

**JDRF/WT Diabetes and Inflammation
Laboratory**

INFORMATION SHEET FOR VOLUNTEERS

Version 6 25/01/2008

Dear Volunteer

**GENES AND MECHANISMS IN TYPE 1 DIABETES IN THE
CAMBRIDGE BIORESOURCE**

We are asking you if you would consider participating in our research study, which involves the taking of a blood sample up to four times per year and asking a few questions on details of your medical history. 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.

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?

You have been selected for this study based on your initial recruitment into the Cambridge BioResource and on the basis of your genetic make-up determined from your first donated blood/saliva sample.

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 required, interpreters will be used. 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(s) will be destroyed.

What will happen to me if I take part?

If you agree to take part, you will be invited to donate a blood sample by attending the Clinical Research Facility at Addenbrooke's Hospital, at a time convenient to you. If travel is difficult or you are unable to get to Cambridge we may be able to offer you a home visit or an alternative

venue, local to you, which is more convenient. The volume of blood to be taken will be up to 50 ml. You will also be asked a few questions on details of your medical history. You may be invited to donate up to four blood samples over the period of one year.

Up to a maximum of **25** consenting volunteers recruited into the study per year will be invited to give a full blood donation of up to 400 ml at one of their visits. Please note these large blood donations are not a requirement of each volunteer recruited into the study and agreeing to take part in the study does not mean that you agree to donate a full blood donation, nor does it mean that you must attend all four visits.

We plan to carry out genetic and immunological studies on the blood samples you donate.

What are the possible disadvantages and risks of taking part?

Some discomfort may occur 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 is no direct benefit to the individuals 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 the 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 an 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 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 by phone on (01223) 763223 or by email sarah.nutland@cimr.cam.ac.uk

Thank you for considering contributing to our study.

Yours sincerely

Sarah Nutland
Study Co-ordinator