 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 several times after you have finished drinking it. The entire test will take about 2 hours.

• EKG:

You will have an EKG test when you have completed one year of follow-up in the study. The test is done to check for abnormalities in heart rhythm. It is done by placing sensors on your wrists, ankles, and chest for a few minutes (it does not hurt).

• Monitoring for Possible Diagnosis of Type 1 Diabetes:

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.



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Blood Samples for Storage

With your permission, we will store remaining samples of your blood, including genetic material, for possible use after TrialNet is over. Your blood samples will be stored indefinitely. These blood samples may be used to help us learn more about what causes type 1 diabetes and how to treat it better. They may also be used to 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. 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 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.

Stored Samples:

Please indicate whether you are willing to allow remaining blood samples to be stored after TrialNet is over, including DNA samples. These blood samples could be used to help researchers learn more about what causes type 1 diabetes and how to treat it better. These samples could also be used to help them 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. You can still be in this study even if you decide not to have your remaining blood samples stored.

I give permission to have my remaining blood samples stored: (check one below)

- Yes, store any remaining blood samples including DNA ____ Initials*
- Yes, store any remaining blood samples but not DNA ____ Initials*
- No, I do not give permission to have my remaining blood samples stored ____ Initials*



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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.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Following the instructions of the Protocol Director and study staff.
- Taking the study drug as instructed.
- Keeping 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.
- Telling the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Telling the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Asking questions as you think of them.
- Telling 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 the Protocol Directors of each study. This



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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

Participation in this study is voluntary. You can withdraw your consent at any time. If you choose to stop being in the study, tell a study staff member. Your current or future care will not be any different if you decide not to be in this study or to stop being in this study at any time. Your doctor may choose to take you out of the study at any time, even without your consent. You will be told of any new findings that may 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 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

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

Common Side Effects:

These side-effects are more likely to occur during the treatment phase and not at follow-up visits. However, it is possible that some of these symptoms could occur following the treatment phase.

Effects on Blood Cells:

Teplizumab can have effects on different types of blood cells. There may be changes in your blood counts that occur after the treatment phase. Thus far all of the blood cell abnormalities that have occurred from the drug in previous studies were reversible.



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- **Low White Cells (*lymphopenia and/or neutropenia*):** It is expected that teplizumab will cause an initial reduction in the number of white blood cells that help to fight infections. About 95% of subjects developed low lymphocyte counts and about 47% developed low neutrophil counts. If the white blood cells remain low you may be at increased risk of infection. However, the levels of white blood cells tend to recover even while the drug is still being given over the two weeks.
- **Anemia (decreased hemoglobin/low red blood cells):** 50% of participants in previous studies had decreased red blood cells. A low red blood cell count might make you feel tired.

Changes in Liver Function: Short term and generally mild changes in liver function tests have occurred in about 45% of subjects, which resolved after discontinuation of treatment. Your liver function tests will be tested before infusions to make sure that the drug is not given if they are abnormal.

Skin Rash: You may develop a skin rash on your face, neck, body, hands, or feet. This usually resolves quickly, but can result in peeling of the skin (40-60% subjects treated with drug have experienced rashes). Occasionally it could take several weeks for the rash to subside.

Antibody Response: Your body may react to the teplizumab as if the drug is a foreign substance that does not belong to your body. If this happens, your body will develop specific proteins called antibodies that can block the teplizumab. Antibodies to the study drug have been detected in up to 50% patients given teplizumab in previous studies. The effects of developing these antibodies are not known. However, if your body makes these antibodies it could limit your response to teplizumab or a related drug if you were to receive the drug in the future.

Whether or not you develop antibodies to the study drug, having received teplizumab may be a consideration as to whether you will be able to enroll in future studies with this or related drugs.

Less Common Effects:

- **Low Platelets (*thrombocytopenia*):** Less than 21% of subjects in previous studies developed low platelet counts (cells that help blood to clot). If platelet counts become very low you may be at an increased risk of bleeding. This risk will be lessened by reviewing platelet counts prior to treatment.



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- **Sustained Low White Blood Cells:** In one individual (of over 400 who have received the drug) a low white blood cell count lasted a long time - up to two years before returning to normal. However, this person received a dose of teplizumab that is higher than the dose in this study. There were no severe infections when the white cell count was low.
- **Severe Liver Function Abnormality:** Rarely there can be a severe abnormality in liver function tests.

Immunizations:

It is not known what effect teplizumab may have on vaccines. Therefore, any vaccinations with a live virus (i.e., live flu shot, varicella, MMR,) that you may need should not be given 8 weeks before, or one year after, receiving the study medication because it may not be safe. Any vaccination with a killed virus (i.e., inactive flu shot) should not be given 4 weeks before, or 4 weeks after receiving the study medication because it may not be effective. If you need any vaccinations, be sure to discuss this with your study doctor.

Effects on Immune System:

Even though the drug is given only during the first two weeks of the study for prevention of diabetes, it is possible that the drug may have other effects on the immune system that last longer. In people that receive teplizumab there is a potential risk of more infections. Please refer to the research volunteer handbook about taking precautions to prevent infections especially during the first month of the study. For your safety, you will be monitored for certain infections (i.e. EBV- the virus that causes mononucleosis). You should contact your physician as soon as possible if you get a fever, nausea/vomiting, sore throat, swollen glands, or cold sores.

Medications like teplizumab that alter responses by the immune system can possibly lead to an increased risk of certain types of cancer. The risk of cancer is unknown but is thought to be very small. An increase in the rate of cancer has not been seen in previous studies of people given teplizumab.

Birth Control and Pregnancy

The safety of teplizumab taken during pregnancy is not known. If you are pregnant or are providing breast milk to your baby, you cannot be in the study because we do not know the risks. For this reason it is important that you do not become pregnant for at least 1 year after receiving teplizumab. 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. It is unknown whether teplizumab affects sperm. It is also unknown whether teplizumab affects the babies of women who become pregnant from men in the study. If you are a male, you should not impregnate a woman for at least 1 year



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after receiving teplizumab. While you are in the study, you will be required to use effective birth control. More information about effective birth control options can be found in the research volunteer handbook.

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.

POTENTIAL BENEFITS

If you decide to take part in this study, there is no guarantee that the drug will delay or prevent type 1 diabetes. It is hoped that the teplizumab will help to maintain the cells that make insulin, but there is no guarantee that this will happen.

We will monitor your health closely and if you do develop type 1 diabetes, it is possible you will be able to start on insulin treatment before you develop symptoms of the disease.

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 at risk of developing type 1 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.



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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 consent to be in this study includes consent for the TrialNet researchers to review all your health records as needed for the purposes of this study. Your consent gives TrialNet researchers permission to collect study information (data) related to this study and to use it for research purposes. Your research records could be shared between TrialNet sites during the study. Your consent also includes permission for the sponsor of this study (NIDDK), MacroGenics, Inc, the Food and Drug Administration (FDA) and other applicable regulatory authorities to review your study records.

Information from your research records will be sent to our central coordinating center at the University of South Florida 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 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.

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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 other applicable authorities or TrialNet may review or ask for a copy of your study records. If this happens, we will provide your records. Also, 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.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

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

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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 teplizumab could help people at high risk of developing type 1 diabetes by delaying or stopping the destruction of beta cells. Blood tests will be performed to monitor the effects of teplizumab 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



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Stanford University Medical Center, Dept. of Pediatric Endocrinology, 300 Pasteur Dr, Room G-313, Stanford, CA 94305-5208.

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, information relating to a particular medical condition, specific blood tests, specific physical examination measures, specific x-rays or MRI imaging information.

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, and 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.



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When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on June 30, 2110, 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

Signature of Legally Authorized Representative

Date

Description of Representative's Authority to Act for Subject

Participant ID:



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FINANCIAL CONSIDERATIONS

Payment

If you decide to be in this study you will receive \$50 for each study visit that you complete. Also, we will pay for minor travel and/or parking costs. By signing this consent form, you understand and agree that, if this research project results in the development of any product that can be sold, you will not receive a share of any money that is made.

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa.

Costs

There is no cost to you for being in this study. There will be no charge for the visits, tests, or drugs required by the study.

Sponsor

This study is sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), with additional sponsorship by 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. MacroGenics Inc. will donate the teplizumab and the placebo for this study and provide some additional support.

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



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you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

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.

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) 723-6807. You should also contact him at 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(650) 498-4450 or toll free at (877) 232-5182.

Alternate Contact: If you cannot reach the Protocol Director, please page the research team at (650) 723-8222, pager # 1-8220.

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;

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- 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.

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 Adult Participant

Date

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 two parents is required for research to be conducted under 21 CFR 50.52, in accordance with 21 CFR 50.55 unless one parent is deceased, unknown, incompetent, not reasonably available, or only one parent has legal responsibility for the care and custody of the child. Not reasonably available means that the other parent is not present during the

Participant ID:



STUDY

Protocol Director: Darrell Wilson, MD

Protocol Title: Type 1 Diabetes TrialNet Protocol TN-10, Anti-CD3 mAb (Teplizumab) for Prevention of Diabetes in Relatives At-Risk for Type 1 Diabetes Mellitus (Follow-up Consent)

consenting process, or will not be available prior to the start of research procedures.

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

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

Participant ID: _____

