PARTICIPANT INFORMATION LEAFLET

Version 4.0 - 13.07.2020

What is the STRIDES study?

STRategies to Improve Donor ExperienceS (STRIDES) is a study aiming to improve donor experiences within National Health Service Blood and Transplant (NHSBT). With over 1 million people donating around 1.6 million whole blood units every year, NHSBT is conducting world-leading research into donor management and, through academic partnerships, addressing wider public health issues.

We would like to invite you to join the STRIDES BioResource (part of the NIHR BioResource) organised by University of Cambridge, NHSBT and National Institute for Health Research (NIHR) BioResource:

1) to collect blood samples, questionnaire data and health records (e.g. measured test results, hospital episode statistics etc.) from whole blood donors for research purposes. Importantly, the knowledge gained will help NHSBT decide the best **STR**ategies to **I**mprove **D**onor **E**xperience**S** (**STRIDES**).

2) to establish a panel, or **BioResource**, of thousands of healthy volunteers who are willing to be contacted and asked if they wish to participate in medical and health-related studies, which may or may not be related with blood donors' health. Invitees are selected based on results from the blood samples or information collected during study participation (such as lifestyle choices or information from health-related records). Participation is completely voluntary and is separate from blood donation.

Please take time to read the following information, and discuss it with others if you wish. Let us know if you have questions.

What is the STRIDES BioResource?

Your blood donation can help us understand how to improve donor health and potentially reduce donation deferrals (being unable to donate blood at that time) for everyone. We can do this by collectively looking at your lifestyle factors, genetic make-up and certain blood biomarkers (these are easily measured blood components that give a clue to health status). This approach may lead to more personalised blood donation in the future.

Genes are made from DNA and are the basic 'instruction book' for your body's development and function. Everyone's genes are slightly different and explain some of the variation between people, such as eye colour. These differences also partly explain why some people, but not others, get certain diseases, and can help researchers discover new tools to diagnose and treat disease.

What is the STRIDES BioResource? (cont.)

Researchers can now quickly read a large fraction of the entire genetic code to help understand the role of genes in health and disease so we can begin to identify better treatments, reduce the effect of a health condition or even cure it. This research depends on the availability of a large number of participants willing to contribute blood samples and allow their health to be monitored through their medical records in studies like this one. The STRIDES BioResource is organised by NHSBT, University of Cambridge and the National Institute for Health Research (NIHR) BioResource. When we refer to the ‘BioResource’ we mean both the STRIDES BioResource and the NIHR BioResource.

Why have I been invited to join the BioResource?

The STRIDES BioResource is recruiting blood donors, and therefore, we are inviting you to join.

You are eligible to take part if you:

- are 18 years or older.
- have an email address and access to the internet.
- fulfil all criteria for routine blood donation.
- are able to provide informed consent.
- have a good understanding of the English language, both written and oral (as study materials are not tailored to support non-English language speakers).

Why should I join the BioResource?

The STRIDES BioResource forms part of the NIHR BioResource (https://bioresource.nihr.ac.uk/): a growing network of research centres recruiting volunteers with and without health conditions. This setup provides a unique infrastructure to support studies looking at how genes and biomarkers influence disease. For example, samples from healthy volunteers can be compared to those from patients as differences may indicate the cause of the disease.

If you agree to join:

- you will become part of a national panel of thousands of volunteers who are willing to help with research (called the NIHR BioResource).
- your samples, data and medical records will contribute to research focusing on blood donation as well as on broader public health investigations looking into the links between genetic information and disease.

What happens if I join today?

WHEN YOU GIVE BLOOD

Part of your routine donations (up to 20ml) is collected for research purposes at each donation

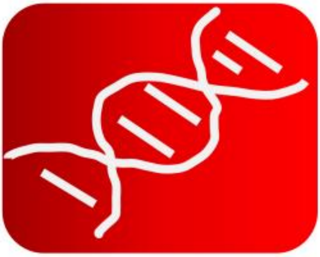
The database for researchers' use will be de-identified and will NOT have your name or contact details.

WHEN YOU ARE AT HOME

You will be asked to complete online questionnaires linked to your blood donation regarding your health

RESEARCH SAMPLES

Blood samples are sent to the laboratory for storage, to count different types of blood cells,and to extract DNA, plasma and serum.



What happens in the future?

Only key members of the BioResource teams will have access to your contact details. They will be kept separately and securely from the database for researcher's use.

IN THE FUTURE

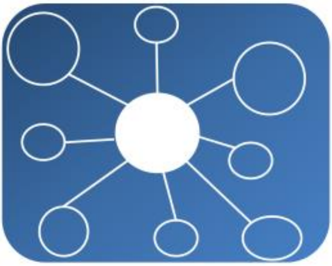
You may be contacted to participate in another study run by the BioResource - up to 8 invites per year

DATABASE for RESEARCHERS' USE

Contains de-identified questionnaire data, genetic/ biomarker results and relevant health records accessed from NHS and other organisations.

GENES AND BIOMARKERS

DNA is analysed to obtain genetic information. Biomarkers are measured in your blood.



What does joining the BioResource involve?

If you agree to join, we will ask you to:

- read and sign a consent form.
- provide samples of your blood (up to 20ml, equivalent to about 4 teaspoons) for research purposes. These samples will be taken at the same time as your routine donations throughout the study period and may be taken from your arm with a separate needle if your haemoglobin levels are slightly below the threshold for donating blood.
- complete health and lifestyle questionnaire online; this will be via an email link you will receive about 1 week after your donation. This will take approximately 30 minutes to complete.
- complete additional brief questionnaires (approx. 5 minutes) linked to your future blood donations over the study period.
- allow us to collect, store and analyse health information about you (including accessing your health, donor and other health-related records).
- agree to be contacted in the future by the BioResource teams and possibly be invited to give more samples or be involved in other research studies (you are under no obligation to accept the invitation).

Do I have to join the BioResource?

No, it is completely up to you whether or not you would like to join. You are also free to withdraw at any time without giving a reason.

Will my details be kept confidential?

Yes. Best ethical and legal practice will be followed to ensure that all information collected about you will be handled in confidence:

- your samples will be labelled with a unique sample study number (rather than your personal details) before being transferred to the laboratory for testing.
- information from tests will not be used or made available for any purpose other than for research in approved studies.
- any information from your blood sample will be stored separately from your personal details (e.g., name, date of birth, address, email address, donor number and NHS number).

Access to your personal details will only be available to key members of the BioResource teams at the University of Cambridge and NIHR BioResource (those who can have direct contact with you) so that they can invite you to take part in other studies, send you communications (e.g. newsletters) and access your health records. You will not be identified personally in any report or publication.

What will happen to the blood samples I give?

Your research samples will be processed and stored in a central NHSBT/NIHR BioResource-approved laboratory. We will:

- count different types of blood cells in your blood.
- store a sample of your DNA.
- separate your blood into serum and plasma for storage.

We may also study other components of your blood such as cells, RNA and proteins. Further analysis will allow us to:

- study your DNA to find out, for example, how genes may regulate blood cells and haemoglobin levels. We will also determine the sequence of part or all of your genetic information.
- measure biomarkers that reflect health status (for example, iron levels and cholesterol).

Your samples and data, including your genetic information, may be used in a number of future scientifically approved research projects.

De-identified samples collected as part of the BioResource may be used by approved researchers within hospitals, universities, non-profit organisations, industry or a company laboratory within and/or outside the UK and EU.

Who will be able to use my information?

The data generated during the study may be passed back to NHSBT and used to improve the provision of blood to NHS patients.

We will access details from your health, donor and other health-related records, including registers of deaths and cancers, held by, but not limited to, NHSBT, NHS Digital, Public Health England and other organisations to understand your current health and track this over many years. These records include medical tests and their results, diagnoses, treatments and visits to your GP or to hospital, as well as other relevant information. To access these records we will securely send your NHS number and other personal details to the relevant organisation to allow them to identify you and provide the requested information.

In addition, de-identified data about you will be stored in electronic data centres by the University of Cambridge and NIHR BioResource and made available only to approved researchers. This data may include:

- part of or all of your genetic information.
- results of other tests performed with your samples.
- information from the database for researchers’ use, including from health records obtained from the NHS, that **does not** identify you personally.

Who will be able to use my information? (cont.)

Researchers share the results of their studies by means of reports or publications, which includes placing results on the internet, in press articles, in project leaflets and through other media.

Researchers will have to make a request to access this data and explain how they will use it, for example, which research question they are trying to answer. This type of system is referred to as 'managed access'. 'Managed access' requests could come from researchers who are working in the public and charitable sector (universities, research institutes) or in commercial companies, either in the UK or overseas. Under no circumstances will information that identifies you personally be disclosed in any of these documents.

Can I know the results obtained from my study samples?

There are no plans to report back any research results to participants.

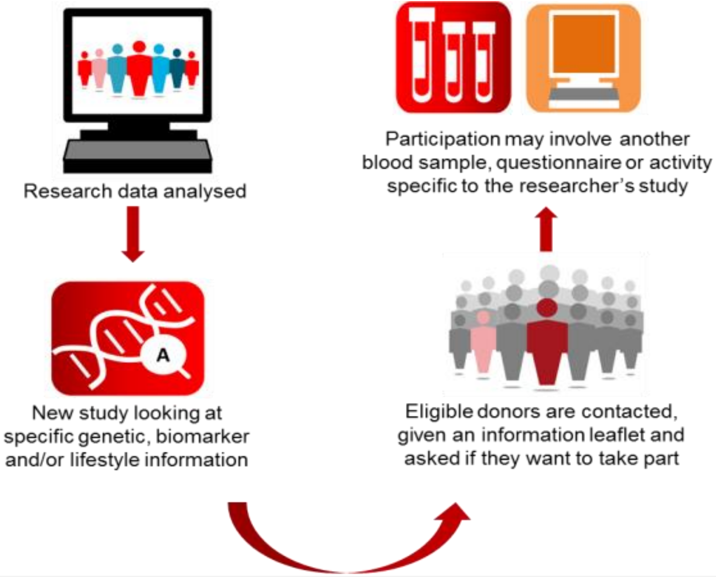
If you are contacted to take part in a future study, this does not mean that your health is at risk. All individuals carry both risk and protective DNA variants. We are a long way from understanding how they balance each other and what combination of variants interacting with other factors (such as age, gender, smoking and drinking habits) are needed to cause disease.

However, a test result would be communicated back to you, following clinical review, if it showed an atypical result requiring immediate medical treatment (like anaemia). Should this happen, we would contact you and your GP. They may wish to invite you to give a further blood sample that will be tested in an accredited laboratory. A repeat test would also be recommended at the next donation visit, to follow up, from a donor care point of view, any minor changes which are not deemed to be clinically significant but to ensure all changes are acted upon.

Invitation to future studies

In the future, a number of studies will be carried out based on the information stored in the BioResource databases. This may involve us inviting you to help in up to 8 other studies per year (with a maximum of 4 face-to-face). You will be provided with full information in advance regarding each study that requires you to do something and will be free to decide whether or not to participate at the time. These invites will come from the NIHR BioResource. The NIHR BioResource team will closely monitor the number of times you are approached and invited to future studies. The team greatly appreciate the effort made by volunteers and are happy to contribute towards travel/parking costs incurred by volunteers participating in studies. We may contact you with information about the progress of the BioResource through newsletters or open events, but you can choose **not** to receive such communications if you would prefer. These updates/open events will be organised by the study teams.

Being recalled for a future BioResource study



What happens if an invention is made using my samples?

Your donated samples and related information are given as an absolute gift, that is, without receiving a payment and without conditions. The BioResource is operating on a non-commercial basis, meaning it does not sell your samples 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 or to commercial companies, a fee may be charged to cover the BioResource operational costs.

What are the risks of joining the BioResource?

The risk of participants suffering harm as a result of taking part is minimal. Nevertheless, insurance is in place to provide compensation for any negligent harm caused by participation.

What if I no longer want to be a member of the BioResource?

You are free to withdraw from the BioResource at any time without giving a reason. If you choose to withdraw:

- it will not affect your blood donation with NHSBT.
- you will have the choice of how you would like to withdraw:

What if I no longer want to be a member of the BioResource? (cont.)

1) no further contact. This will allow for the continued use of existing samples for analysis and retrieval of health records in the future, but you will not be contacted further about the BioResource, so you will no longer receive newsletters, or be asked to participate in further research studies or to provide more samples.

2) no further use. All samples stored centrally will be destroyed and no new information will be collected from your health records. Any sample that has already been distributed for research cannot be retrieved or destroyed. Information already generated from your samples cannot be erased. It will not be possible to destroy samples already prepared or already distributed for testing. Your personal information will be retained in secure archives so that a record remains of your initial consent and the withdrawal process.

Who funds and sponsors the BioResource?

The STRIDES BioResource is funded by the University of Cambridge, NHSBT and NIHR BioResource. The STRIDES BioResource study is sponsored by NHSBT and is based in the UK. The NIHR BioResource is sponsored by the Cambridge University Hospitals NHS Foundation Trust and is based in the UK. We will be using information from you and/or your health-related records in order to undertake this study and NHSBT, University of Cambridge and Cambridge University Hospitals NHS Foundation Trust will act as data controllers for this study. This means that we are responsible for looking after your information and using it properly. Data will be processed by the University of Cambridge and Cambridge University Hospitals NHS Foundation Trust to conduct the study. For information on how we use your data, please see our privacy and confidentiality pages on the following websites: NHSBT, *https://www.nhsbt.nhs.uk/;* University of Cambridge, *http://www.strides-study.org.uk/;* NIHR BioResource *http://www.bioresource.nihr.ac.uk/*

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information by contacting the study team and/or by visiting the NIHR BioResource website using the information on the next page. When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations under the managed access process described above. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad.

Who funds and sponsors the BioResource? (cont.)

Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research**.** Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government. Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee. The STRIDES study has been approved by Cambridge South Research Ethics Committee (18/EE/0284).

Further information

If you have any concerns, complaints or want to withdraw from the BioResource, please get in touch.

Visit our website: www.strides-study.org.uk

Email us at: helpdesk@strides-study.org.uk

Phone the freephone number: 0800 021 7182 (Mon-Fri 0900h–1700h)

Alternatively, please send your letter to the STRIDES BioResource coordinator, University of Cambridge, Department of Public Health and Primary Care, Wort’s Causeway, Cambridge CB1 8RN.

If you wish to discuss your participation in the NIHR BioResource please contact: NIHR BioResource General enquiries:

email: nbr@bioresource.nihr.ac.uk or **by calling** 0800 090 2233

Thank you for considering joining the STRIDES BioResource, part of the NIHR BioResource.

STRIDES BIORESOURCE CONSENT FORM (DONOR COPY)

Chief Investigators: Professor Emanuele Di Angelantonio and Professor John Danesh,
University of Cambridge, NHS Blood and Transplant and NIHR BioResource

You need to tick all boxes from 1 to 10 to be eligible to take part in the BioResource

Donor Number: ________________________________

1. I confirm that I have read and understood the participant information leaflet dated 13.07.2020 (version 4.0) for the BioResource. I have had the opportunity to ask questions, and these have been answered fully.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and that this will not affect my routine blood donations.	
3. I understand and grant permission for relevant sections of my blood donation records to be retrieved and used by the BioResource teams. I agree for my personal details (e.g. name, address, DOB, phone number, email etc.) to be stored in secure databases and used to send me communications about the BioResource.	
4. I agree to donate a small sample of blood for use in health-related research and I give permission for long-term, de-identified storage of my blood samples (including cells and DNA) for health-related research purposes (even in the event of my incapacity or death). I relinquish all rights to these samples which I am donating to the BioResource. I understand that my de-identified samples may be used in research without my further permission.	
5. I agree that any data collected about me may be included in publications and/or placed in electronic archives with no connection to my name or other personal identifiers. I understand these data will only be accessible to researchers on application to ensure the results are only used to advance scientific and medical understanding.	
6. I give permission for the BioResource to access my health-related records now and in the future. I understand that information from my medical notes and other health-related records may be used to provide information about my health status and I give permission for long-term de-identified storage of this and other information about me for health-related research purposes (even in the event of my incapacity or death).	
7. I understand that none of my results (other than those which have an immediate impact on my health care) will be given to me and that I will not benefit financially from taking part (e.g., if research leads to commercial development of a new treatment or blood test).	
8. I understand the BioResource Team may contact me about health-related research studies, which I will be able to accept or decline on a case-by-case basis. I understand that this contact may be based on data held or accessed about me by the BioResource and the results of tests (including DNA markers) performed by the BioResource on my donated research samples. I will be provided with full information about these studies, when and if I am contacted.	
9. I confirm that I am 18 years or over.	
10. I agree to join the STRIDES BioResource, part of the NIHR BioResource.	

Participant first name and surname (PRINT):

Signature:

Date: