

STANFORD UNIVERSITY Research Consent Form

Protocol Director: Dr. Darrell Wilson

IRB Use Only

Approval Date: 03/26/2012

Expiration Date: 2/28/2013

Protocol Title: **TrialNet Natural History Study of the Development of Type 1 Diabetes: SCREENING** IRB# 13922

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

INTRODUCTION TO RESEARCH STUDIES

A research study is designed to answer specific questions, sometimes about a drug or device's safety and its effectiveness. Being in a research study is different from being a patient. When you are a patient, you and your personal doctor have a great deal of freedom in making decisions about your health care. When you are a research subject, 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 are invited to participate in a research study called the TrialNet Natural History Study of the Development of Type 1 Diabetes. TrialNet is a research group dedicated to the study, prevention, and early treatment of type 1 diabetes (T1D). This study will help us learn more about how type 1 diabetes occurs. You were selected as a possible subject in this study because you have a relative with type 1 diabetes.

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.

The study is divided into two parts : Screening and Monitoring. This consent form is only for the Screening part of the study. During screening, you will be tested for diabetes related autoantibodies

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in the blood. Autoantibodies are proteins that are made by the body's immune system. If these proteins are present, it could mean that cells in the pancreas that produce insulin are damaged. Certain kinds of autoantibodies can be found in the blood years before type 1 diabetes occurs. Several different kinds of autoantibodies can be seen. About 3-4% of relatives of people with type 1 diabetes will have autoantibodies (for example, 3 to 4 people out of every 100). If you are found to have autoantibodies, you will qualify for the monitoring part of the study. Blood tests will be performed in order to find out more about your risk for type 1 diabetes. There will be a separate consent form, which explains more about this part of the study. This consent form is only for screening only.

DURATION OF STUDY INVOLVEMENT

The screening part of this research study is expected to take only a few minutes to complete the screening forms and to have your blood drawn. If you are found to have autoantibodies, you will qualify for the Monitoring part of the study. This would require an initial risk assessment visit, then one visit every 6 months to a year, depending on the assessed risk, for at least five years or until the end of the study.

PROCEDURES

To be screened for diabetes related autoantibodies, you will need to give a blood sample. If at least one autoantibody is present on the first sample, you will need to give a second blood sample on a different day. The reason for the second sample is to help us be more sure that autoantibodies are truly present. We will take up to 1 tablespoon of blood from your vein for each of the samples. After we have obtained your blood sample it will be shipped to a TrialNet core laboratory where it will be tested for the autoantibodies. You will learn whether you have autoantibodies that increase your risk of developing type 1 diabetes. We will also ask you to provide basic demographic information (birth date, age, gender, and ethnicity) about yourself and your family history of diabetes.

The blood specimen will be forwarded to a laboratory to measure the levels of antibodies. We will then inform you of the test results. You will learn whether you have autoantibodies that indicate you have an increased risk of getting T1D.

A member of the TrialNet research team will contact you if you have one or more autoantibodies present in the blood (you are positive). You will be asked to return for a repeat blood test to confirm the presence of autoantibodies. They can also answer any questions that you may have. Testing positive does not mean that you will get type 1 diabetes. It means that your chances are greater than if your test showed that you did not have autoantibodies. If we do not find autoantibodies in your blood (you are negative), you will receive these results by letter. Testing negative for autoantibodies

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does not mean you will never get diabetes, although the chances are much lower than if you tested positive. It is still possible that you could develop autoantibodies in the future. For this reason, we will offer to test you each year until you turn 18.

We may ask some people who are negative for antibodies to be in the monitoring part of the study so that we can compare their results with people who are positive.

Whether you have autoantibodies or not, we will plan to contact you in the future to ask about your health or ask you to provide additional blood samples to help us learn more about type 1 diabetes.

BLOOD SAMPLES FOR UNDERSTANDING TYPE 1 DIABETES:

An important part of this study is 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 on-going, your remaining blood samples will be used only by approved TrialNet researchers. You will not routinely be provided with test results from these studies.

Storage of Samples in NIDDK Repository

When TrialNet is over, we intend to put any remaining 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

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. 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 sample(s) 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

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TISSUE SAMPLING FOR GENETIC TESTING, OTHER TESTING, OR BANKING FOR FUTURE RESEARCH

1. Introduction.

Research using tissues (blood, cells, tissues or body fluids) is an important way to try to understand human disease and/or the role genes play in disease. You have been given this consent form because the investigators want to include your tissues in a research project, or because they want to save such samples for research. There are several things you should know before allowing your tissues to be studied:

2. Subject Identification.

Your tissues will be stored under another unique identifier. Your name or other public identifiers will not be included with any data shared with other investigators.

3. Risks.

By genetic research, we mean research that studies the characteristics, genes, gene versions that are transmitted by parents to offspring. This may include many types of information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and/ or family medical histories, reactions to medication, and responses to treatment.

Disease testing and genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety and other psychological distress. 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. 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. Donation of tissues for these research purposes is not genetic testing. (However, if you are interested in such clinical testing or genetic counseling, you should contact your physician.)

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4. Reporting Results To a Subject.

At the completion of the study the staff will discuss with you whatever results are available with respect to your participation in the study. Any new information developed during the course of the study that may affect your participation in this study will be provided to you.

5. Right to Withdraw.

You have the right to refuse to allow your tissues to be studied now or saved for future study. You may withdraw from this study at any time. The investigators might retain the identified samples, e.g., as part of your routine clinical care, but not for additional research.

6. Completion of Your Research.

With your permission, your blood samples will be stored for a number of years, but we can't say for how long.

7. Follow Up Contacts.

Investigators in this study may try to re-contact you in the future. If you are re-contacted and want to know what the investigators have learned about your tissue samples, you should understand the following possibilities:

Information may be too sketchy to give you particular details or consequences.

You may be determined to carry a gene for a particular disease that can be treated. You may be determined to carry a gene for a particular disease for which there is no current treatment.

You carry a gene for a disease and might consider informing relatives that they, too, might carry the gene. Genetic counselors can help sort out the various options in such a case.

8. Use in Commercial Development of Products.

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

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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:

- 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

If you first agree to participate and then you change your mind, you are **free to withdraw** your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

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).

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- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

You could have discomfort and/or a bruise when you get your blood drawn. Once in a while, some people may faint. It is rare, but some people may get an infection, a small blood clot, swelling of the vein and surrounding tissue, or bleeding where the needle enters the skin. If you learn that you are at greater risk for diabetes, it could make you worry. If you are very worried, we can offer a referral for counseling. Money to pay for counseling will not be provided.

POTENTIAL BENEFITS

There is no guarantee that you will benefit from this study. If you were to develop diabetes, it is possible it would be found sooner and decrease the chance of sickness and hospitalization. This study may also increase knowledge about the prevention of type 1 diabetes.

WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.

ALTERNATIVES

An alternative to your participation in this study is your decision not to participate.

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 if any new information is learned which may affect your condition or influence your

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willingness to continue participation in this study.

CONFIDENTIALITY

You must give consent in order to participate in this study. 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. Your consent also includes permission for the sponsor of this study (NIDDK) and the Food and Drug Administration (FDA) to review your study records..

Personal information is information such as your name that directly identifies you. This personal information will be maintained in a database at the central TrialNet Coordinating Center at the University of South Florida. Your personal information will be kept separate from the data obtained in this study.

Upon entry into this study you will be assigned a unique study code number. All information obtained from this study will be identified with your unique study number, and will not be kept with your name. Data from examinations and procedures collected for purposes of this study will be sent to the central TrialNet Coordinating Center at the University of South Florida.

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

You have the right to refuse to allow your blood to be studied now or saved for future study. You may withdraw from this study at any time. The investigators might retain the identified samples, e.g., as part of your routine clinical care, but not for additional research.

A Certificate of Confidentiality has been obtained from 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 disclose information that can be used to identify you. For example, we cannot be forced to disclose identifying information to insurance companies. Also, we cannot be forced to disclose 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. Please understand that we will maintain the confidentiality of your research record, but we cannot guarantee the confidentiality of test results provided to you if you wish to share them with anyone.

There are some rare exceptions to the protection offered by the Certificate of Confidentiality. TrialNet

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researchers are not prevented from disclosing matters such as child abuse, certain infectious diseases, or threatened violence to yourself or others.

TrialNet researchers will consider your records private. Rarely the 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 you 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.

INVITATION FOR QUESTIONS

You are encouraged to ask any questions you may have about the study. The staff of the research program will be happy to discuss any questions with you. If you wish, the staff will discuss with you the test results when available.

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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 specific purpose of the TrialNet Natural History Study of the Development of Type 1 Diabetes is to learn more about how type 1 diabetes occurs. TrialNet researchers will review all your medical records as may be necessary for the purposes of this study. Information from your research records will be sent to our central coordinating center at the University of South Florida 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 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. 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

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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, (Phone (650) 723-5791).

What Information Will Be Used or Disclosed?

Your health information related to this study, including, but not limited to all medical information collected from or about the subject in connection with this study. The results of blood samples and related records, physical examinations, x-rays, MRI's, etc, may be used or disclosed in connection with this research study.

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 M Wilson

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, here at Stanford University and at the other 15 study sites and data collection centers.

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

The TrialNet Coordinating Center at the University of South Florida

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Other members of the TrialNet team at the other study sites.

Your information may be redisclosed if the recipients described above 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 continue until September 13th, 2103.

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

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There will be no direct cost to you to participate in the study.

PAYMENT

No financial compensation is available for being in this study. This means that no payment will be given to you for being in this part of the study. If this research project results in a product that can be sold, you will not receive a share of money that is made.

SPONSOR

This study is sponsored by the National Institutes of Health (NIH), primarily the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Other support is from the Juvenile Diabetes Research Foundation and the American Diabetes Association.

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 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, Stanford, CA 94305-5401.

Appointment Contact: If you need to change your appointment, please contact Trudy Esrey or any other TrialNet Study Coordinator at 877-232-5182.

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

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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.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

Persons who participate in a medical experiment are entitled to certain 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 subjects, 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;
- 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.

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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

OR

*Signature of Legally Authorized Representative
(e.g., parent(s), legal guardian or conservator)*

Date

Description of Representative's Authority to Act for Subject

Person Obtaining Consent

The IRB determined that the permission of one parent is sufficient for research to be conducted under 45 CFR 46.404, in accordance with 45 CFR 46.408(b).

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the participant has been provided with the Experimental Subject's Bill of Rights, if appropriate, that I have discussed the research project with the participant 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 participant to ask questions and that all questions asked were answered.

Signature of Person Obtaining Consent

Date

Print Name of Person Obtaining Consent