Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM- SCREENING

Protocol Title: **Natural History Study of the Development of Type 1 Diabetes**

Application No.: **NA_00073075**

Sponsor: **National institute of Diabetes and Digestive and Kidney Diseases (NIDDK)**

Principal Investigator: **Thomas Donner, MD**
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1. What you should know about this study:

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Please ask questions at any time about anything you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
- Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.
- If you have clinical tests done as part of this research study, a statement will be added to your medical record that you are in this research study. Results from any clinical tests you have will be included in your medical record. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- If children and adults can join this study, the word "you" in this consent form will refer to both you and your child.

2. Why is this research being done?

This research is being done to help us learn more about how type 1 diabetes occurs. In addition, the study will help us identify people who may be eligible for diabetes prevention trials.

The study is divided into two parts: Screening and Monitoring. During the 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 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.

How many people will be in this study?
Worldwide, about 200,000 persons will be screened. At Johns Hopkins, we plan to screen about 400 people.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

You will provide information about yourself and your family history of diabetes.

We will draw up to 1 tablespoon of blood to test for diabetes related antibodies. 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 (for participants who enter the study as minors). 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.

Future Contact
Whether you have autoantibodies or not, we would like your permission to 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.

Please initial your choice below:
_____ Yes, you may contact me in the future
_____ No, I do not want you to contact me about other studies

How long will you be in the study?
You will be in this study for the time it takes to draw your blood and to send you your results. You will also be contact periodically in the future to see whether you have developed type 1 diabetes.

Optional 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

4. What are the risks or discomforts 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 where the needle enters the skin.

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.

There is the risk that information about you may become known to people outside this study. There will be protections in place to keep information about you confidential. You will be given a unique study code number. It will identify the information collected from you from study examinations and procedures and will be sent to the central database at the 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.

5. Are there benefits to being in the study?

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.

6. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

No.

8. Will you be paid if you join this study?

No.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.
- If you leave the study early, Johns Hopkins may use or give out your health information that it already has if the information is needed for this study or any follow-up activities**.**

10. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You fail to follow instructions.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it already has if the information is needed for this study or any follow-up activities**.**

11. How will your privacy be protected?

Johns Hopkins has rules to protect information about you. Federal and state laws also protect your privacy.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and other details. Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Johns Hopkins may see or give out your information. These include people who review research studies, their staff, lawyers, or other Johns Hopkins staff. People outside of Johns Hopkins may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and NIDDK, the sponsor of the study. The results of this study may be published for scientific purposes. Your records and results will not be identified as belonging to you in any publication.

We cannot do this study without your permission to use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Hopkins who receive your information may not be covered by this promise. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee this.

The use and disclosure of your information has no time limit. You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

12. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses

- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

b. What do you do if you have questions about the study?
Call the principal investigator, Dr. Thomas Donner at 410-955-2908. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What happens to Data and Blood that are collected in the study?
Scientists at Johns Hopkins work to find the causes and cures of disease. The data and blood collected from you during this study are important to both this study and to future research.

If you join this study:

- You will not own the data, or the blood given by you to the investigators for this research.
- Both Johns Hopkins and any sponsor of this research may study your data and the blood collected from you.
- If data or blood are in a form that identifies you, Johns Hopkins may use them for future research only with your consent or IRB approval.
- If data or blood are in a form that we believe does not identify you, they may be shared with other academic medical centers, non-profit organizations, corporate sponsors and other commercial companies without your consent or IRB approval.
- You will not own any product or idea created by the researchers working on this study.
- You will not receive any financial benefit from the creation, use or sale of such a product or idea.

d. What are the Organizations that are part of Johns Hopkins?
Johns Hopkins includes the following:

- The Johns Hopkins University
- The Johns Hopkins Hospital
- Johns Hopkins Bayview Medical Center
- Howard County General Hospital
- Johns Hopkins Community Physicians.
- Suburban Hospital
- Sibley Memorial Hospital

13. Assent Statement

This research study has been explained to my child in my presence in language my child can understand. He/she has been encouraged to ask questions about the study now and at any time in the future.

14. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

_____

Signature of Participant Name (Printed) Date/Time

_____

Signature of Person Obtaining Consent Name (Printed) Date/Time

_____

Signature of Parent/Guardian Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; AND, IF APPROPRIATE A COPY OF THE CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS. IF THIS CONSENT FORM DOES NOT HAVE A JOHNS HOPKINS MEDICINE LOGO, DO NOT USE IT TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.