

**Genetic and cellular mechanisms protecting from tuberculosis
in the Cambridge BioResource**

INFORMATION SHEET FOR VOLUNTEERS

Version 2, 30/10/2010

Dear Volunteer

We are asking you if you would consider participating in our research study, which involves the taking of a blood sample from you. This study has been reviewed and given a favourable opinion by the Cambridgeshire 1 Research Ethics Committee. 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. 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 and to understand biological mechanisms that are involved in protecting humans from infectious diseases, in particular, from tuberculosis. Tuberculosis remains a global health problem. Every year there are approximately 9 million new patients and more than 1 million deaths due to tuberculosis. Currently available vaccine called BCG does not prevent pulmonary tuberculosis, the most common form of the disease. New, more efficient vaccines are required. However, to design such vaccines researchers need to better understand biological mechanisms of infection and immunological protection against it. Our study is designed to collect this valuable information.

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. We will reimburse your travel expenses, including costs of car parking at Addenbrooke's Hospital. 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 (approximately three and a half tablespoons). You will also be asked a few questions on details of your medical history. This is just to make sure that you don't have a condition (such as common cold or another disease) that may affect your blood sample.

Why the blood sample is being taken and what will happen to it?

Your blood sample will be taken to the laboratory. There we will isolate immune cells from your blood and will study in detail how these cells react to the bacteria that are known to cause tuberculosis. We will also compare cells from different people. Our goal is to understand why immune cells of some people can kill these bacteria efficiently, while cells of other people cannot. We will study genes of all study participants to find out if such a protection against bacteria is genetically determined.

Why have I been chosen?

You have been selected for this study only because previously you have agreed to participate in the Cambridge BioResource. Altogether this study includes approximately 1,000 Cambridge BioResource volunteers, and we hope that you would be one of them.

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 are the possible disadvantages and risks of taking part?

The only medical procedure you will be involved in is venepuncture. It is a common medical procedure, however, 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 occur.

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 are involved in protecting people from infection.

Ultimately we hope this will help to design better vaccines to prevent tuberculosis. The study has no direct therapeutic value, but is a contribution to science. It may also lead to discoveries of relevance to diseases and conditions other than tuberculosis.

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?

Our main goal is to advance and disseminate knowledge in this area of science. Accordingly, results of this study will be published in the scientific literature for other researchers and in other media for the awareness of the general public. In addition, Cambridge University 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 762605 or by email sn262@cam.ac.uk. You may also wish to contact NHS Patient Advice & Liaison Service (tel: 01223 216 756, email: pals@addenbrookes.nhs.uk).

Thank you for considering contributing to our study.

Yours sincerely

Sergey Nejentsev
Chief Investigator