

John A Todd, PhD, FMedSci
Professor of Medical Genetics, Director JDRF/WT DIL
Fellow of Gonville and Caius College



Juvenile Diabetes Research
Foundation/Wellcome Trust
Diabetes and Inflammation
Laboratory

INFORMATION SHEET FOR HEALTHY VOLUNTEERS Version 2b 22/01/07

Dear Volunteer

THE CAUSES OF TYPE 1 DIABETES

We would like to invite you to take part in our research study, the causes of type 1 diabetes. It involves donating a small blood sample and answering a few questions on details of your medical history. If you agree to take part, the blood sample would be taken at a time convenient to you, perhaps in your home, if appropriate. The total amount to be taken will be 1-3 tablespoons (10-40 ml). We may require up to 4 blood samples over a period of one year. We plan to carry out genetic and immunological studies on the blood samples. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully. Please ask us if there is anything that is not clear or if you would like more information. Participation is entirely voluntary.

What is the purpose of this study?

The purpose of this study is to find the genes that cause insulin-dependent (also called type 1) diabetes to enable us to identify individuals at risk of developing the disease and to understand its basic causes. Ultimately we hope this will lead to preventive treatment in these at risk individuals.

Why have I been chosen?

For the study we require a group of healthy controls. We need to compare diabetic patients with people like you without diabetes. This will enable us to establish differences between those who develop diabetes and those who do not. You yourself will not have diabetes and this is why we are asking you as a non-diabetic to consider participating in our study.

Do I have to take part?

Taking part in this research study is entirely voluntary. It is up to you to decide whether or not you wish to take part. If you decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you do decide to take part you are still free to withdraw from the study at any time without giving a reason. A decision to withdraw or not to take part, will not affect the standard healthcare you receive. If you choose to withdraw from the study your sample will be destroyed.

Cambridge Institute for Medical Research
Wellcome Trust/MRC Building
Addenbrooke's Hospital
Hills Road
CAMBRIDGE
CB2 0XY

Tel: 01223 762101/3
Fax: 01223 762102
john.todd@cimr.cam.ac.uk
<http://www-gene.cimr.cam.ac.uk/todd/>

What will happen to me if I take part?

If you agree to take part, you will be invited to donate a blood sample of up to 40 ml (1-3 tablespoons) either by attending the Clinical Research Facility at Addenbrooke's Hospital, or by a home visit or by attending another venue local to you, at a time convenient to you. You will also be asked a few questions on details of your medical history.

What are the possible disadvantages and risks of taking part?

Blood sampling can cause some discomfort, when the needle is placed in the vein and the blood is drawn and there is the possibility that a bruise may develop. Light-headedness and fainting may also result from blood sampling.

What are the possible benefits of taking part?

There are no direct benefits to the volunteers that take part in this study but we hope the research will help us to identify the genes that cause diabetes and to enable us to identify individuals at risk of developing the disease. Ultimately we hope this may lead to preventive treatment in these at risk individuals. The project has no direct therapeutic value but is a contribution to science. The research study may also lead to discoveries of relevance to diseases and conditions other than type 1 diabetes.

Will my taking part in this study be kept confidential?

Yes, in order to maintain confidentiality, each individual participating in the study will be assigned a study number which will be maintained throughout the study; all specimen samples will be stored and referred to by this study number only; and the identity of the volunteers will not be available to anyone in the research team who will use the samples. The study will be carried out in a completely anonymous fashion.

What will happen to the results of the research study?

Cambridge University and the sponsors of the study, the Juvenile Diabetes Research Foundation and the Wellcome Trust, both research charities, may have an interest in using the genetic and biological information found from the testing or analysis of your blood (and its derivatives) for the development of new products that might help the diagnosis, treatment and prevention of the disease. Patent applications may be made in these respects.

If you want more information or have any queries about anything concerning the study, please feel free to contact me. My telephone number is (01223) 762101. Thank you for considering contributing to our study.

Yours sincerely

John Todd
Professor of Medical Genetics

Cambridge Institute for Medical Research
Wellcome Trust/MRC Building
Addenbrooke's Hospital
Hills Road
CAMBRIDGE
CB2 0XY