**Vanderbilt University Institutional Review Board**
**Informed Consent Document for Research**

**Principal Investigator: William E. Russell, MD** **Revision Date: 13FEB2012**
**Study Title: TrialNet Natural History Study of the Development of Type One Diabetes (Screening)**
**Institution/Hospital: Vanderbilt Eskind Diabetes Clinic**

## Screening for Risk of Developing Type 1 Diabetes (T1D)

This informed consent is for children volunteers ages 13 to 17 and adult volunteers 18 to 45 years.

**Name of volunteer: _____ Age: _____ Date of Birth: _____**

The following is given to you to tell you about this diabetes research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. You will be given a copy of this consent form.

You do not have to be in this study. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told. Then you can decide whether or not you still want to be in this study.

### 1. What is the purpose of this study?

You are being asked to be in a research study called the TrialNet Natural History Study of the Development of Type 1 Diabetes (T1D). The goal of the TrialNet program is to research how to prevent T1D.

The purpose of this study is to learn more about how T1D occurs. Blood relatives of someone with diabetes are at greater risk for T1D than others. We are screening only close blood relatives of people with T1D. This includes brothers, sisters, parents, children, cousins, aunts, uncles, nieces, nephews and grandchildren of people with T1D.

The study is divided into two parts: Screening and Monitoring. This consent form is for Screening only. During Screening, you will be tested for diabetes-related autoantibodies in the blood. Autoantibodies are proteins made by the body's immune system. If these proteins are present, it could mean that cells in the pancreas that make insulin are damaged. Certain kinds of autoantibodies can be found in the blood years before T1D occurs.

If the screening blood tests show that you have autoantibodies, we will ask you to be in the monitoring part of the study. There is a separate consent form that explains the monitoring in detail.

### 2. What will happen and how long will you be in the study?

We are asking you to give a blood sample to be screened for autoantibodies. We will take up to 2 teaspoons of blood from your vein for each sample. In a few volunteers age 18 or older who weigh at least 110 pounds (50 kg), we will take an extra sample of blood up to 2 teaspoons. The extra samples will be used to make sure the test results are accurate. Your blood sample will be shipped to a TrialNet laboratory where it will be tested for the autoantibodies.

It will take about 6 to 8 weeks for you to learn if you have autoantibodies that may increase your risk of developing T1D.

If your tests show that you do not have autoantibodies, you should receive a letter in the mail.

If you are 18 or older, your blood is tested only one time if you don't have autoantibodies.

If you are under 18, we would like to check to see if your autoantibody levels change as you grow. We are asking you to sign this consent form for the initial testing and yearly retesting until your 18$^{th}$ birthday or until the study ends. It will be the same test each year. You may change your mind and withdraw your consent at any time.

If you have one or more autoantibodies present (meaning you are positive), the Vanderbilt TrialNet research team will notify you by phone or in person. If you have one autoantibody present, we are asking you to return for a repeat blood test to confirm the results. If you have two or more autoantibodies present, we will ask you to enter the Monitoring phase of the study. There is a separate consent form for the next phase of the study.

If you are 18 or older and have one autoantibody present on the first sample but not present on the second sample, we are asking you to come for repeat testing every year for two additional years. This consent form includes your permission for retesting if needed.

Your signature on this consent form allows ongoing consent for retesting autoantibodies as outlined above. However, you may withdraw your consent at any time.

We will ask you to give us basic information about yourself. This includes your date of birth, age, and ethnicity. You will also be asked to give your contact information.

If you have your 18th birthday during this phase of the study, you will need to sign a new consent. You can have any future samples destroyed that will be obtained during the study. Samples collected from earlier testing when your parents gave permission cannot be destroyed.

If you were previously screened for the DPT-1 study, we will obtain data on your DPT-1 test results. When you sign this consent form you are giving your permission for TrialNet researchers to use your data from the DPT-1 study.

The research team can also answer any questions you have. Testing positive does not mean that you will get T1D. It means that your chances may be greater than if your test showed that you did not have autoantibodies. Testing negative for autoantibodies does not mean you will never get diabetes. However, the chances may be lower than if you tested positive. It is still possible that you could develop antibodies in the future.

We will ask a small number of people who test negative for autoantibodies to return for testing of autoantibodies and other tests once a year for 5 years or until the study ends. We will randomly select people (by chance) and they would need to sign another consent form before participating.

**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. For this purpose, we will store any remaining blood from your blood samples already obtained for screening visits. While TrialNet is ongoing, these samples will be used only by TrialNet approved researchers. You will not routinely be provided with any test results from these studies. Your samples will be bar-coded and stored without your name or any other identifying information.

**If You Are Pregnant:** Pregnant women will only be enrolled for Screening. They will not be enrolled for Monitoring because the results of the tests may be altered by the effects of pregnancy hormones. Pregnant women are included during Screening because the results obtained from this study might be of benefit to both the mother and her fetus. While screening for diabetes is a standard part of the evaluation of pregnant women, if we find that you have antibodies against the insulin producing cells of your pancreas, we will notify you and ask you to bring this to the attention of your obstetrician or health care provider. They can then test or retest your blood for the presence of diabetes. If you are found to have diabetes during your pregnancy, early detection and treatment can reduce the health risks to both you and to your baby. The risks of untreated diabetes to infants include birth defects, excessive or retarded growth, and low blood glucose.

**3. Costs to you if you take part in this study:** There will be no cost to you for taking part in this study. The National Institutes of Health (NIH) provides the major funds for this study. The Juvenile Diabetes Research Foundation and The American Diabetes Association provide additional financial support.

**4. Side effects and risks that you can expect if you take part in this study:** There are some risks to having your blood drawn. Pain, redness, soreness, bruising, or rarely, infection may occur at the needle stick site. Rarely, some people faint.

You can decide if you want some numbing cream or spray on your skin so you will not feel the needle stick as much. The numbing cream or spray may make your skin have a change in skin color, but this is rare.

If you are found to have autoantibodies, it could make it harder for you to get health insurance or a job. There are protections in place to keep information about you private. Your stored samples and test results will be stored by a code and without your name.

If you are at greater risk for diabetes, it could make you worried. To reduce worry, we will explain the meaning of test results to you. If you are very worried, we will offer a referral for counseling. Money to pay for counseling will not be provided.

**5. Risks that are not known:** This study may include risks that are unknown at this time.

**6. Payment in case you are injured while in this study:** If you are injured because you are in this study, you can get reasonable, immediate, and necessary medical care for your injury at Vanderbilt without charge to you. There are no plans for Vanderbilt to pay for the costs of care beyond your injury, or to give you money for such injury.

**7. Good effects that might result from this study:** The benefits of this study to other people that might result are that we might eventually learn how to prevent T1D. The benefits you might get are that if you were to develop diabetes, it is possible it would be found sooner. Early recognition and treatment of T1D can prevent hospitalization and potential health complications. If diabetes is recognized in the early stages, you might qualify for research studies for those with new onset T1D. These studies test treatments that might help the pancreas to keep producing some insulin. If you are found to be at high risk for developing T1D, you might qualify for research studies that might delay or prevent the onset of T1D. We cannot promise a benefit to you for taking part in this study.

**8. Other treatments you could get if you decide not to be in this study:** You do not have to take part in this study. You have other options.

**9. Payments for your time spent taking part in this study or expenses:** You will not be paid for being screened in this study. The tests and procedures in this study will not cost you anything. If this research project results in a product that can be sold, you will not receive a share of money that is made.

**10. Reasons why the study doctor may take you out of this study:** The study doctor may take you out of the study if you have problems because of the study or if you cannot finish the study. If this happens, the study doctor or research nurse will tell you why.

**11. What will happen if you decide to stop being in this study?**
Participation in this study is completely voluntary. You are free to withdraw your consent and stop being in this study at any time. Your current or future care will not be any different whether or not you are in the study. If you decide to stop being in the study, please tell your study doctor or research nurse.

**12. Who to call for any questions or in case you are injured:** You are encouraged to ask questions 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 the test results when available. In the event of a research related injury, please contact one of the research staff immediately. Please call the Vanderbilt Eskind Diabetes TrialNet office at 615-936-8638 if you have any questions about this research study. If you are hurt by being in this study, please call 615-322-7842 or 615-322-5000 and ask the operator to page the pediatric diabetes doctor on-call and they will contact Dr. Russell.

For additional information about giving consent or to discuss your rights in this study, please call the Vanderbilt University Institutional Review Board (IRB) Office at (615) 322-2918 or toll free at (866) 224-8273.

**13. Confidentiality:** Your consent to be in this study gives TrialNet researchers permission to get 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 (USF) and in a secure data base in the Vanderbilt TrialNet Research Office. Only research staff at the USF TrialNet Coordinating Center and at the Vanderbilt TrialNet Research office that needs access to the data will have the secure access to your personal information. USF will keep personal information separate from study information obtained during this study. If you are in this study, you will have a unique study code number. It will identify your information from study examinations and procedures. Coded study information will be sent to the central TrialNet Coordinating Center at USF.

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. Please notify the study coordinator or the principal investigator if you would like to remove your name from our contact list. Your name will not be linked to your code without the approval of the NIDDK.

When TrialNet is over, 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.

Researchers who are not part of TrialNet may be allowed to use your stored blood samples for specific studies. However, they will not be able to learn if a sample belongs to you. After TrialNet is over, it will no longer be possible for any researcher to learn if a blood sample belongs to you.

A Certificate of Confidentiality has been obtained by the 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 out information about you to insurance companies. We also cannot be forced to give out any 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 mean that you cannot tell others if you wish. Please know that we will keep your research record private. We cannot guarantee the confidentiality of test results given to you if you share them with anyone.

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 could be required to give out information about you to the United States Department of Health and Human Services (DHHS). This would be done if requested by DHHS as required by the Federal Food, Drug, and Cosmetic Act.

TrialNet researchers 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 Vanderbilt 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 your results in any publication.

**14. Privacy of Protected Health Information:** All efforts, within reason, will be made to keep your personal information in your research record private, but total confidentiality cannot be guaranteed. PHI is your health information that is, or has been, gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. William E. Russell and his study team may share the results of your study and/or non-study linked lab tests, as well as portions of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University IRB, the NIDDK, and the TrialNet Coordinating Center. Federal privacy rules may not apply to these groups. They have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is over. At that time, the research data that has not been put in your medical record will be destroyed. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. William E. Russell in writing and let him know that you withdraw your consent. His mailing address is Vanderbilt Eskind Diabetes TrialNet Office, 8410 Medical Center East, South Tower, 1215 21st Avenue South, Nashville, TN 37232-8160. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment, or enrollment in any health plans or affect your ability to get benefits.

**NATURAL HISTORY – SCREENING AUTHORIZATION:**
**Storage of Samples in NIDDK Repository**
When TrialNet is over, we plan 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. 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 of your remaining de-identified 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.

Will you allow us to put any of your remaining blood samples in the NIDDK repository? (check yes or no and initial)

_____**YES** _____**NO** _____**Initials**

**SIGNATURES:**
***I have read this consent form or it was read to me. The research study has been explained to me. I know what will happen, both the benefits and the risks. I know I can stop being in this study at any time and that I will still get the***

***usual medical care. I will get a copy of this form. All of my questions have been answered. I freely and voluntarily choose to be in this study.***

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|---|---|---|
| **Signature of Volunteer** | **Printed Name of Volunteer** | **Date** |

***Consent obtained by:***

| | | |
|---|---|---|
| **Staff Signature** | **Printed Name and Title** | **Date** |