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# Can you help with our research?

NHS Blood and Transplant Cambridge BioResource  
Participant Information Sheet

University of Cambridge, NHS Blood and Transplant, Long Road, Cambridge CB2 0PT  
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# Can you help with our research?

We would like to invite you to join the NHS Blood and Transplant (NHSBT) Cambridge BioResource. Before you decide, you need to understand why the BioResource is being set up and what it involves. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Please take time to decide whether or not you wish to take part.

## Background

Our genetic make-up directs much of our lives. It not only influences our physical characteristics, but also our risk of developing certain diseases. However, genes are not the only players in the game; environmental factors such as smoking and exercise also contribute to our health. Understanding the complex interplay between genes and lifestyle remains one of the biggest challenges in healthcare research.

Genes are made up of DNA, which contains a code that researchers are able to read. By deciphering this code, they 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. The exciting news is that hundreds of genes that are possibly involved in disease have been identified. But to progress this work we need more help from healthy volunteers like you.

DNA (Deoxyribonucleic Acid) is the chemical substance that makes up our genetic information. You could call it the 'alphabet of life'. Each human cell contains 3.2 billion letters of DNA that form 22,000 words or genes. For each gene, we have two versions: one from our mother and one from our father. These genes are found on chromosomes in every cell.

## What is the purpose of the BioResource?

The BioResource aims to establish a bank of genetic and lifestyle information from healthy volunteers. The National Blood Service (NBS), part of NHS Blood and Transplant (NHSBT), is working closely with the University of Cambridge on this project.

Information and samples from this resource will be made available to scientists working in biomedical and healthcare research for future studies investigating the links between genes, the environment and diseases. All future studies carried out will require ethical approval.

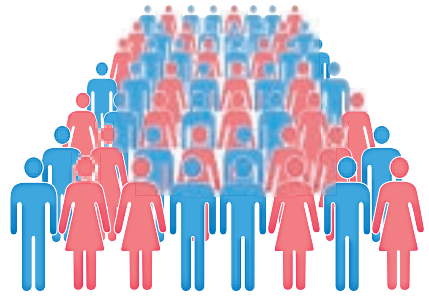
## Why have I been asked to help?

Researchers need blood samples from healthy people to carry out a wide range of biomedical and genetic studies. As a blood donor you complete a health check questionnaire each time you donate, and are therefore ideal for the BioResource as a healthy volunteer.

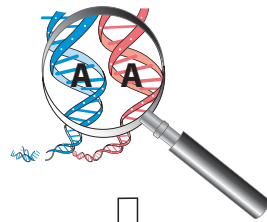
## Do I have to take part?

No, it is completely up to you. If you decide to take part you will be asked to sign a consent form. You are free to withdraw at any time, without giving a reason. Your decision has no influence on your blood donation or your choice to donate in the future.

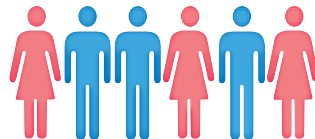
Samples of many healthy volunteers



Read genetic code



Call suitable donors back



Take another blood sample for research



**NHSBT Cambridge BioResource: By screening the samples of many healthy volunteers we will find individuals who carry interesting genetic variants on both their maternal and paternal chromosome.**

## What happens if I take part?

If you decide to join the project, then you will be enrolled in the BioResource. This involves the following:

- During your routine donation an extra 25 ml of blood (2 tablespoons) will be taken from the sample pouch without any additional needles being inserted.
- This blood will be used to perform routine NBS tests and a full blood count.
- DNA and other blood components, such as the plasma, will be isolated and tested in detail to establish a bank of genetic information and biomarkers. The isolated components will be stored for use in future ethically approved research studies. Components from your blood may be transferred to other research institutions as well as private sector companies in the UK and abroad for ethically approved research.
- You will be asked to complete a questionnaire covering health

related and lifestyle questions. Touchscreen questionnaires may be available at the end of the donation session. Alternatively, you will receive the questionnaire at your home address or be invited to access it via the internet. The questionnaire data will be entered into the BioResource database.

- Your donor record will be reviewed to extract relevant information including blood group, tissue type, gender, and month and year of birth. These will be stored in the BioResource database.
- Data from laboratory experiments performed with your blood, as well as month and year of birth, gender, the first three digits of your postcode (e.g. CB2) and additional data from the questionnaire, will be linked to your genetic information and stored in the BioResource database. Your contact details will be kept on a completely separate database within the NBS.
- Data from the BioResource database will be made available to other research and healthcare groups in the public and private sector for ethically approved research. All data will be separate from your identity, i.e. the researcher will not know who you are, and only the BioResource Research Nurse can get in touch with you.
- You may be contacted by a BioResource Research Nurse on behalf of the NBS to ask if you

Biomarkers are body substances that can be easily measured and give a clue to cellular function and health status. For example Haemoglobin, which is the main iron carrier in the blood, is measured routinely by the NBS to ensure blood donors do not become iron deficient (anaemic).

would be willing to give a saliva sample, if we have been unable to isolate the DNA from your blood. In this case we would post you a sampling kit to collect your saliva and a freepost envelope in which to return it.

- The NBS is establishing the BioResource for the benefit of scientists in healthcare and biomedical research. In the future, depending upon results obtained with your sample, you may be contacted by a BioResource Research Nurse to ask if you would like to participate in research studies which have received ethical approval. Remember that you are free to withdraw from the

BioResource at any time, and consenting to join the BioResource does not mean you have to come back for further studies. You can decide if you want to take part in a particular study and this will not affect your choice to take part in other future studies. These studies may involve visits to Addenbrooke's Hospital in Cambridge for more detailed tests and check-ups, like a scan or an exercise test.

- For studies only needing access to your stored samples and data at the BioResource, we will not contact you again. However, the researcher has to obtain ethical approval before using your samples and data.

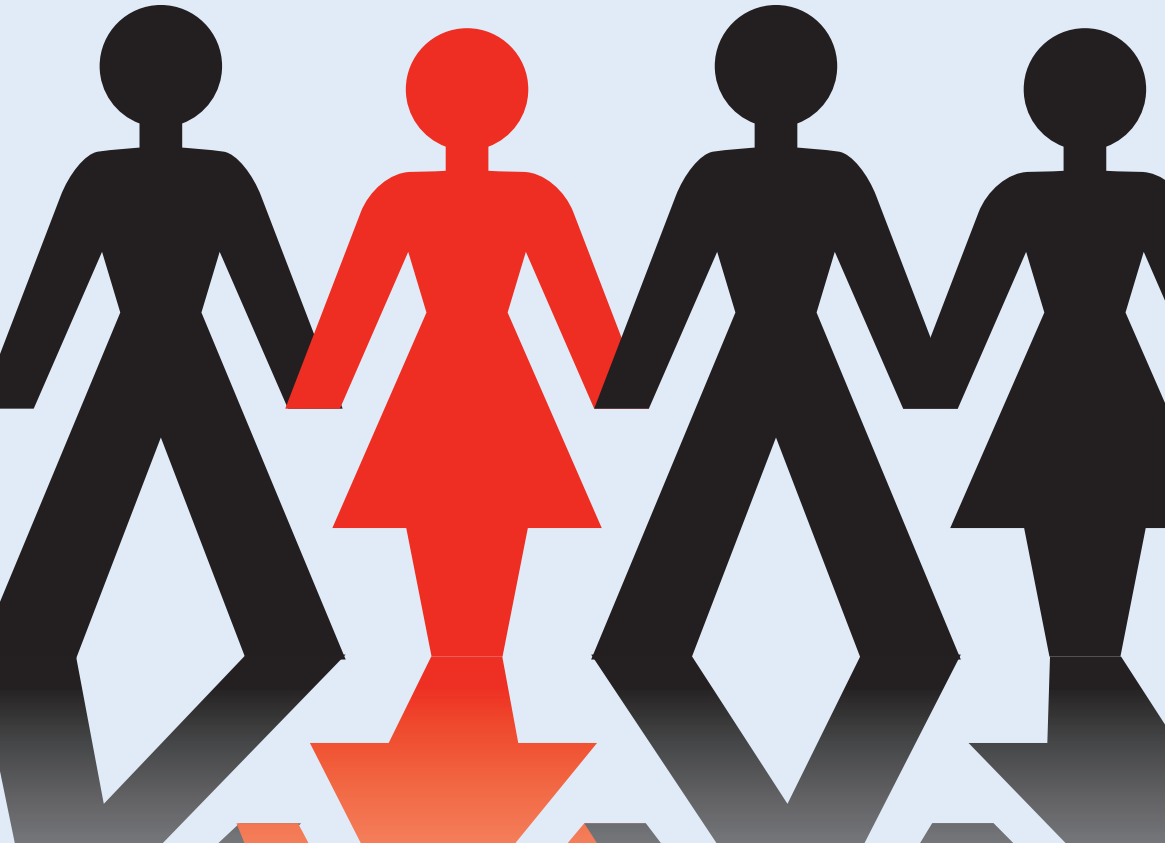


## What are the possible risks of being enrolled in the BioResource?

The blood samples for the BioResource will be drawn at the time of your routine donation by trained NBS staff. A whole blood donation is 470 ml (nearly a pint) and we would like to take up to an extra 25 ml (two extra tablespoons) for research. Your haemoglobin level is checked before every donation to ensure that you do not become iron-deficient when giving blood.

## What is the benefit of being involved in the BioResource?

There will be no direct benefit to you if you choose to participate. However, there will be a benefit to the future development of healthcare provision, and the long-term prevention and treatment of many diseases.



## Will my information be kept confidential?

We will protect your privacy at all times. Your sample is sent to the BioResource laboratory at the University of Cambridge/NBS centre in Cambridge with your signed consent form and a barcode label. The BioResource study team will give it a new unique BioResource study number and store it in the research bank for future testing. Your consent form will be filed separately.

We will not label samples with your name or contact details, but only with BioResource study numbers.

The laboratory results obtained with your samples will be stored on the BioResource database, which is not connected to the NBS database that contains your personal details. Access to the information linking the BioResource study number to your identity is strictly limited, and this information will always be kept within the NBS. Therefore, researchers working with your sample will never know your identity, and the BioResource Research Nurse who may contact you does not know the test results obtained with your samples.

If a future research study involves meeting a researcher directly, for example for a fitness test, the BioResource Research Nurse will be the only person contacting you. The Nurse will explain in detail what the study involves. If you would like to participate, the Nurse will arrange the meeting.

## What will happen to the results obtained from my samples?

Laboratory and other data linked to your sample will be made available to genuine researchers for future ethically approved studies. However, your personal details will not be released. Results of BioResource studies will be made available to the public through scientific publications, including placing information on the internet, in press articles and project leaflets. Your identity will never be disclosed in any publication.



## Can I know the results you get using my blood sample?

As outlined above, for protection of your privacy, your blood sample will be kept completely separate from your personal details. It is not planned to feed back any genetic testing results to you as it would be of no direct benefit. The Research Nurses will not know any results obtained with your samples. The only time any laboratory test results would be communicated back to you would be if we discover anything that has an immediate impact on your healthcare. In this case, the researcher would tell an NBS medical professional what the problem is, and the Research Nurse would tell the NBS medical professional who you are. The NBS medical professional would use the routine NBS procedures to get in touch with you and offer advice which may involve contacting your GP.

## Will any of the results obtained with my sample predict my risk for disease?

Unfortunately, we cannot answer this question. The aim of the BioResource is to enable researchers to access samples from healthy individuals. Many of the studies that will be carried out using these samples aim to discover variations in the genetic code (called genetic markers) that might predict the risk for certain diseases. However, it may take years before we can confirm how

important or accurate these markers are and determine the associated risk. Also, any predictions will have to take into account environmental factors and lifestyle.

If you are contacted to take part in a future study, this does not mean that your health is at risk. Every healthy individual carries risk markers and protective markers in their genes. We are a long way from understanding how they balance each other and what combination of markers, interacting with other factors such as age, gender, smoking habits etc. cause disease.



If we discover markers which are strongly linked to disease, and which would be valuable for predicting and preventing that disease, we will make this public knowledge. New tests and treatments can then be developed for use in routine NHS care for the benefit of all.

## Can I change my mind and withdraw my consent?

Yes, you can withdraw from the study at any time and without giving any reasons. However, we hope that you will continue to give blood as a regular donor, even if you withdraw

from the research. If you wish to withdraw, please contact the BioResource study team at the University of Cambridge, NHS Blood and Transplant, Long Road, Cambridge, CB2 0PT or call freephone **0800 085 3650** and we will send you a withdrawal form. Please note that we will not be able to remove results of any tests already obtained with your sample from the computer. However, we can assure you that no new data will be added, and the stored data will not be used after we have received your written notification. All reasonable effort will be taken to destroy your stored samples.



## What happens if the external funding for the BioResource stops?

The BioResource is currently funded by the National Institute for Health Research (NIHR) Cambridge Biomedical Research Centre (BMRC). If the external funding ceases, the BioResource will be maintained as a National Collection by the NBS or BMRC. To cover the operational costs, a reasonable fee may be charged for access to the stored samples and information. No profit will result from these charges.

## Who has approved the BioResource?

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 project has been reviewed and was given a favourable opinion by the Cambridgeshire 1 Research Ethics Committee.

## What happens if an invention is made using my sample?

You are giving your sample as an absolute gift. An “absolute” gift is a gift which is given as a donation, i.e. without receiving a payment and without conditions. The BioResource will operate on a non-commercial basis, meaning it will not sell your sample to make a profit, and will not allow anyone else who is working with the sample to do so either. However, if samples are made available to other research institutions, a fee may be charged to cover operational costs.



In the future, your sample may help researchers in the public and private sector to make an invention, e.g. develop a new product to diagnose or treat disease. If an invention results from the research undertaken with your sample, you will not receive any compensation or payment. BioResource partners in the public sector may work together with commercial companies to develop inventions for the benefit of patients; and we hope that such products are brought into use by the NHS to improve healthcare in the future. Part of the profits earned by marketing such products may be returned to BioResource public sector

partners and can be invested in further research. However, the BioResource itself will always remain non-profit making.



## Committed to translate scientific discoveries to better patient care

The collection of samples from UK blood donors will be co-ordinated by a project team at the National Blood Service Cambridge centre. The team will work in close partnership with the Cambridge BioResource, the Medical Research Council Epidemiology Unit and the University of Cambridge. The Cambridge BioResource is establishing a bank of genetic information for health related research and is currently recruiting healthy volunteers from the Cambridge area.

Both BioResources are aiming at supporting biomedical research, and they are led by one management committee.

Many research fund providers, like the Medical Research Council, medical charities (Cancer Research UK, British Heart Foundation, etc.), the NHS Research & Development, the European Union, the Juvenile Diabetes Research Foundation, the Wellcome Trust and the NHS, together with patients and healthy individuals like you, have made this endeavour possible. The BioResource is currently funded by the National Institute for Health Research (NIHR) Cambridge Biomedical Research Centre.

### Get in touch

If you have a concern or a question about any aspect of the BioResource, please contact the Project Team.

#### **NHSBT Cambridge BioResource**

Project Leader: Willem H Ouweland MD PhD FRCPath, Honorary Consultant Haematologist, University of Cambridge/NHS Blood and Transplant, Long Road, Cambridge CB2 0PT

**Freephone:** 0800 085 3650 **Email to:** [bioresource@bloodomics.org](mailto:bioresource@bloodomics.org)

If you have any questions about blood donation or your next session then please call **0300 123 23 23**.