

PARTICIPANT INFORMATION SHEET**The NIHR BioResource Research Tissue Bank****Version 4.1 15th March 2023**

*If you require this information to be translated into another language or in a different format, please speak to a member of the BioResource team

We are inviting you to join the NIHR BioResource Research Tissue Bank, referred to as the 'BioResource'.

Many people live with health conditions such as diabetes, heart disease or mental health problems, which can have a major impact on their quality of life and on their family. We would like to invite you to join the BioResource, which supports research into health and medical conditions. Please read the following information carefully and discuss it with a friend or relative if you need to. Feel free to ask us if anything is not clear, or if you would like more information. You can also visit: <https://bioresource.nihr.ac.uk/>, which explains how to join the BioResource.

What is the BioResource?

The BioResource is a panel of hundreds of thousands of volunteers, with and without health conditions, who wish to participate in health research. The National Coordinating Centre is in Cambridge, with several BioResource centres around the country. Volunteers joining the BioResource are asked to donate a small blood or saliva sample and give consent to be invited to participate in health related research studies on the basis of data gathered from samples and information they have provided. Information and samples that the BioResource holds may also be made available to researchers working in biomedical and healthcare research. This extends the value of the BioResource enormously. More than half the studies we support just use samples and data we already hold.

The BioResource is a unique and powerful resource for studying disease mechanisms and for investigating the links between our genes, the environment, health and disease. Through the BioResource researchers can study diseases or identify treatments.

Why am I being asked to join?

The BioResource is recruiting volunteers, both with and without health conditions.

Do I have to join the BioResource?

No. It is completely up to you to decide whether or not you wish to join. If you decide not to join, your decision will not affect the healthcare you receive in any way. If you join, you will be free to withdraw at any time, without having to give a reason.

What will I need to do if I take part?

- Read and sign a consent form;
- Provide your name, date of birth, NHS/CHI number and contact details and allow us to store them;
- Complete a questionnaire about your health and lifestyle;
- Allow us to collect, store and analyse health information about you, including accessing your medical records, other health-related records, (for example, through NHS Digital or other databases), educational (if required) and social care records;
- Donate a small sample of blood (3-4 teaspoons) or saliva; in the future, you may be invited to provide further samples;
- Agree to be contacted in the future about research studies, including clinical trials, which we believe you are suitable for based on the information we hold. You will be provided with information about any study you are eligible for, and you can decide whether you would like to take part. You are under no obligation to do so. We will monitor how often you are approached. We are happy to contribute towards any travel costs. Some research will not need any further input from you as the samples and data you provide will be enough;
- Agree to be contacted by the BioResource about updates, newsletters, invitations to open events, etc. You can choose not to receive these if you prefer.

What are the disadvantages/risks?

Qualified, experienced staff will collect blood samples. Blood sampling can sometimes cause minor discomfort, and there is a possibility that a small bruise may develop.

What will happen to the samples I give?

We want to know how genes influence health and disease. Genes are made up of DNA (deoxyribonucleic acid). We will extract DNA from your blood or saliva sample and study your genetic makeup. We may also test other components of your blood, such as cells, RNA, protein and metabolites. Your samples will be kept in a secure location.

Will my details be kept confidential?

Yes. Best ethical and legal practices will be followed to ensure that all information collected about you will be handled safely and securely. Your personal details will never be released to researchers without your consent.

Your samples will be labelled with a unique number before being transferred to the laboratory for testing. Data about you (e.g. personal details and health information) will be stored in secure electronic databases. Any information from genetic and other tests or analyses will be stored separately from your personal details. Access to your personal details will only be available to authorised members of the BioResource (for example, to invite you to take part

in other research studies). Your samples and data can only be accessed by researchers once they've been de-personalised (i.e. with all identifying information removed).

Information from these tests will not be used or made available for any purpose other than for research.

Researchers can apply to access your samples or data, and they have to explain how they will use it, e.g. the research question they wish to answer. This is referred to as 'managed access'. Data may be accessed in a number of ways, for example, by logging in to secure data analysis environments or by downloading from the BioResource. Researchers will be reminded of their obligation to keep your data safe and secure by accepting the terms of a data transfer/access agreement. Researchers who analyse the information should not be able to identify you, and promise not to try to do so as a condition of data access.

'Managed access' requests could come from researchers from the public and charitable sector (Universities, Research Institutes) or from commercial and pharmaceutical companies. These can be based either in the UK or overseas.

The BioResource will request further details about you from public bodies, like the NHS (via NHS Digital or other registries) and the UK Health Security Agency. To do this, identifiable information, like your name, NHS number and date and birth, will be sent securely to these agencies, so that they can find you in their databases.

Researchers can share the results of their studies in reports or publications which are published on the internet and in press articles, etc. Under no circumstances will information that identifies you personally be disclosed in any of these documents.

An explanation of how the BioResource complies with the General Data Protection Regulation (GDPR) can be found at the end of this information leaflet.

The National Genomic Research Library

The National Genomic Research Library is a secure national database of de-identified genomic and health data that is managed by Genomics England, which is a company set-up by the Department of Health and Social Care. Approved researchers can use the samples and data in a form that does not identify you to study diseases and look for new treatments. Adding your personal health and genomic data to the Library helps by adding to others' data to make the Library a rich source of data for researchers. Everyone is unique and the more the Library holds, the better the outcomes for everyone.

If you agree to take part in the Library, we will provide basic identifiers such as your name, date of birth, postcode and NHS Number to NHS Digital and other organisations so that they may collate your medical history records and provide the data to the Library. All identifying information is removed before researchers are able to use it. Your data will be kept in secure

systems. Your data cannot be removed from the Library and any results of research that are taken out cannot be used to re-identify you.

Your data may include:

- Electronic copies of all your past and future records from the NHS, your GP and other organisations (such as NHS Digital and Public Health bodies);
- Information about any illnesses or stays in hospital;
- Copies of hospital or clinic records, medical notes, social care, and local or national disease registries, and data from other research studies;
- Relevant images from your NHS records, such as MRI scans, X-rays, or photographs;
- Data from other research registries and studies that may be relevant (but only where you have given them your permission to share that information).

Only researchers who are trying to better understand diseases and how to treat them will have access to the National Genomic Research Library. Researchers may come from all over the world, pooling international data and research gives the best chance of new discoveries. Approved researchers may work for not-for-profit organisations, such as research charities, universities, or hospitals, and for-profit (commercial) companies such as drug or technology companies. They will only have access to your de-identified genomic and health data in the National Genomic Research Library if they apply and are approved by Genomics England.

You can leave the Library at any time without giving a reason. You will need to sign a withdrawal form to record your decision. The form can be requested from Genomics England.

Can I know the results obtained from my study samples?

The BioResource does not provide a report or feedback on any genetic or laboratory results obtained from your sample, as it is taken for research purposes only.

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

We cannot answer this question. Many of the studies that the BioResource supports aim to discover variations in the genetic code ('genetic markers') that might predict the risk of certain diseases. However, it may be years before researchers can confirm how important or accurate these markers are and determine the associated risk.

If you are contacted to take part in a future study, this does not mean that your health is at risk. Genetic variation between individuals can both protect and put individuals at risk of disease. We are a long way from understanding how they balance each other and what combination of markers combined with other factors such as age, gender, smoking and drinking habits, increases the risk of disease.

Some of the studies the BioResource may invite you to take part in could reveal unexpected/previously unknown health conditions or future health risks. You will have the opportunity to confirm if you are happy to be invited to these studies at the time.

What happens if an invention is made using my sample?

Your donated samples and related information are given as a gift, which may help researchers in the public and commercial sector make an invention that could improve the future healthcare of patients and blood/organ donors, such as a new product to diagnose or treat a condition. If an invention results from the research undertaken with your sample, you will not receive any compensation, recognition or payment. The BioResource will not share your sample to make a profit. Published studies are available to view on the NIHR BioResource website <https://bioresource.nihr.ac.uk/studies/>

Withdrawal process

If you choose to withdraw, you have two options.

1. You can allow us to continue accessing your healthcare records (and any required social and educational records) from central NHS records, your hospital, your GP, school and/or research done with your sample. This is a 'no further contact' withdrawal.
2. You can ask us to stop further use of your data and to destroy your remaining samples. Any research that has used your data or sample(s) cannot be undone. This is 'no further use' withdrawal.

Your personal information will be retained in an archive so that a record remains of your initial consent and the withdrawal process. If the BioResource is unable to confirm your decision, your sample(s) and data will be retained for future use, and you will not be contacted again.

Who funds and manages the BioResource?

The BioResource is funded by the National Institute for Health and Care Research (NIHR). The Research Tissue Bank has been reviewed and given a favourable opinion by the East of England - Cambridge Central Research Ethics Committee.

The BioResource is led by Professor John Bradley (Chief Investigator) and Nathalie Kingston PhD (Director). The organisation responsible for the management of the NIHR BioResource Research Tissue Bank is Cambridge University Hospitals NHS Foundation Trust.

Further information

If you require further information before deciding to join the BioResource, or have any queries, please feel free to contact the BioResource team on 0800 090 2233 or email us on nbr@bioresource.nihr.ac.uk.

Thank you for reading this information sheet and for considering joining the BioResource.

General Data Protection Regulation (GDPR)

Here, we explain how we comply with the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679). Please also read our <https://bioresource.nihr.ac.uk/media/04nhduml/privacy-notice-v2.pdf>, which explains what we do with the information we hold about you, how you can request access to this personal data, and other data rights.

[Cambridge University Hospitals NHS Foundation Trust \(CUH\)](#) is responsible for managing the NIHR BioResource Research Tissue Bank.

We will be using information from you, and your healthcare, social care and education (if required) records in order to support research studies, and CUH will act as the data controller for the information we hold. We are responsible for looking after your information and using it properly.

Cambridge University Hospitals NHS Foundation Trust will keep identifiable information about you for 10 years after the study has finished, and we may approach you to extend this.

How will we use information about you?

We, the NIHR BioResource, will use information from you, from your medical records, including from your GP, hospital records and other health-related central records for this research project. The NIHR BioResource will also access your social care and if required, your education records.

This information will include your:

- Full name;
- NHS/CHI number;
- Date of birth;
- Contact details, including address, phone number and email address;
- Name and contact details of your GP;
- Health-related information, e.g., on your lifestyle, disease history, medication etc;
- Social care and education information, e.g., level of education;
- Genetic information that will be generated from your blood or saliva samples or provided by, for example, NHS health-related central records, disease registries etc.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name, NHS/CHI number, date of birth or contact details (which are your “personal identifiable information”). Your data will have a code number instead.

We will keep all information about you safe and secure.

Information about you, but not your personal identifiable information, will be sent to researchers in other countries worldwide. They must follow our rules about keeping your information safe.

If and when the NIHR BioResource finishes, we will keep some of the data so we can check the results. We will write our reports in a way that ensures no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason;
- If you choose to stop taking part in the study, you have two options as outlined in the ‘Withdrawal process’ section. Further information on leaving the BioResource can be found here: <https://bioresource.nihr.ac.uk/participants/members/leave-us/>;
- You may request a copy of the information we hold about you;
- We need to manage your records in specific ways for the research to be reliable. We will be able to change some of the information we hold about you (for example, your contact details and contact preferences) if you ask us to; however, we won’t be able to let you change other data we hold about you (such as your genetic information).

Where can you find out more about how your information is used?

You can find out more about how we use your information

- At www.hra.nhs.uk/information-about-patients/
- Our privacy notice available from <https://bioresource.nihr.ac.uk/media/04nhduml/privacy-notice-v2.pdf> which includes the contact details of the Data Protection Officer at CUH;
- By asking one of the research team;
- By sending an email to nbr@bioresource.nihr.ac.uk;
- By calling us on Freephone 0800 090 2233.

Attach barcode here

PARTICIPANT CONSENT FORM
The NIHR BioResource Research Tissue Bank
Version 4.1 15th March 2023

Please
initial box

1. I confirm that I have read (or had read to me) the information sheet 15/MAR/2023 version 4.1. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected.
3. I agree that the BioResource may access my medical, health, social care, and educational (if required) records held by public bodies, and to analyse and store this information long-term. I understand that this may include the provision of information about my health status. I understand that in order to access these records, identifiable personal details – like name, NHS number, date of birth will be sent to these public bodies.
4. I agree to give blood or saliva for health related research. I understand that my samples may be shared to support future research, including commercial studies. I understand my samples will be tested, and that this may include the reading of my entire genetic code. I understand my sample will be stored long-term.
5. I agree to provide personal and contact details. I agree to provide information for example, through the completion of questionnaires. I agree to be contacted by the BioResource to invite me to participate in other research studies.
6. I understand that relevant sections of my medical/health related, social care and education (if required) records and data collected during the study may be looked at by approved individuals for auditing and monitoring purposes. I give permission for this.
7. I understand my samples and de-personalised data may be shared with researchers through a 'managed access' process.

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8. I understand that my samples are taken for research, and the BioResource will not feed back any genetic or other test results.

9. I agree to join the NIHR BioResource Research Tissue Bank.

CONSENT TO THE NATIONAL GENOMIC RESEARCH LIBRARY
OPTIONAL: Please put your initials in ONE box only

This section gives you the choice to join the National Genomic Research Library

10. I understand that my data will be held by the National Genomic Research Library and I give my permission for researchers to access my data for approved research. I understand I can withdraw from the National Genomic Research Library at any time. I agree for my data to be held by the National Genomic Research Library. Please initial the box.

OR

I DO NOT want my data to be held by the National Genomic Research Library. Please initial box.

.....			
Participant: First Name and Surname (BLOCK CAPITALS)	Date of Birth	Signature	Date
.....			
.....			
Person receiving consent: First Name and Surname (BLOCK CAPITALS)		Signature	Date

FOR WITNESS AND/OR TRANSLATOR USE ONLY

WITNESS/TRANSLATOR STATEMENT: If participant is not able to read the text and/or sign for themselves but has capacity to give consent OR if the Participant Information Sheet and Consent Form has been translated.

Witness/translator [to delete either as appropriate]:

I witnessed accurate reading of the consent form to the potential participant, who could ask any questions and received satisfactory answers

or

I was present during the meeting between [insert name] and the participant. I translated for the participant the Participant Information Sheet and the Consent Form.

I confirm that they gave their consent freely.

.....
Witness/translator: First Name and Surname
(BLOCK CAPITALS)

.....
Signature

.....
Date