



**A study of the long-term safety and mechanism of action of alemtuzumab
(Campath-1H)**

**INFORMATION SHEET FOR HEALTHY VOLUNTEERS FROM
THE CAMBRIDGE BIORESOURCE**

We would like to invite you to take part in our research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

Part 1 – tells you the purpose of this study and what will happen to you if you take part.

Part 2 - gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear.

Part 1

What is the purpose of the study?

The purpose of this study is to try and understand how a person's "genetic make-up" influences how their immune system works, and how they respond to drug treatments.

The specific context is the treatment of multiple sclerosis with a drug called alemtuzumab. Multiple sclerosis is an autoimmune disease in which the patients' own immune system attacks their brain and spinal cord causing damage. It is the most common cause of disability in young adults in the western world. Clinical trials have shown alemtuzumab to be very effective in treating multiple sclerosis, now we are trying to work out why. We also know that alemtuzumab has side-effects; in particular 1 in 3 patients treated with alemtuzumab develop a new autoimmune disease - that is their immune system stops attacking their brain and spinal cord, but begins to attack another part of their body. In most cases this is the thyroid gland. Here we aim to try and understand why this happens. We believe that understanding this may, one day, enable us to prevent this side effect from occurring.

Why have I been invited?

You have been invited to take part in 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. We would like to compare how your immune system works to individuals with different genetic make-ups and to patients with multiple sclerosis that have been treated with alemtuzumab.

Do I have to take part?

No. It is up to you to decide whether or not you would like to take part. If you do, you will be given this information sheet to keep and will be asked to sign a consent form. You are free to withdraw at any time, without giving a reason. A decision to withdraw, or not to take part, will not affect any future medical care you may need, or your involvement with any other study.

What will happen to me if I take part?

Taking part in this study is very straightforward. You will be asked to give a blood sample of about 100mls in total (a teacup full or ¼ of a standard UK blood donation), and you may also be asked to provide a sample of saliva (5mls). You may be asked if you would be happy to donate another blood or saliva sample at some point in the future, within the next 5 years.

Your samples will be taken at Addenbrooke's Hospital in Cambridge

What are the possible disadvantages and risks of taking part?

Aside from the very minimal risk, e.g. bruising, after having blood taken, the only disadvantage to you is the time taken in attending for your appointment.

What are the possible benefits of taking part?

There is no intended clinical benefit to you from this study; but we hope our work will contribute to the development of safe and effective treatments for multiple sclerosis.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

Expenses and Payments?

We will pay for the cost of travel to Addenbrooke's Hospital for any visits made as a result of taking part in this study.

This completes Part 1.

If the information in Part 1 has interested you and you are considering taking part, please read the additional information in Part 2 before making any decision.

Part 2 of the information sheet

What will happen if I don't want to carry on with the study?

Taking part in this study is entirely voluntary and you can withdraw at any time without having to explain why. If you withdraw from the study we will destroy what remains of your donated sample/s.

What if there is a problem?

If you have a concern regarding any aspect of this study please ask us and we will do our best to answer your questions. If you remain unhappy, and wish to formally complain, you can do so through the NHS complaints procedure.

Will my taking part in this study be kept confidential?

Yes. All information which is collected about you during the course of the research will be kept strictly confidential and handled in accordance with the UK Data Protection Act (1998).

Involvement of your General Practitioner/ Family Doctor (GP)

Usual practice is that we will inform your GP that you have donated samples to contribute to this study, but only with your permission.

What will happen to any samples I give?

We will ask you to donate your samples to the University of Cambridge, Department of Clinical Neurosciences. Your donated samples will be treated as "gifts", which means that the department will have control over what happens to the samples, how they are used and all rights to any "inventions" (such as drug treatments or tests) which might come out of research performed using your samples.

Most of the blood you donate will be analysed on the day it is taken, however, some samples will be frozen for future studies. All stored samples will be kept in an anonymous form. Your sample will only ever be used for research that is approved and deemed appropriate by an Ethics Committee. We may share blood or the components of blood (i.e. plasma/serum, cells) with other collaborating academic or industrial third parties that are under contract to carry out sample analysis in agreement with the study objectives.

Will any genetic tests be done?

You have been approached to take part in this study on the basis of your genetic make-up determined from the blood/saliva sample you donated when you joined the Cambridge BioResource. We may wish to look at your DNA in more detail, in particular we would like to look at parts of your genetic code that have been shown to be important in multiple sclerosis and its treatment. DNA can easily be extracted from your blood and/or saliva sample – you would not need to give an additional sample. The results we obtain will not affect you as an individual, nor will they affect your family. We will not feedback any of the results we obtain to you or to anyone else (including your GP). Taking part in this study will not affect any health insurance you may have. Any DNA that remains unused will be destroyed on or before 1 January 2060.

You will be asked to indicate if you are happy to donate your DNA on the consent form. If you decide not to donate your DNA you can still take part in the rest of the study.

What will happen to the results of the research study?

The results of this study may be published in a scientific journal or book, and where appropriate through formal press releases. No one taking part in the research will be identified in any of these reports.

Who is organising and funding the research?

Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge are jointly sponsoring the study. Our research group receives funding support from various charities such as the MS Society, Wellcome Trust and the Academy of Medical Science.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your interests. This study was reviewed and given favourable opinion by Cambridgeshire 2 Research Ethics Committee.

Further information and contact details If you have any questions about this study please contact:

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Thank you for taking the time to read this document, and for considering taking part in the study.