



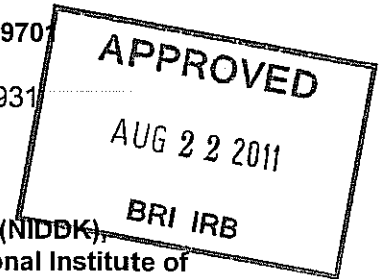
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**TrialNet Natural History Study of the Development of Type 1 Diabetes  
Phase 1: Screening for Diabetes Related Autoantibodies  
Consent to Participate in a Research Study**

IR Number: 10102

VM/BRI Acct. Number(s): 1920, 32970

PRINCIPAL INVESTIGATOR: Carla Greenbaum, MD (206) 342-6931



SPONSOR(S): National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Child Health and Human Development (NICHD), National Center for Research Resources (NCRR) American Diabetes Association (ADA), and Juvenile Diabetes Research Foundation (JDRF).

24-hour emergency number: (206) 264-4322, ask for Dr. Carla Greenbaum.

**PARTICIPANT'S NAME:** \_\_\_\_\_

This is a type of medical research study. Research studies include only patients who choose to take part. Please take your time to make your decision. Discuss it with your friends and family.

You are being asked to take part in this study because you have a family member with type 1 diabetes. This particular research in humans is designed by a consortium of medical research facilities and regulated by the NIH (National Institutes of Health).

The following is a summary of the information you were given when this study was discussed with you. Please read it and ask any questions you may have.

**WHY IS THIS STUDY BEING DONE?**

You (you means you or your child) are being asked to be 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. This study will help us learn more about how type 1 diabetes occurs.

The study is divided into three phases: Screening (Phase 1), Baseline Risk Assessment (Phase 2), and Follow-Up Risk Assessments (Phase 3). This consent form is only for Screening (Phase 1). 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 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.

If the Phase 1 blood tests show that you have autoantibodies, we will ask you to participate in Phase 2 and Phase 3. There are separate consent forms for Phase 2 and Phase 3, which explain each of those phases in detail.

### **HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

Our goal is to screen as many people as possible at this site, and we hope to screen 100,000 nationally at all sites.

### **WHAT IS INVOLVED IN THE STUDY?**

You will need to give a blood sample. We will ask you to provide information about yourself. We will take up to 1 tablespoon of blood at each visit. In a small number of individuals eighteen years of age or older, we will take an extra sample of blood of up to 2 teaspoons. These extra samples will be used to help us make sure that the test results are accurate.

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.

If we do not find autoantibodies in your blood (you are negative), you will receive results by letter. Testing negative for autoantibodies does not mean you will never get diabetes. 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 recommend that you are tested each year until you reach age 18.

Whether you have autoantibodies or not, we plan to contact you in the future. We would like to know if you ever develop type 1 diabetes and to inform you about other research studies.

### **HOW LONG WILL I BE IN THE STUDY?**

The length of your participation in Phase 1 will depend upon the results of your antibody tests. If you are under age 18 and your antibody tests are negative, you will be invited back yearly until your 18<sup>th</sup> birthday. If you are over 18 and your antibody tests are negative, you will not be rescreened.

### **WHAT ARE THE RISKS OF THE STUDY?**

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 at the needle puncture site. If you are found to have autoantibodies, it could make it more difficult for you to get or keep health insurance. There will be protections to keep information about you confidential. 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.

### **ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**

No benefit can be promised to you from being in this study. If you were to develop diabetes, it is possible it would be found sooner. The TrialNet research program might increase knowledge about the prevention of type 1 diabetes in the future.

### **WHAT OTHER OPTIONS ARE THERE?**

You can choose not to participate in this study.

### **WHAT ABOUT CONFIDENTIALITY?**

Your consent to be in this study gives the TrialNet researchers permission to collect personal information about you and to use and share it for research purposes indefinitely. Your consent also includes permission for the sponsors of this study and the Food and Drug Administration (FDA) to review your study records. If you change your mind about us using or sharing your personal information, you need to let us know. However, the information you already gave us may continue to be used if needed for study or

regulation purposes. Also, if you do change your mind about allowing us to use or share your information, you may no longer be able to participate in this research study.

Personal information is information that directly identifies you. This personal information is provided by you to the TrialNet researchers. It includes your name, your contact information, your date of birth, family history of diabetes, and your Social Security Number, if you elect to provide it. This personal information will be kept at the participating TrialNet clinical site and in a database at the central TrialNet Coordinating Center at the University of South Florida.

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

Even though the information we collect about you for this study will not be kept with your name, there will still be a way to link your code to your name. This will only be done if it is necessary to contact you, if we have important information to share. Your name will not be linked to your code without the approval of the NIH.

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 NIH. Once this happens, it will no longer be possible to link your code to your name or other personal identifying information

If you were previously screened for the Diabetes Prevention Trial – Type 1 Diabetes Study (DPT-1), we will obtain data on your DPT-1 test results. By participating in this study, you are also giving permission for TrialNet researchers to use your data from the DPT-1 study.

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. This 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 Benaroya Research Institute 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.

#### **WHAT ARE THE COSTS?**

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

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.

If you get injured because of this study, the study team will offer medical care. Money to pay for injuries is not normally provided. Money is not available for things like lost wages, disability, or discomfort due to injury.



**PATIENT'S AUTHORIZATION**

I have read and understand this consent form and agree to take part in this study. By signing this form I do not give up my rights, if any, which may be available to me by law. My signature also indicates that I have been given a copy of this consent form.

\_\_\_\_\_  
PARTICIPANT SIGNATURE  
(or legally authorized representative)

\_\_\_\_\_  
PARTICIPANT'S NAME (Print)

\_\_\_\_\_  
DATE

\_\_\_\_\_  
PARENT/LEGAL GUARDIAN'S SIGNATURE  
(for patients less than 18 years old)

\_\_\_\_\_  
DATE

**CERTIFICATE OF PERSON OBTAINING CONSENT:**

I have provided an explanation of the above research study, and have encouraged the patient to ask questions and request additional information regarding the study and possible alternatives. A copy of this consent form has been given to the patient.

\_\_\_\_\_  
SIGNATURE OF PERSON OBTAINING CONSENT

\_\_\_\_\_  
NAME OF PERSON OBTAINING  
CONSENT (print)

\_\_\_\_\_  
DATE

\_\_\_\_\_  
(206) 264-4322 ask for Dr. Carla Greenbaum  
EMERGENCY PHONE NUMBER

\_\_\_\_\_  
BRI at VM  
RESEARCH SITE

**BENAROYA RESEARCH INSTITUTE AT VIRGINIA MASON (BRI)  
VIRGINIA MASON MEDICAL CENTER (VMMC)  
INVESTIGATIONAL STUDY PARTICIPANTS  
BILL OF RIGHTS**

The rights below are the rights of every person who is asked to be in a research study. As an investigational study participant, you have the following rights:

1. To be told what the study (research) is trying to find out.
2. To be told what will happen to you and whether any of the procedures, drugs, or devices is different from what would be in standard practice.
3. To be told about the frequency and/or important risks, side effects or discomforts of the things that will happen to you for research purposes.
4. To be told if you can expect any benefit from participating and, if so, what the benefit might be.
5. To be told the other choices you have and how they may be better or worse than being in the study.
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study.
7. To be told what sort of medical treatment is available if any complications arise.
8. To refuse to participate at all, or to change your mind about participation after the study has started. This decision will not affect your right to receive the care you would receive if you were not in the study.
9. To receive a copy of the signed and dated consent form.
10. To be free of pressure when considering whether you wish to agree to participate in the study.
11. To be informed of any researcher's financial interest in the study.

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If you have other questions, you should ask the researcher (doctor). In addition, you may contact the Institutional Review Board, which is concerned with protection of volunteers in research projects. You may reach the committee office by calling (206) 342-6916, or by writing the Institutional Review Board, BRI, 1201 Ninth Avenue, Seattle, Washington 98101-2795.