

PARTICIPANT INFORMATION LEAFLET

A BLUEPRINT OF BLOOD CELLS

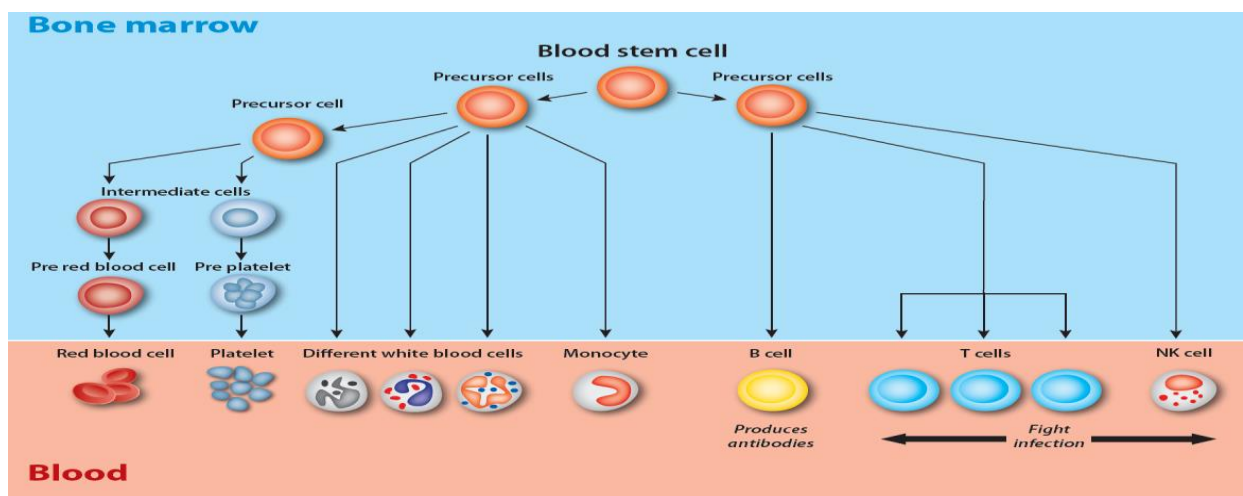
You are invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Thank you for reading this.

What is the purpose of the study?

Our genetic make-up directs much of our lives. Genes are made up of DNA and you have two copies, one from your mother and the other from your father. You could call it the "alphabet of life". Researchers can now read the genetic code much faster than was previously possible and a large fraction of the entire genome can be deciphered within days.

By deciphering this code, we can track down the genes that make people more likely to develop certain diseases. To get a first clue about which genes cause disease, researchers have been comparing samples from thousands of patients with those of healthy individuals. To progress this work further, we need help from healthy volunteers like you.

We want to better understand what genes control the behaviour of cells and how differences in the DNA code between individuals affect this behaviour. This work will involve growing cells in the laboratory for prolonged periods of time and will involve the storage and testing of genetic material such as DNA. Blood and bone marrow are ideal models to study because many different types of cells, each one performing a different function, can be studied. In the long term, it is hoped that this research can lead to better prevention or treatment of diseases of the blood, autoimmunity, cancer and heart disease.



Why have I been selected to be invited?

There will be one of several reasons why you have been selected to receive an invitation to participate in the Blueprint study. These are: (i) your participation in earlier research studies at which time you granted us permission to contact you for

other studies. Examples of such studies are the Cambridge Bioresource, Platelet Profiling, Cambridge Cardioresource, Genetic Analysis of Platelets in Healthy Individuals, etc; ii) you have enrolled as a donor with NHS Blood and Transplant, which includes donors of the British Bone Marrow Registry; (iii) NHS Blood and Transplant, the Cambridge University Hospitals NHS Foundation Trust or the University of Cambridge may have information on their databases and you have given permission to use this information as a reason for selection.

Do I have to take part?

No. It is entirely up to you to decide whether to take part. This information leaflet tells you all about the study and will help you to decide. You are still free to withdraw at any time and without giving a reason.

What will happen if I decide to participate?

If you decide to take part you will be asked to sign a consent form and a copy will be returned to you. We will ask you by e-mail, phone, via the internet or face-to-face for information about your health and medical history and that of your close relatives.

If you are a blood donor, we would like to seek your permission to i) take your entire 470 ml routine donation of whole blood for research; or ii) take your platelet or white blood cells donation obtained by apheresis for research; or iii) take a sample generally of 50 ml but on occasion of up to 100 ml of blood either before or after your routine blood/platelet donation using a separate venepuncture. We may ask you for repeat donations of whole blood, platelets or white blood cells according to the guidelines set by the NHS Blood and Transplant. We also may use parts of your donation that are superfluous for use in the NHS (e.g. your white cells, blood fluid).

If you are not a blood donor, we will invite you to attend to give a sample for research only and no more frequently than four times per 12 months. We will take a sample generally of 50 ml but on occasion of up to 100 ml of blood. We may occasionally ask for other samples such as saliva used to extract DNA.

The sample(s) will be generally collected at a NHS Blood and Transplant donation session site (e.g. at the Cambridge Blood Donor Centre), but we may ask you also to attend your local NHS hospital (e.g. the Addenbrooke's Treatment Centre), or your local surgery. Samples will be taken by an experienced member of NHS staff. Alternatively, we may be able to visit you at your home or work address if this would be more convenient for you.

What do we do with your donated samples?

We will isolate, analyse, amplify, and store your DNA

Genes are made of DNA and DNA is translated to RNA. The entire or part of the genome (DNA) and the translated part of the genome (RNA) will be analysed and compared with the ones from others individuals.

We will isolate, analyse and store blood cells and other blood components

We will isolate and store any type of cell and other components like proteins, carbohydrates and lipids that we can obtain from your donation and perform tests on these. Biomarkers, which are body substances that can easily be measured and give a clue to cellular function and health status (e.g. haemoglobin) will also be measured.

We will isolate, test, clone and store cells

We will store any type of blood cell and perform tests on these cells. We will use the donated cells to create cloned induced pluripotent stem (IPS) cells that will be kept for prolonged periods of time and used in future research.

What will happen to the results of the research study?

Results of this study will be made available to the public through scientific publications, including placing information on the Internet, in press articles and project leaflets. This information may include a part or the entire code of your DNA or RNA. Under no circumstances would your identity be disclosed in any publication. Please be aware that the government has extended the genetic test insurance moratorium until 2017. This means there are restrictions which prevent providers from using genetic test results to deny people insurance cover until that set date.

What happens if an invention is made using my sample?

Your donated samples and related information are given as an “absolute gift”. An absolute gift is given as a donation i.e. without receiving a payment and without conditions. You should understand that you give samples as a non-returnable absolute gift. In case an invention results from the research undertaken with your samples, for example if a new blood test to improve diagnosis or better medicines for treatment of patients are developed, you will not receive any compensation nor will funds be forthcoming to you. We and our collaborators may work in partnership with the private sector in the UK and abroad (e.g. pharmaceutical or biotech industry) to successfully develop any invention for the benefit of patient care. Part of the profits earned with inventions will be retained by the university.

Can I know the results obtained from my samples?

For the protection of your privacy, your samples will be kept completely separate from your contact identifiers. It is not planned to feedback any research results to participants, as it would be of no direct benefit. The only time a test result would be communicated back to you would be in the unlikely event that something is discovered that has an immediate impact on your healthcare (i.e. low haemoglobin and anaemia). In this case, we would contact you and advise you to see your General Practitioner. A further sample may then be taken for re-testing in a Clinical Pathology Accredited laboratory. If the results obtained with this second sample confirm the health concern then your doctor will discuss with you the most appropriate next step.

What if something goes wrong and what arrangements have been made for indemnity?

In the highly unlikely event that you suffer any harm as a consequence of this study you will have a right to complain or take legal action against the NHS Blood and Transplant. As sponsors of this study, cover is provided under the NHS indemnity scheme.

Will I be reimbursed for taking part?

We will cover reasonable expenses for travelling to the site where the sample will be taken in the event that you agree to come and give a sample for research only.

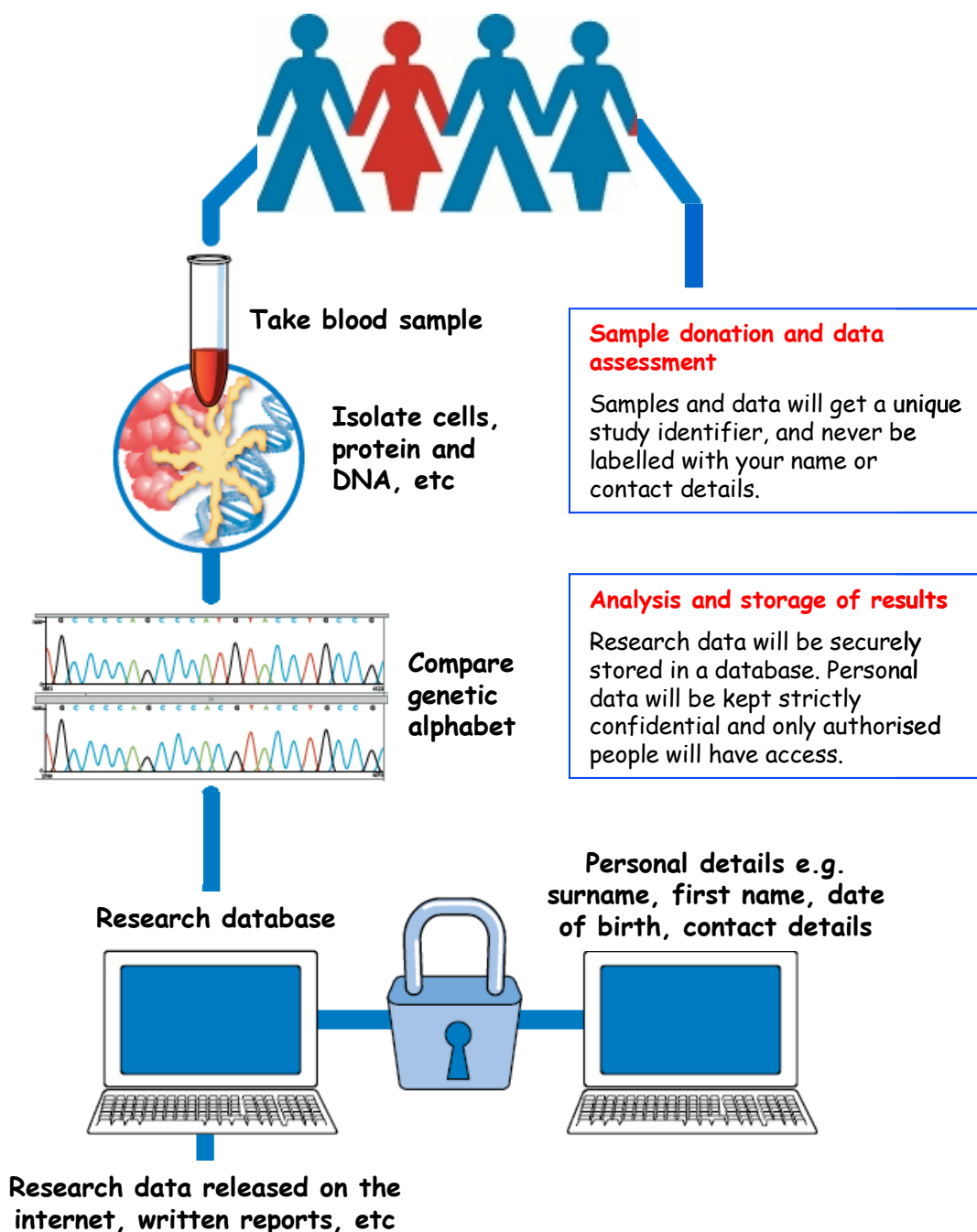
What about confidentiality?

All research information that is collected about you during the course of this study will be kept strictly confidential. We will protect your privacy at all times. Your donated 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 sample to ensure that the scientists never know who you are. The consent form will be

archived separately. Test results obtained from your sample will be stored in laboratory notebooks and research databases, which are not connected to the database that contains your contact details. Therefore, information from genetic and other tests will be kept separate from your surname, first name and contact details.

Access to the table linking sample numbers to contact details will only be available to members of staff with a NHS (honorary) contract. They will use the link table if they wish to contact you for further studies.

Study Design



What happens to my sample if I withdraw from the study?

If you withdraw, all stocks of your samples from the main repository will be removed. It is not possible to withdraw already distributed materials. We are not able to erase information from the research databases or notebooks if you withdraw. Results that were obtained prior to your withdrawal (that is while you were consented to the study) may be used in further analysis. However, no new data will be added to your records on the research databases or notebooks from the moment that the study team has confirmed your withdrawal. Once you withdraw, you will not be contacted again for this study.

Who will work with my samples?

Blueprint is an international project and many laboratories are collaborating across the globe, but particularly in Great Britain and Europe. Your samples will therefore be exchanged between laboratories for the purpose of research. In Britain, the laboratories are part of the University of Cambridge, Cambridge University NHS Foundation Trust Hospitals, NHS Blood and Transplant, the Wellcome Trust Sanger Institute in Hinxton and of several London Universities. We are, however, also collaborating with other research groups worldwide, including private companies and pharmaceutical industries. Your identity, however, will never be disclosed to any of these collaborators.

Who is organising and funding the research?

This study is funded by the European Commission, the National Institute for Health Research (NIHR) of England and NHS Blood and Transplant. If the funding ceases, all samples and data will be safeguarded by NHS Blood and Transplant. Alternatively, if a decision has to be taken to destroy the materials and related information, we will follow procedures that are applied in the NHS.

What is cell cloning and what can we achieve with cell cloning?

The Human Fertilisation and Embryology (HFE) Act 1990 and subsequent updates regulate the use of human induced pluripotent stem (IPS) cells in research. Under the current law, research must relate to one of eight categories, one of them is “to increase knowledge about serious disease”.

Cloning refers to the process of making copies of cells in the laboratory in order to obtain cells which are immortal. These immortalised and cloned cells can be stored at low temperatures for later recovery and use. The cloned cells will possess the same genetic material (DNA) as the person from which they are derived. The cloned cells will be used for research and for the possible generation of standards. Another benefit of IPS cell technology is that it allows for the creation of cell lines that are genetically customized to an individual; this allows scientists to study the relationship between the genetic make-up (genotype) of individuals with their characteristics or traits (phenotype).

IPS cells can be grown in the laboratory and can be produced from cells in the blood. IPS cells have a great potential to make different cell types and we hope that this will help us to understand more about the mechanisms of different diseases and what genes are involved.

What are the possible benefits of taking part?

Taking part in this study will not directly benefit you if you choose to participate. There will be, however, a benefit to the future development of healthcare provision and the long-term prevention and treatment of many diseases.

What are the possible disadvantages?

The taking of a blood sample carries a small risk of bruising, inflammation or fainting. There is also a small chance of anaemia developing if blood is taken, but NHS Blood and Transplant monitors your level of haemoglobin at every donation. If it is too low, you will be advised not to donate.

Can I change my mind after giving the sample?

Yes, you can change your mind at any time during the study and withdraw consent without giving a reason. If you wish to withdraw, please contact the study team (details below).

Who has approved the study?

All research in the NHS is reviewed by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and was given a favourable opinion by the Hertfordshire Research Ethics Committee.

Where can I find further information and whom can I contact if I have further questions or wish to withdraw?

Please talk to a member of the study team if you have any questions or would like more information. They are happy to help and you will find their contact details below. More information about the study including a question and answer section of frequently asked questions can be found either on the study website www.cambridgebioresource.org.uk or provided as paper copies on request and also available during appointments with the study team.

Study team:

NHS Blood and Transplant, Long Road, Cambridge, CB2 0PT

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Email: nhsbt@cambridgebioresource.org.uk or nicola.foad@nhsbt.nhs.uk

Study leader:

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