PARTICIPANT INFORMATION SHEET
NIHR BIORESOURCE

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In England around 30% of the population are said to be living 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 BioResource, has been set up to help in the fight against disease. 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 comprises of a number of local BioResources around the country and consists of a panel of thousands of volunteers who are willing to help with research looking into the links between genetic make-up and disease. 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 and give consent to be invited to participate in medical research studies on the basis of data gathered from samples and information they have supplied. Information and samples from this resource may also be made available to other scientists working in biomedical and healthcare research.

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.

Who can join the NIHR BioResource?

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 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 wish/agree to join, you will be free to withdraw at any time and without having to give a reason.

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What will happen if I agree to join the NIHR BioResource?

If you agree to join, you will be asked to sign a consent form and provide a small sample of your blood (3-4 teaspoons) or saliva. **We can arrange for your sample to be collected in a health care/clinical research facility near to where you live/work.** In the future you may be invited to provide a further small sample of your blood, or 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. You will also be asked to provide your contact details and answer a short questionnaire about your health and lifestyle. Further relevant information about your health may be obtained from your medical records and other health-related records. 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.

What will happen to the samples I give?

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 available now or to be developed in the future, we will determine your genetic makeup. This may include determining the sequence of all or part 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. Your samples will be kept in a secure location.

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 in years, your 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 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.

Invitation to future studies

The BioResource supports many different research studies. We may, on the basis of the data held in the research database, contact you to ask whether you would like to take part. You will be provided with information regarding each of these studies and will be free to decide whether or not to participate.

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

How often will I be contacted?

We closely monitor the number of times you are approached and invited to future studies. We 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 communication if you would prefer.

What are the risks and disadvantages of joining the NIHR BioResource?

Joining the 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.

What are the benefits of joining the 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.

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 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. 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.

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.

The only scenario where a test result would be communicated back to you would be if tests showed an atypical result requiring immediate medical treatment (e.g. anaemia). Should this happen we would contact you, and your GP or clinical care team. They may wish to invite you for a further sample that will be tested in an accredited laboratory.

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 BioResource is operating on a non-commercial basis, meaning it does 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 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. 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.

What if I no longer want to be a member of the NIHR BioResource?
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 BioResource.
- If the BioResource is unable to confirm your decision, your sample(s) and data will be retained for future use, but you will not be contacted again.

Further information
If you want more information before deciding or have any queries, please feel free to contact the NIHR Bioresource team on **01223 769 215** or e-mail us on cbr@bioresource.nihr.ac.uk.

Thank you for considering joining the NIHR BioResource.