

MODEL INFORMED CONSENT FORM

[To be modified to meet requirements of Networks and Ethics Committees. Words in [brackets] are optional and sentences in italics are instructions. These should be deleted in the final version of this form. It is permissible to change the order of sentences or paragraphs. Other changes also may be permissible, but they should be discussed with the Network first. The final version of this form must be translated back into English and sent to the regional Network center.]

Type 1 Diabetes Genetics Consortium

**Sponsor: United States National Institutes of Health (NIH),
National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK)**

[Name of Local Institution]: _____

You are invited to participate in the Type 1 Diabetes Genetics Consortium. This is an international effort to identify genes that affect the risk of type 1 (or juvenile) diabetes. The researchers listed below are in charge of this study at this institution. Other staff will help or act for them, and they are working with other researchers around the country and the world who are also part of this study.

Before you can decide whether or not you should agree to join this study, you should learn about its risks and benefits. This is called informed consent. If you decide to join the study, you will sign this Informed Consent Form and you will have a copy to keep for your records.

PURPOSE OF THE GENETIC STUDY

Type 1 (or juvenile) diabetes is an important health problem that affects many people. Doctors know that genes (DNA) play a major role in type 1 diabetes. This means that the risk for developing type 1 diabetes can run in a family and be passed from parents to children. Recent advances in science allow doctors to study the genes in families of people with a disease to learn more about which genes affect the risk of the disease. This can help to develop better treatments or prevent health problems, which is why we are conducting this study. However, to do this, lots of different families are needed to provide samples of their blood to analyze their genes (DNA). More detailed information on this study is available on the web site: www.t1dgc.org.

DESCRIPTION OF THE STUDY

If you agree to be part of this study, we will take 3 to 5 tubes of blood (about 3 soup spoons [or 39 ml]) from your arm and process this sample so that DNA and other parts of your blood can be taken out, stored, and used for research. We will also ask you some questions about your health and your family. This is being done for our research purposes only. You will not learn anything through this research about yourself or your family members. *[Or: describe policy for reporting results.]*

With your permission, your blood samples and information will be stored by _____ *[specify local clinic]* and also sent to storage locations in _____ *[specify regional network storage]*

sites] and a central repository in the United States so they can be shared with other qualified researchers and companies worldwide to study the genetics of type 1 diabetes, its complications, and other autoimmune diseases. These researchers may or may not be part of this study. Because of the sensitive nature of genetic materials, guidelines described below have been developed to protect your privacy.

[Delete this sentence if there is a policy to report some results:] You will not receive any information from us after we take your blood sample. However, we might ask for your help in contacting your family members to participate in this study, and we might contact you again for permission to collect additional samples or information.

CONSENT TO PRODUCE A CELL LINE

To allow more researchers to work with your blood sample, we are requesting permission to produce and store a living cell line, which means we will keep some of your white blood cells alive for future research. If you agree, this will give researchers a large supply of DNA without needing to draw additional blood samples. We will allow other researchers to use your stored sample only to study type 1 diabetes, its complications, and other autoimmune diseases. [We will not do or allow any human cloning.]

OWNERSHIP AND RIGHT TO HAVE GENETIC MATERIAL DESTROYED

When you give your blood sample, you will no longer own it or the genetic materials we obtain from it. However, you have the right to request at any time that your blood sample and genetic materials be destroyed. Your request will be honored and we will tell you when your samples have been destroyed.

RISKS AND DISCOMFORTS

There are no major risks associated with drawing blood. Having your blood drawn can be uncomfortable, occasionally causes bruising, and, in rare cases, causes fainting. Only trained people will draw your blood. There is also a very small risk that some breach of confidentiality may occur. The specific protections put in place to prevent this are discussed in the confidentiality section of this form.

BENEFITS

There are no direct benefits to you from this study. By participating in this study, you may or may not help doctors develop better treatment or prevention for type 1 diabetes, its complications, and other autoimmune diseases. Throughout the study, research findings will be posted on the web site: www.t1dgc.com.

ALTERNATIVES AND RIGHT TO WITHDRAW FROM THE STUDY

Participating in this study is entirely up to you. You may refuse to participate or withdraw from the study at any time, and this will not affect your current or future health care or other benefits at *[Name of Institution]*.

CONFIDENTIALITY

We will keep all of your medical and genetic information confidential to the extent the law allows. However, we cannot guarantee absolute confidentiality. Information about you will not

be given to insurance companies, your employers, or be used for any purposes other than those described in this agreement. The information from this research will be made widely available to researchers, doctors, scientists and other people, but your identity will not be released.

Your blood and DNA samples and the information you give us will be stored in different places under a code number, without your name or other identifying information. However, we will still be able to identify you if we need to for research reasons.

Because other family members are participating in this study, it is possible that we may find out personal information that you or your relatives do not know or do not want others to know [(for example, that someone's biological father is not who they thought it was)]. If we discover this, we will not tell you or anyone in your family under any circumstances.

In some cases, people from the government agency that is paying for this research, the U.S. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), may need to see your records to verify study information, but they will not be told who you are. Also, the _____ [*name of institution Ethics Committee/IRB*] may have access to your records to ensure that your rights are being properly protected.

COSTS, COMPENSATION, AND TREATMENT

There is no charge to you for being in this study. You will also not receive any payment for being in this study. [Or: We will pay you \$____ to cover your travel or other expenses for being in this study.] Your blood, DNA, and information will not be sold. However, it is possible that information or materials from this study might be used to develop products that have commercial value. If this happens, you will not receive any share of the profits. We will not give you any treatment as part of this study.

QUESTIONS

If you have any questions about your rights as a research participant, please phone [*include name of Ethics Committee/IRB representative if appropriate*] of the Ethics Committee [Institutional Review Board], at [*insert phone number*]. Moreover, if you have any questions or concerns regarding this study, or if problems arise, you may call the Principal Investigator, [*insert name*], at [*insert phone number*].

PARTICIPANT'S STATEMENT

I understand that, by participating in this study, I agree:

- A. To give 3 to 5 tubes of blood for storage, processing, and research on the genetics of type 1 diabetes, its complications, and other autoimmune diseases; to have blood tests done relating to diabetes if needed; and to answer questions about my health and my family, understanding that this information will be kept confidential at all times and that I can ask to have my samples destroyed at any time.

Yes

B. And, to allow my information and the DNA extracted from my blood samples to be sent to the United States and given to other qualified scientists worldwide, even after this study ends, to be analyzed for genetic information relating to Type 1 diabetes, its complications, and other autoimmune diseases.

Yes

I also agree:

C. To allow my genetic material to be made into a living cell line that will create an unlimited supply of DNA that can be used to study type 1 diabetes, its complications, and other autoimmune diseases.

Yes

No

D. To be contacted in the future about possibly participating in additional studies related to diabetes, its complications, and other autoimmune diseases.

Yes

No

SIGNATURES

Your signature below shows that you have read this consent form and agree to join this study.

Signature

Date: _____

Signature of Witness

Date: _____

Type 1 Diabetes Genetics Consortium Study Investigators:
[include names, addresses, phone numbers]