



MODEL INFORMED CONSENT

TrialNet Natural History Study of the Development of Type 1 Diabetes:

MONITORING

PARTICIPANT'S NAME: _____

PURPOSE:

You (you means you or your child) are being asked to continue as a research volunteer in the TrialNet Natural History Study of the Development of Type 1 Diabetes. As you know, TrialNet is an international research group dedicated to the study, prevention and early treatment of type 1 diabetes. The study will help us learn more about how type 1 diabetes occurs. In addition, the study will help us identify people who may be eligible for prevention trials.

You recently participated in TrialNet Natural History Screening. If you were found to have autoantibodies in Screening you may be more likely to develop type 1 diabetes than other people. The Monitoring part of the TrialNet Natural History Study offers follow-up visits for people who are at risk for type 1 diabetes. We are also asking some people without autoantibodies to take part in Monitoring to help us better understand differences between people with and without autoantibodies over time.

PROCEDURES:

Annual Monitoring for those with Autoantibodies at Screening

Individuals with one autoantibody will have an Oral Glucose Tolerance Test (OGTT) and HbA1c at the first monitoring visit to determine their monitoring plan. If these results confirm you are at a lower 5-year risk for diabetes, you will have Annual Monitoring.

Annual monitoring visits include testing for autoantibodies and HbA1c. If your HbA1c increases or you develop two or more autoantibodies you will be asked to come for Semi-Annual Monitoring so that you can be followed more closely for possible progression towards type 1 diabetes.

We will ask about your health, current medications and ask you questions about your diet and activity at each annual visit.

Semi-Annual Monitoring for those with Autoantibodies at Screening

Individuals in this group have a higher 5-year risk of diabetes. They will be asked to come in for Semi-Annual Monitoring. This includes individuals found to have two or more autoantibodies during Screening. It also includes individuals with one autoantibody and other test results that indicate a higher 5-year risk of diabetes at the first monitoring visit.

Semi-annual Monitoring visits include blood tests for autoantibodies, HbA1c, as well as an (OGTT).

At each visit, we will ask about your health and current medications. Once a year we will ask you questions about your diet and activity.

Annual Monitoring for those without Autoantibodies: Some individuals without autoantibodies during screening will undergo annual testing for autoantibodies, HbA1c, as well as an OGTT. If you develop autoantibodies, you will change to the Annual or Semi-annual monitoring schedule as outlined above.

These tests are described here:

- **Oral Glucose Tolerance Test (OGTT)**

After an overnight fast (not eating during the night), you will have an OGTT. 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. We will measure your height and weight. To make taking the blood easier, we will place an intravenous needle and plastic tube (IV) in a vein in your arm. Blood samples will be drawn through the IV before you drink the liquid and then at several times after you have finished drinking it. The entire test will take about 2 1/2 hours.

- **Autoantibody Test**

This test looks to see if you have diabetes-related autoantibodies in your blood. Autoantibodies are proteins that are made by the body's immune system. They are a sign that the cells in the pancreas that produce insulin could be damaged. These proteins can be found in the blood years before a person develops type 1 diabetes.

- **HbA1c Test**

This blood test measures a person's average blood glucose level for last 2-3 months before the test.

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, these samples will be used only by TrialNet approved researchers. As such, we will be collecting blood samples including genetic samples for these studies at most of your visits. You will not routinely be provided with test results from these studies.

All together, the studies in the Annual Monitoring and Semi-Annual Monitoring visits will require about 1/3 cup of blood in adults. For those under age 18, we will not take more than is safe for your age and weight.

In addition, we may occasionally contact you to ask if you would be willing to donate blood again. This will be no more than six times a year. We will always tell you what we need and how much blood we expect to draw, and then let you decide if you are able to help us at that time. For adults the maximum amount of blood drawn for all tests combined will be about 2 cups of blood every 8 weeks. For those under age 18, we will take up to 1 tsp for every kg (2.2. pounds) of body weight. For example, the maximum amount for a child weighing 55 lbs will be ½ cup.

Additional Information

You will be offered the results of your OGTT, autoantibody and HbA1c testing after each visit. In some cases, we may ask you to repeat certain tests before your next routine study visit to see if you are eligible for a prevention study. If you decide to participate in a prevention trial, you will be asked to sign another consent form and you will not have any further visits as part of the Natural History Study. If you were to develop type 1 diabetes, you might qualify for research studies for people with new-onset type 1 diabetes. The data obtained from this study will be combined with data from any other TrialNet studies you might enter.

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 where the needle enters the skin. There are also some risks to the OGTT. Some people may feel nauseous when they have the OGTT. There will be protections in place to keep information about you confidential. If 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.

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 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.

COST TO SUBJECT:

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

SUBJECT PAYMENT:

You will receive a small amount of money for each study visit as well as for minor travel and/or parking costs. 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:

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.

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 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.

If you participate in this study, you will be given a unique study code number. It will identify the information and samples collected from you from study examinations and procedures. It 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.

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, for auditing purposes, employees of the *(institution's name)* _____ 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.

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.....). If you have any questions about your rights as a research subject, you may contact at phone.....

AUTHORIZATION:

Storage of Samples in NIDDK Repository

When TrialNet is over, we intend to put any remaining samples including genetic 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

Natural History Study Authorization

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: _____