



Welcome to Type 1 Diabetes TrialNet and **Phase 1 (Screening)** of the Natural History Study of the Development of Type 1 Diabetes. We appreciate your interest in our study.

WHAT IS TRIALNET?

TrialNet is a network of 18 clinical centers working in cooperation with screening sites throughout the United States, Canada, Finland, United Kingdom, Italy, Germany, Australia, and New Zealand. This network is dedicated to the study, prevention, and early treatment of type 1 diabetes. TrialNet is supported by the National Institutes of Health, which is part of the United States federal government. It is also supported by other major diabetes organizations.

WHAT IS THE NATURAL HISTORY STUDY?

The Natural History Study is part of the TrialNet Type 1 Diabetes studies. The goal of this study is to learn more about how type 1 diabetes develops in “at-risk” individuals. Close relatives of people with type 1 diabetes are being studied in three steps (phases): Screening, Baseline Risk Assessment, and Follow-Up Risk Assessments. Participants in the Natural History Study may be offered the opportunity to enter into prevention or early treatment studies when these become available.

The purpose of screening is to identify people at risk for developing type 1 diabetes. Individuals at greater risk may be offered the opportunity to continue on to other phases of the Natural History Study to receive close monitoring for the development of diabetes. They may also participate in studies testing new treatments to delay or prevent the onset of diabetes. If participants develop diabetes during the Natural History Study, they may be eligible to participate in studies aimed at slowing the progression of type 1 diabetes.

WHAT IS TYPE 1 DIABETES?

Type 1 diabetes is a life-long disease that occurs in both children and adults. It develops when the body attacks and destroys insulin-producing cells in the pancreas. Insulin is a hormone the body needs to use food for energy. Patients with type 1 diabetes

lose the ability to produce insulin and need to take insulin injections.

WHO IS AT RISK FOR TYPE 1 DIABETES?

TrialNet will screen relatives of people with type 1 diabetes because they have a 10 to 15 times greater risk for developing the disease than people with no family history.

WHO CAN PARTICIPATE IN THE NATURAL HISTORY STUDY?

To participate in Phase 1 of the Natural History Study, you must be:

- 1 to 45 years of age *and* have a brother, sister, child, or parent with type 1 diabetes, OR
- 1 to 20 years of age *and* have a cousin, aunt, uncle, niece, nephew, half-sibling, or grandparent with type 1 diabetes.

In general, your relative may have type 1 diabetes if they were diagnosed before age 40 and required insulin injections within a year of diagnosis.

WHAT IS THE SCREENING TEST?

The screening test is a blood test to see if you have autoantibodies associated with a risk of developing diabetes. Autoantibodies are a sign that your immune system may be attacking the insulin-producing cells in your pancreas. Autoantibodies are proteins made by the immune system. About 4% of family members of people with type 1 diabetes have autoantibodies. The presence of some autoantibodies indicates you may be at risk for developing type 1 diabetes.

To do the test, a small sample of blood is drawn from your arm. It is sent to the TrialNet central laboratory for analysis. You can have the blood sample drawn in a TrialNet clinic or you can have a test kit sent to you. You can then take this test kit to a local laboratory or your own physician to have your blood drawn.

You will be notified of your test results in one of two ways:

- By letter if the antibody test shows NO autoantibodies are present (**negative result**). Testing negative for autoantibodies does not mean you will never get diabetes. It does mean that the chances are much lower than if you tested positive. If you are under 18 years of age, you can be tested every year since antibody levels can change.
- By phone if autoantibodies are present (**positive result**). We will call you to discuss your results and future testing options. Testing positive does not mean that you will get type 1 diabetes. It means you have a greater chance than if you tested negative. You may return to the clinic for more tests to confirm these results. If the repeat tests indicate the presence of at least one of the same autoantibodies, you may have additional tests to determine your risk for developing diabetes.

Additional tests to further determine your risk of developing type 1 diabetes are done in **Phase 2 (Baseline Risk Assessment)** and will estimate your chances of developing type 1 diabetes over the next 5 years.

If you wish to continue the testing, you may participate in **Phase 3 (Follow-Up Risk Assessments)**. In Phase 3 you will be closely monitored for the development of type 1 diabetes.

You may also be offered enrollment in diabetes prevention studies as they become available. Individuals that develop type 1 diabetes while participating in the Natural History Study may be

offered enrollment in a TrialNet study to save your ability to produce insulin.

All of these study options (Phase 2 and 3, and diabetes prevention studies) would require that you visit a TrialNet clinical center or Affiliate clinic. You would not be able to have a test kit sent to you for testing at a local physician's office or laboratory as can be done in Phase 1.

HOW DO YOU GIVE CONSENT FOR THE AUTOANTIBODY TEST?

Before you have the autoantibody screening test, you will be asked to sign an "Informed Consent" form. This form gives your permission to take the test. Parents must give permission for children under 18 years of age to be tested. Although a representative of the study will speak to you about the study, it is important that you read the consent form carefully. If you have questions or concerns, you should contact your TrialNet health professional. If you participate in Phase 1, you are not required to participate in any other phase of the Natural History Study.

If you choose to participate in Baseline Risk Assessment (Phase 2) or Follow-Up Risk Assessments (Phase 3) of the study, we will ask you to sign a separate consent form for each phase. Even if you do not wish to take part in Phase 2 or Phase 3, we might contact you in the future by phone or mail to see if you are interested in taking part in another diabetes-related research study. We would also like to learn if you have developed type 1 diabetes.

You may also learn about TrialNet at www.DiabetesTrialNet.org

OTHER TRIALNET FACT SHEETS AVAILABLE INCLUDE:

- TrialNet Natural History Study, Phase 2: Baseline Risk Assessment
- TrialNet Natural History Study, Phase 3: Follow-Up Risk Assessments

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