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RESEARCH INTO THE CAUSES OF CLONAL BLOOD CELL DISORDERS

Patient information sheet

You are being invited to take part in a research study. The study is organised by the Department of Haematology, University of Cambridge and is funded by the Leukaemia Research Fund. Ethical approval for the study has been granted from the 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 causes of disorders of the blood and bone marrow, with the aim of developing more effective diagnosis and treatment for these conditions in the future. The specific disorders we are interested in, include the myeloproliferative disorders, leukaemias and lymphomas, all of which are conditions where a single blood / bone marrow cell begins to multiply abnormally, giving rise to a large number of cells (i.e. a clonal blood disorder). You have been chosen for an invitation to participate as you are being investigated for one of these conditions.

Deciding whether to take part in the study

Although our study aims to improve our understanding and management of such conditions, you may not benefit directly as a result of participating. 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

Patients who enter our study will be asked to donate blood, hair and mouth-swab samples. We would also like to request permission to use any excess material taken from you that would otherwise be discarded. This would include left-over material from biopsies, bone marrow / stem cell harvests and blood samples sent to the hospital laboratory as part of your routine care. This excess material would otherwise be discarded after routine tests have been performed. Some patients may be asked to donate further blood

samples on future occasions. This will usually be requested and performed during routine clinical follow-up.

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).

When your samples are collected from the clinic or laboratory, they will be allocated a code number by the Cambridge Haematology Tissue Bank. This is a secure facility with supervised access. Samples will remain linked back to you, via the secure tissue bank database, so that basic clinical information can be linked to your samples. Designated staff from the Cambridge Department of Haematology will have access to your samples, however, all work in our laboratory and in collaborating laboratories will be done on samples after they have been made anonymous with a code number. At the proposed end of the study (currently 2012), or at the end of subsequent ethically-approved studies, samples will be removed from the tissue bank and disposed of securely.

In the unlikely event of us discovering any unexpected findings of medical importance with your samples, we shall inform your consultant haematologist.

New information about your condition

New information about your condition may become available as a result of our study. Your consultant will be informed of any such information that would improve the management of your condition. We will also endeavour to submit relevant new data for publication in scientific journals and share any new knowledge with the medical and scientific communities.

Access to medical notes and confidentiality

Whilst you remain enrolled in our study, we will document your progress by studying your medical notes at intervals in order to assess your clinical progress and relate it to research findings. This will be done by a doctor or nurse from our team. All information collected about you during the course of the research will be kept strictly confidential and the handling, storage and destruction of data will be done in accordance with the Data Protection Act 1998. Your personal data, such as age and sex will be linked to disease-related data taken from your medical notes. This information will be stored securely in a database, on a password-protected computer. Only departmental, tissue banking and other clinical staff from the Cambridge Department of Haematology, and senior administrative audit staff will have access to identifiable data that would link you to your samples. Any information about you and your samples which leaves the hospital will have your name and address removed so that you cannot be recognised from it. At

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the proposed end of the study (currently 2012), or at the end of subsequent ethically-approved studies, data will be removed and deleted from the tissue bank.

Study organisers and sample/data analysis / Contact for further information

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 Professor Green's group at the University of Cambridge. Professor Green would be happy to explain anything concerning the research. He can be contacted by telephone on 01223-596279

Thank you for reading this information sheet.