Pathway to Prevention Study

Screening: Adult Consent and Parental Permission

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Study Location: Stanford University
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Stanford CA 94305-5208
650-723-5791

PURPOSE:
You (you means you or your child) are being asked to be in a research study called the TrialNet Pathway to Prevention Study. TrialNet is a research group dedicated to the study, prevention, and early treatment of type 1 diabetes. Type 1 diabetes is now understood as a disease that develops over time in stages. Stage 1 starts with the appearance of two or more autoantibodies. This is followed by Stage 2, which is the development of abnormal blood glucose levels. Stage 3 is the diagnosis of type 1 diabetes. This study will help us learn more about how type 1 diabetes occurs and provides monitoring to individuals at risk. In addition, the study will help us identify people who may be eligible for prevention trials.

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 in the blood. Autoantibodies are proteins that are made by the body's immune system. If autoantibodies are present, it could mean that cells in the pancreas which produce insulin are damaged. Certain kinds of autoantibodies can be found in the blood years before type 1 diabetes occurs.

If the Screening blood tests show that you have autoantibodies, we will invite you to participate in the Monitoring part of the study. We will then ask you to sign a separate consent form which explains more about this part of the study.

PROCEDURES:
We will ask you to provide information about yourself and your family history of diabetes. You will have a blood test to test for diabetes-related autoantibodies. The blood test can be done by placing a needle into a vein in your arm. We will take up to 1 tablespoon of blood at each screening visit.
You can also be screened by pricking your finger tip to collect about ½ teaspoon of blood (10 drops). If it is not possible to collect enough blood from your fingertip, you may need to repeat the test with a regular blood draw.

If you are positive for autoantibodies you will be contacted by a member of the TrialNet research team and may be invited to participate in the monitoring phase of the study. If we do not find autoantibodies in your blood (you are negative), you will receive results by letter or secure electronic communication. Testing negative for autoantibodies does not mean you will never get diabetes, but the chances are much lower than if you tested positive. It is still possible that you could develop autoantibodies in the future. Whether you have autoantibodies or not, we may contact participants younger than 18 in the future to be re-screened, or to ask about your health.

**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. TrialNet is an ongoing diabetes research study that could last for many years. While TrialNet is ongoing, your remaining blood samples will be used only by TrialNet approved researchers. You will not routinely be provided with test results from these studies.

**RISKS:**
You could have discomfort and/or a bruise when you get your blood drawn from your arm or your fingertip. When having 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 the blood sample was collected from your fingertip, it is possible that you will be unable to collect enough blood or that the sample cannot be used for testing. In this case you will need to come to a study site for a regular blood test to obtain blood from your vein.

If you learn that you are at greater risk for diabetes, it could make you worry. If you are very worried, we will offer a referral for counseling. Money to pay for counseling will not be provided.

**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.

**ALTERNATIVES:**
You can choose not to participate in this study.

**SOURCE OF FUNDING:**
This study is supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health and JDRF.
**COST TO SUBJECT:**
There will be no cost to you to participate in the study.

**SUBJECT PAYMENT:**
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.

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

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

**CONFIDENTIALITY:**
Your consent to be in this study gives the TrialNet researchers permission to collect personal information about you and to use it for research purposes. Personal information is information such as your name that directly identifies you. This personal information will be kept in a database at the central TrialNet Coordinating Center at the University of South Florida.

This information may be shared with TrialNet centers and affiliates and the TrialNet Clinical Hub, as needed and in accordance with country-specific guidelines, to help with the study. Your consent also includes permission for the sponsor of this study (NIDDK) and the Food and Drug Administration (FDA) to review your study records.

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

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

TrialNet researchers will consider your records private. Rarely, representatives of the United States Department of Health and Human Services (DHHS) or TrialNet may review or ask for a copy of your study records. If this happens, we will provide your records. Also, 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.
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will collect your personal and medical information such as:

- Past and present medical records with your permission
- Research records and results
- Your contact information
- Records about your study visits and contact with your study team

Who may use and give out information about you?
The study doctor and the study staff may use and share this information.

Who might get this information?
Your PHI may be used by and shared with the following groups of people during the conduct of this research:

- The medical staff that takes care of you and those who are part of this research study;
- TrialNet research sites and study teams involved in this research;
- Any laboratories, pharmacies, or others who are part of this research study;
- The sponsor(s) of this research;
- The data and safety monitoring board or others who monitor the data and safety of the study;
- The TrialNet Clinical Hub at the Benaroya Research Institute in Seattle, Washington;
- The TrialNet Coordinating Center at the University of South Florida

Your information may also be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- The University of Miami Institutional Review Board (IRB) and the offices of Research Compliance & Quality Assurance (RCQA) at the University of Miami

Why will this information be used and/or given to others?
- to do the research,
• to study the results, and
• to see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

**What if I decide not to give permission to use and give out my health information?**

Then you will not be able to be in this research study.

**May I review or copy my information?**

Yes, but only after the research is over.

**May I withdraw or revoke (cancel) my permission?**

Your authorization for the use and/or disclosure of your health information will continue until September 13th, 2103, or when the research project ends, whichever is earlier.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor Dr. Darrell Wilson at G313 Med Center MC 5208, Stanford CA 94305. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

**Is my health information protected after it has been given to others?**

Once the information is shared with others, it may no longer be protected by the HIPAA Privacy Rule.

__________________________________________
Signature of Subject

__________________________________________
Signature of Legally Authorized Representative

__________________________________________
Date

__________________________________________
Description of Representative's Authority to Act for Subject
STUDY WITHDRAWAL:
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.

INVITATION FOR QUESTIONS:
You are encouraged to ask any questions you may have about the study. In the event of a research related injury, you should contact one of the investigators immediately (phone 650 723 5791). If you have any questions about your rights as a research subject, you may 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, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

The TrialNet Study Group has a central Institutional Review Board (CIRB) at the University of Miami, which oversees the scientific conduct of the study. If you have any questions about your rights as a research subject, you may contact the Human Subjects Research Office at (305) 243-9977.

Additional Information:
A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

PATHWAY to PREVENTION SCREENING AUTHORIZATION:

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.

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

Are you willing to allow us to put any remaining blood samples in the NIDDK repository?

☐ YES  ☐ NO
SIGNATURES: By signing this consent form, you agree that you have read this informed consent form and that the study has been explained to you. You also agree that your questions have been answered and that you agree to be in this study. You do not give up any of your legal rights by signing this informed consent form. You will receive a copy of this consent form.

I have read this paper about the study or it was read to me. I know what will happen, both the possible benefits and the possible risks. I choose to be (or to have my child) in this study. I know I can stop being in the study at any time, and I will still get the usual medical care. I will get a copy of this consent form.

Participant
Print Name of participant: ______________________________________

Signature of participant (age 12 or older): ____________________________

Date of participant’s signature: _________________________________________

Parent or guardian (if subject < age 18)
Print Name of parent or guardian: __________________________________

Signature of parent or guardian: ________________________________

Date of parent’s or guardian’s signature: ______________________________

Consent obtained by:
Print name of researcher: _________________________________________

Signature of researcher: __________________________________________

Date of researcher’s signature:____________________________________

EXPERIMENTAL SUBJECT’S BILL OF RIGHTS

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

• be informed of the nature and purpose of the experiment;

• be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;

• be given a description of any attendant discomforts and risks reasonably to be expected;
• be given an explanation of any benefits to the subject reasonably to be expected, if applicable;

• be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;

• be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;

• be given an opportunity to ask questions concerning the experiment or the procedures involved;

• be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;

• be given a copy of the signed and dated consent form; and

• be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.