

## HUMAN BIOMATERIALS RESOURCE CENTRE

### Healthy Volunteer Information Sheet (over 18s)

#### Introduction

- The Human Biomaterials Resource Centre (HBRC) is a 'tissue bank' (also called a 'biobank' or 'bioresource'). It collects and stores human samples in a secure environment for ethically approved biomedical research.
- This information sheet explains what happens when a sample is donated to the HBRC. Please take time to read it carefully and ask if anything is not clear. If you have any questions at a later date, please contact us using the details at the bottom of this sheet.

#### Why do scientists need samples from healthy individuals?

Scientists study human tissues, cells and body fluids from patients with particular diseases in order to identify reliable 'markers' which may help with diagnosis, or otherwise prove valuable for predicting how diseases progress or respond to treatment. In most settings it is also vital for scientists to have access to samples from healthy individuals, so that data about the normal levels of these markers can be used for comparison.

#### What are we asking you to do?

- We are inviting you to donate one or more samples to the HBRC. Typically, these will be a blood sample or a small amount of urine or saliva. We will normally ask for about 30ml of blood (about 2 tablespoons), and the sample will be collected by a trained phlebotomist, research nurse or doctor. It will take about 10 minutes. The maximum amount we ask for is 120ml (about 8 tablespoons), but this is only when we have had a request to support a specific research project.
- Very occasionally, and only when there is a specific research need, we may ask to collect a small amount of skin. Small biopsies or 'tape-strips' will always be taken by a suitably trained member of staff, and only using NHS-approved equipment.
- It is possible that we will contact you again in the future to ask whether we can take further samples. However, we will only do this if you are well and are completely happy to donate again. You are free to say no at any time. We will keep a record of all samples that you give.
- We will also ask you to complete a short questionnaire about your medical history and your health in general. You are free to fill in as little or as much of this questionnaire as you are prepared to.
- We will ask for your permission to do this using a consent form. You will be given a copy to keep. Please also keep this information sheet to remind you of what you were asked to do, and why.

#### What will happen if you agree?

- When your sample arrives at the HBRC, a member of staff will assign it a unique sample code. The link between the sample code and your identity will be retained securely within the University under restricted access.
- Samples may be released straightaway to an approved research project, or stored in the HBRC until required.
- Samples may be released for genetic studies, but only to research projects aimed at providing clues to the nature of disease, or if it is already known that genes are important.
- Samples may also be used to support ethically approved biomedical research which uses animals, but only when this is absolutely necessary and experiments cannot be performed in any other way. Animal models can be invaluable for increasing our understanding of disease and advancing treatments.
- Sometimes scientists need to grow cells in a culture dish for a long time and again, this type of approach can be invaluable for biomedical research.
- All information about you will remain confidential and will be stored in accordance with the UK Data Protection Act 2018.
- No information will ever be released to an insurance company, used to sell you anything, or given to other organisations except for the purposes of biomedical research.
- Scientists receiving your samples will **NOT** be provided with any personal information such as your name, address or phone number. The information received will relate to your medical history and general health only, and **NOT** your identity.
- Your samples and associated information from your health records will be used mainly by local scientists, but they may also be made available to scientists outside of Birmingham, elsewhere in the UK or overseas. Scientists may work in universities, hospitals or private/commercial companies that carry out biomedical research. Commercial collaborations are vital for the development of suitable drugs and treatments.

- You will not receive any personal financial reward for your donation, and the samples you have gifted will never be 'sold' for profit. However, we will ask scientists to cover some of the costs incurred in sample collection and storage.
- Participation in the HBRC is 'enduring', i.e. we can receive donations from you until you withdraw. This does **NOT** mean that you must donate – just that there is no need for you to re-consent.
- However, if you lose mental capacity in the future, we will expect someone to inform us, so that we can ask a 'consultee' to advise whether your existing samples and associated information should be destroyed or retained.

### **Do you have to agree?**

**NOT AT ALL.** It is entirely up to you. You do not have to donate a sample or give a reason for choosing not to.

### **What happens if you change your mind?**

- You can withdraw consent at any time by contacting your doctor or the HBRC directly (details below). You do not have to give a reason why.
- If you tell us you have changed your mind, this will not affect your care or treatment in any way, now or in the future. All samples held in the HBRC will be destroyed in the way human samples are normally destroyed by hospitals. Similarly, any information we store about you will be deleted (apart from records allowing us to trace your samples' history). We will contact any research groups using your samples and ensure that any unused samples and associated information are destroyed.
- If you change your mind after a long period of time, the samples and associated information may already have been used. Unfortunately, we cannot recall samples or associated information from scientists if this is the case.

### **What are the benefits to you?**

It is unlikely that there will be any direct benefit to you, since it takes many years for research to produce advances in the way diseases are diagnosed, treated, or prevented. You can benefit from the knowledge that research will make faster progress if more human samples are studied, and you are personally contributing to this, particularly as a healthy volunteer.

### **What are the risks to you?**

Taking a blood sample can sometimes cause discomfort and even bruising. We only allow doctors, research nurses, or trained phlebotomists to take the blood sample to minimise the risk of discomfort. Otherwise, there is **NO** increased risk to your health. Your identity will remain confidential, and when we provide samples to scientists, they will be obliged to use the samples only for the research declared in their ethical approval. They will be bound by a strict agreement to ensure this.

### **Can you find out the results?**

- The development of reliable new clinical tests takes many years, so the HBRC will not routinely report individual research results. You can find out more generally about the types of research projects using your samples by contacting us using the details below. You can also ask to visit us the same way.
- As a healthy volunteer, it is very unlikely that research using your samples will generate a clinically significant result. If it does happen, we will contact you and advise you to contact your GP.

### **Our contact details**

The General Manager, Human Biomaterials Resource Centre, College of Medicine and Health, University of Birmingham, Edgbaston, Birmingham B15 2TT (07584 312396; [hbrc-tissuebank@contacts.bham.ac.uk](mailto:hbrc-tissuebank@contacts.bham.ac.uk)).

If you have a concern or complaint about the HBRC, please contact the Research Ethics Governance & Integrity Team, College of Medicine and Health, University of Birmingham, Birmingham B15 2TT ([researchgovernance@contacts.bham.ac.uk](mailto:researchgovernance@contacts.bham.ac.uk)).