

**Participant Information Sheet**  
**NIHR BioResource Centre Newcastle**  
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In England around one third of the population lives with a long term health condition such as diabetes, heart disease or mental health conditions. Living with a chronic disease has a major impact on a person's quality of life and on their family. The NIHR BioResource Centre Newcastle as part of the NIHR BioResource has been set up to help research health and medical conditions. We would like to invite you to join the NIHR BioResource. Please take the time to read the following information carefully and feel free to ask us if there is anything that is not clear or if you would simply like more information.

**What is the purpose of the NIHR BioResource?**

The NIHR BioResource is made up of a number of local BioResources around the country (including Newcastle) and consists of a panel of thousands of volunteers who are willing to help with research. The NIHR BioResource National Coordinating Centre Headquarters is based in Cambridge. Volunteers joining the panel will be asked to donate a small blood or saliva sample along with some health and lifestyle information. Participants will give their permission (consent) to be invited to participate in medical research studies on the basis of data gathered from the samples and information they have supplied. Information and samples from the NIHR BioResource may also be made available to other scientists working in medical research locally, nationally, and even internationally.

The NIHR BioResource is supporting studies looking at how genes and other factors influence disease. By gaining more information on the genes involved in disease we can begin to identify better treatments to reduce the effect of the disease or even cure it. A more complete understanding may enable researchers to prevent some diseases occurring altogether in the future.

**TAKING PART**

**Who can join the NIHR BioResource Centre Newcastle?**

The NIHR BioResource is recruiting volunteers with and without health conditions. By joining, you will be helping researchers investigate and understand why some individuals have a disease.

**Do I have to join the NIHR BioResource?**

It is completely up to you. If you decide not to join your decision will not affect the healthcare you receive in any way. If you agree to join, you will be free to withdraw at any time and without having to give a reason.

**What will happen if I agree to join the NIHR BioResource Centre Newcastle and NIHR BioResource?**

If you agree to join, you will be asked to

- Read and sign a consent form
- provide your name, date of birth, NHS number and contact details (including email and mobile if available and allow us to store them,
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- donate a small sample of blood (3-4teaspoons) or saliva. **We can arrange for your sample to be collected in a health care/clinical research facility near to where you live or work.**
- Complete an questionnaire about your health and lifestyle (online or paper)
- Allow us to collect store and analyse health information about you (including accessing your medical or other health-related records, for example through NHS Digital)
- Agree to be contacted in the future to be involved in other research studies. We will use your blood/saliva sample, and additional information, to match you to research studies that are looking for volunteers. If you meet the selection criteria for a study we may invite you to take part, but you are under no obligation to do so.

In the future you may be invited to provide a further small sample of your blood, or other further samples, if the initial sample you provided was insufficient for certain types of testing. DNA will be isolated from your sample and will be used to determine your genetic make-up.

## SAMPLES

### What will happen to the samples I give?

Your sample will be sent to the NIHR BioResource Research Tissue Bank to be stored in a secure central storage facility in Milton Keynes. Samples may also be stored in Newcastle University at secure storage locations prior to being used, or before being sent to Milton Keynes. Your information will be provided along with the samples and will be collated by the NIHR BioResource Centre Newcastle and NIHR BioResource Research Tissue Bank Headquarters in Cambridge.

We want to know how genes influence disease. Genes are made up of DNA. We will isolate, analyse and store a sample of your DNA from your donated blood or saliva sample and, using advanced laboratory techniques, some that are available now and some which may be developed in the future, we will determine your genetic makeup. This may include determining the sequence of part of or even all of your DNA code. We may also isolate and test other components of your blood such as cells, RNA, protein and metabolites.

Researchers may seek access to your samples and related data, but your personal details will never be released to researchers without your knowledge and permission.

## DATA AND COMMUNICATION

### 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 the strictest confidence. Your data will be stored on secure, password-protected NHS computers located in lockable offices with restricted access.

Your samples will be labelled with a unique sample study number before being transferred to the laboratory for testing and information from genetic and other tests will be stored separately from your personal details. Access to your personal details will only be available to necessary members of NIHR BioResource staff, and IT staff that manage our database. Information from these tests will not be used or made available for any purpose other than for research. You will not be identified personally in any report or publication.

### **What will happen to any data produced from the samples I give?**

Anonymous data about you may be stored in an electronic archive and made available to researchers. This data may include part of, or your entire DNA code, or the results of other tests performed with your samples and other information from the research database that does not identify you personally, e.g. your age and gender.

Researchers will have to make a request to access this data and explain how they will use it, e.g. which research question they are trying to answer. This type of system is referred to as 'managed access'. Genuine researchers will be given access to the data for their research, and they will be reminded of their obligation to keep your data safe by accepting the terms of a secure data transfer/access agreement.

'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. Researchers share the results of their studies by means of reports or publications, which includes placing information/data on the internet, in press articles, in project leaflets and through other media. Under no circumstances will information that identifies you personally be disclosed in any of these documents.

### **Transparency Statement under General Data Protection Regulation (GDPR)**

The Newcastle upon Tyne Hospitals NHS Foundation Trust is responsible for managing the NIHR BioResource Centre Newcastle part of the national NIHR BioResource Research Tissue Bank. The Cambridge University Hospitals NHS Foundation Trust is responsible for managing the NIHR BioResource- Research Tissue Bank based in the United Kingdom. Both the NIHR BioResource Centre Newcastle and the NIHR BioResource- Research Tissue Bank will be using information from you and your medical records in order to undertake these studies and will act as the data controllers. This means that we are responsible for looking after your information and using it properly. We will keep identifiable information about you for 10 years after the study has finished (to March 2032 in the first instance), and we may approach you to extend this.

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 at URL: <https://bioresource.nihr.ac.uk> or by contacting: [nbr@bioresource.nihr.ac.uk](mailto:nbr@bioresource.nihr.ac.uk)

Newcastle upon Tyne Hospitals NHS Foundation Trust will collect information from you and your medical records for this research study in accordance with the NIHR BioResource Research Tissue Bank instructions.

Your local NIHR BioResource Centre Newcastle will use your name, NHS number and contact details including address, phone number and email address (where available) to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the NIHR BioResource (which is managed by the Cambridge University Hospitals NHS Foundation Trust) and regulatory organisations may look at

your medical and research records to check the accuracy of the research study. The NIHR BioResource Centre Newcastle will pass these details to NIHR BioResource along with the information collected from you and/or your medical records.

The only people in NIHR BioResource who will have access to information that identifies you will be people who need to contact you to send newsletters, invite you to events such as open days, or invite you to further studies, or audit the data collection process. The people who analyse the information will be told not to attempt to identify you and will not be given your name, NHS number or contact details.

The NIHR BioResource will collect information about you for research from medical records, health registries and sometimes we will ask you to complete questionnaires. This information will include your name, NHS number, contact details and health information, which is regarded as a special category of information. We will use this information to try to elucidate the causes of common and rare disease, and generate faster ways to diagnose patients.

Your information could be used for research in any aspect of health or care, and could be combined with information about 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.

### **Invitation to future studies**

The NIHR BioResource supports many different research studies. We may, on the basis of the information held in the research database, contact you to ask whether you would like to take part. Recall to future studies may be co-ordinated centrally (via Cambridge) or locally (via Newcastle). You will be provided with information regarding each of these studies and will be free to decide whether or not you want to take part.

Some research will not require any further input from you as the sample, the data generated from your sample and the information you provided or give us access to when you joined can still be used for research purposes.

### **How often will I be contacted?**

We closely monitor the number of times you are invited to future studies. The maximum number of invitations to studies will be 4 each year although it is likely to be a lot less.

We may also contact you with information about the progress of the NIHR BioResource Centre Newcastle and NIHR BioResource through newsletters or open events.

## RISKS AND BENEFITS OF JOINING

### **What are the risks and disadvantages of joining the NIHR BioResource Centre Newcastle and NIHR BioResource?**

Joining the NIHR BioResource will involve donating a small sample of your blood or saliva. Qualified, experienced staff will collect the blood sample but blood sampling can cause some discomfort when the needle is placed in the vein and the blood is drawn. There is also a possibility that a small bruise may develop. Other than this there are no risks.

### **What are the benefits of joining the NIHR BioResource Centre Newcastle and NIHR BioResource?**

There will be no direct benefit to you but you will be making a contribution to science and there may be a benefit to the future development of healthcare provision.

### **Can I know the results obtained from my study samples?**

The NIHR BioResource does not intend to undertake analysis of data generated by genotyping or sequencing of DNA samples collected at the time of enrolment to identify variants that may have clinical significance, and hence does not plan to provide feedback of genetic findings. We will notify you if this changes.

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

We cannot answer this question. Many of the studies that will be carried out using these samples aim to discover variations in the genetic code (so called genetic markers) that might predict the risk of certain diseases. However, it may be years before we 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. All individuals carry risk and protective DNA variants in their genes, and 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 and drinking habits, etc. cause disease.

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

Your donated samples and related information are given as an absolute gift, i.e. without receiving a payment and without conditions. The NIHR BioResource operates 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 any samples 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.

In the future, your sample may help researchers in the public and commercial sector to make an invention, for example, develop a new product to diagnose or treat a disease. If an invention results from the research undertaken with your sample, you will not receive any compensation, recognition or payment. In any case, your contribution is very likely to be the result of hundreds if not thousands of other individuals' help with the BioResource and working out the individual contribution would be extremely difficult. BioResource partners in the public sector may work together with commercial companies to develop inventions for the benefit of patient and donor care, and we hope that such products are brought into use to improve healthcare in the future.

## WITHDRAWAL PROCESS

### What if I no longer want to be a member of the NIHR BioResource Centre Newcastle?

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

- You will be asked to specify whether you would like us to destroy the sample(s) you have donated and which are stored at the central archive.
- It will not be possible to destroy samples already prepared or already distributed for testing.
- Your personal information will be retained in an archive so that a record remains of your initial consent and the withdrawal process.
- Should you wish, no further data will be retrieved from your health-related records and no new data from laboratory measurements will be added to the research databases; pre-existing data will not be used in further analysis wherever possible.
- Pre-existing data and data that has already been distributed to other researchers cannot be destroyed.
- Once confirmation of your decision to withdraw is received, you will not be contacted again by the NIHR BioResource or NIHR BioResource Centre Newcastle.
- If the NIHR BioResource or NIHR BioResource Centre Newcastle is unable to confirm your decision, your sample(s) and data will be retained for future use, but you will not be contacted again.

## FUNDING AND SPONSORSHIP

### Who funds and sponsors NIHR BioResource Centre Newcastle?

NIHR BioResource Centre Newcastle is part of the NIHR Newcastle Biomedical Research Centre, a partnership between the Newcastle upon Tyne Hospitals NHS Foundation Trust and Newcastle University. NIHR BioResource Centre Newcastle has been reviewed and approved by Newcastle and North Tyneside Research Ethics Committee 1.

The NIHR BioResource is funded by the National Institute for Health Research (NIHR). The study has been reviewed and approved by East of England - Cambridge Central Research Ethics Committee.

Cambridge University NHS Foundation Trust is the establishment responsible for the management of the NIHR BioResource – Research Tissue Bank.

### Further information

If you want more information before deciding or have any queries, please feel free to contact the NIHR Bioresource Centre Newcastle team on (0191) 208 5001 or [NewcastleBioresource@ncl.ac.uk](mailto:NewcastleBioresource@ncl.ac.uk).  
<https://www.newcastlebrc.nihr.ac.uk/nihr-newcastle-bioresource/>

Thank you for considering joining the NIHR BioResource.

### What do I do if there is a problem?

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff due to your participation in the research, NHS and

Newcastle University complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this. If you prefer to raise your concerns with someone not involved in your care, you can contact the Patient Advice and Liaison Service (PALS). This service is confidential and can be contacted on Freephone: 0800 032 0202

Alternatively, if you wish to make a formal complaint you can contact the Patient Relations Department through any of the details below:

Telephone: 0191 223 1382 or 0191 223 1454

Email: [patient.relations@nuth.nhs.uk](mailto:patient.relations@nuth.nhs.uk)

Address: Patient Relations Department

The Newcastle upon Tyne Hospitals NHS Foundation Trust

The Freeman Hospital

Newcastle upon Tyne

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