TrialNet Type 1 Diabetes Pathway To Prevention Study

Consent Form

The following pages contain the CONSENT form for participation in the TrialNet Type 1 Diabetes *Pathway To Prevention* Study.

All screening participants age 18+ must complete and sign this form.

Parents/legal guardians of screening participants under the age of 18 must complete and sign this form. Screening participants between the ages of 7 and17 must complete and sign the ASSSENT form.

Please contact the Naomi Berrie Diabetes Center at (212) 851-5425 with any questions.

Thank you!

Columbia University Medical Center Consent Form

Attached to Protocol: IRB-AAAA3272
Principal Investigator: Robin Goland (rsg2)
IRB Protocol Title: TrialNet Type 1 Diabetes Pathways to Prevention Study

Consent Number: **CF-AAAM3761**
Participation Duration: 10 yrs
Anticipated Number of Subjects: 4000

Contact

Contact	Title	Contact Type	Numbers
Ellen Greenberg	Sr Staff Assoc	Study Coordinator	Telephone: 212 851-5425
Mary Gallagher	Assistant Professor	Co-Investigator	Telephone: 212-851-5492
Robin Goland	Irving Assoc Prof At Ph	Principal Investigator	Telephone: 212-851-5492
Rachelle Gandica	Pediatric Endocrinology Fellow	Co-Investigator	Telephone: (212)305-6559

Research Purpose

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 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 immune system. If these proteins 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 ask 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.

Information on Research

PROCEDURES:

We will ask you to provide information about yourself and your family history of diabetes. We will take up to 1 tablespoon of blood at each visit to test for diabetes related autoantibodies. 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 then be asked to return for a repeat blood test to confirm the presence of autoantibodies.

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, but 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 may 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 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.

Blood samples for storage:

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 NIDDK to use samples from the repository.

In order to participate in this study subjects' residual samples will be stored for future TrialNet research while TrialNet is ongoing as described above in the section "Blood Samples for Understanding Type 1 Diabetes"

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 (please

initial yes or no)?

_____YES _____NO

Funding: This study is sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), with additional sponsorship of 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.

Risks

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.

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.ture.

Alternative Procedures

You can choose not to participate in this study.

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. 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 kept in a database at the central TrialNet Coordinating Center at The University of South Florida. It will be kept separate from study information obtained during this study.

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. This study information will not be kept with your name. 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 NIDDK.

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

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 your 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 the Naomi Berrie Diabetes Center/Columbia University Medical Center 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.

Research Related Injuries

If you get injured because of this study, medical care will be made available. This medical care will be through the study investigators and staff. Money to pay for injuries is not normally provided. It is not available for things like lost wages, disability, or discomfort due to injury.

Compensation

No financial compensation is available for being in this study. This means that no payment will be given. There will be no expense to you for any of the test procedures or visits required by your participation in this study. By signing this consent form, you acknowledge and agree that there are no plans to compensate you in the event that this research project results in the development of any marketable product.

Additional 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.

Voluntary Participation

Participation in this study is completely voluntary. You are free to withdraw your consent at any time. This means that you are free to stop being in this study at any time. Your current or future care will not be any different if you decide not to be in this study or stop being in this study at any time. You may request at any time to have any of your stored samples destroyed to the extent possible. As long as TrialNet continues, you can have your stored blood sample(s) destroyed at any time if you wish. However, once TrialNet is over, your sample(s) cannot be destroyed, since they can no longer be identified as belonging to you.

Additional Information

You are encouraged to ask any and all questions which come to your mind 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. In the event of a research related injury, you should contact Dr. Goland immediately at 212-851-5492. If you have any questions about your rights as a research subject, you may contact: Institutional Review Board, Columbia University Medical Center, 722 West 168th street, 4th Floor, New York, NY 10032 Telephone: (212) 305-5883. The Institutional Review Board is a committee organized to protect the rights and welfare of human Subjects involved in research.

NATURAL HISTORY 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 (please initial yes or no)?

_____YES _____NO

We are planning to ask a small number of people who test negative for autoantibodies to return for testing of autoantibodies and other tests once a year for five years or until the end of the study. These people will be selected randomly (by chance) and would need to sign another consent form before they could participate. If you are not found to have autoantibodies, would you be willing to participate further in the Natural History Study?

_____YES _____NO _____INITIALS

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 good and bad (benefits and 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. (Initial all the previous pages of the consent form.)

Signature

Study Subject
Print Name_____Signature_____Date_____

Person Obtaining Consent

Print Name_____Signature_____Date_____