



University of Cambridge
DEPARTMENT OF HAEMATOLOGY
Cambridge Institute for Medical Research
Hills Road
Cambridge, CB2 0XY

Professor A R Green PhD, FRCP, FRCPath, FMedSci
Head of Department

Tel: Direct 01223 336835
Academic PA 01223 336820
Clinical PA 01223 762668
Fax 01223 762670
Email: arg1000@cam.ac.uk
Website: www.haem.cam.ac.uk

Genes and Mechanisms in Clonal Blood Disorders

Information sheet for Cambridge BioResource Volunteers

You are being invited to take part in a research study. This study is organised by the Department of Haematology, at the University of Cambridge, and 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. Ethical approval for the study has been granted by an NHS Research Ethics Committee (REC) and researchers are not being paid to carry it out. 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 and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

Purpose of the study and why you are being invited to take part

We are studying the way normal blood cells are formed to better understand diseases of the blood system. You have been asked to participate as a normal subject without a blood disease, to help us understand how natural variation in genes affects the formation of blood cells. We would like to use this information to help us understand why some other people can go on to develop blood disorders.

Deciding whether to take part in the study

Our study aims to improve our understanding and management of clonal blood disorders. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What you will be asked to do / handling of samples

If you agree to take part, you will be invited to attend an appointment at Addenbrooke's Hospital to donate a blood sample at a time convenient for 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. You will also be asked a few details of your medical history, and the nurse will ask you to sign a consent form if you decide to take part. The volume of blood to be taken will be 100ml. You may be invited to donate one more blood sample over the period of 6 months. All direct contact with you will be through members of the BioResource team only. If you are called

back, it is because we want to compare how your cells behave compared to cells from other normal people, and whether any differences are due to normal genetic factors widely present in the general population. You have been requested to donate 100ml volume of blood as certain cell types that we would like to study are very rare in the bloodstream and we need to ensure we have collected sufficient numbers of these rare cells types. Although these larger donations might be associated with a higher risk of feeling faint, this volume is less than a quarter of that collected for a standard NHS blood donation.

The samples will be treated as gifts to our research team and will be analysed, using modern laboratory technologies, at the Department of Haematology, University of Cambridge (gifting samples in such a way equates to waiving your rights to benefit commercially or otherwise from any developments resulting from the research). The samples will be stored in the Human Research Tissue Bank at Addenbrookes Hospital. Some samples may also be used outside the department in collaboration with other researchers.

Will my taking part in this study be kept confidential?

Yes, we will protect your privacy at all times. Your blood samples will be labelled with a unique sample number before being transferred to the research laboratory. Your name and contact details will never appear on the blood sample to ensure the laboratory researchers never get to know who you are. The consent form will be archived separately by the BioResource team at the University of Cambridge. The study will be carried out in an anonymised fashion. At the end of the study, or at the end of subsequent ethically-approved studies, samples will be removed from the tissue bank and disposed of securely.

The only way researchers can get a further sample is by providing the unique sample number to selected BioResource personnel who have access to the table linking your sample number with your contact details. A member of the BioResource team will call you back for another sample. The team members calling you back will not know the results obtained with your samples, and the reason why another sample is needed.

Follow up information

The research results from your samples will be analysed as part of the overall study. These results will not be revealed to individual participants. As participation in our study does not alter any treatments you receive, we will not inform your General Practitioner of your participation.

Study organisers

Professor A.R. Green, at the Department of Haematology, University of Cambridge is the Lead Researcher and sample custodian for this study. All samples/data will be sent to the Department of Haematology at the University of Cambridge or our collaborators.

Further information and Contact Details

If you would like further information on any aspects of this information or the study please do not hesitate to contact the study coordinator:

Cathy MacLean
Haematology Trials Project Manager
Cambridge Cancer Trials Centre
Box 279 (S4)
Hills Road
Cambridge, CB2 0QQ

Tel: 01223 348 450

Thank you for reading this information sheet.