HUMAN BIOMATERIALS RESOURCE CENTRE
Nominated Consultee Information Sheet

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. Scientists need human samples to find out how diseases start, and to find new ways of diagnosing and treating illnesses.
- 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 have you been approached, and what are we asking you to do?

- Unfortunately, some of our patients do not have the capacity to make decisions because of their condition or illness. We consider it important that they have the chance to contribute to relevant biomedical research.
- The patient has been identified as having a condition or disease that scientists are currently researching, or which is considered rare. We ask for samples, in order to make sure we have enough for research now, and in the future.
- The HBRC has been approved by an NHS Research Ethics Committee and we want to make sure that sample donation does not cause any undue distress.
- You may be someone who already knows the patient, working with them as a paid carer, or working in a professional capacity (such as a doctor or solicitor).
- We would like advice from you regarding the wishes and feelings of the patient about donating samples to the HBRC (or whether they would like to continue doing this, if they have agreed in the past but have lost capacity since). In doing this, you are known as a ***Nominated Consultee***.

What are we asking of the patient?

- The HBRC would like to collect one or more samples. These may be tissue, blood, or other types of body fluid which would normally be disposed of, or which are surplus to diagnostic requirements and obtained from the hospital pathology laboratories.
- On some occasions, we may ask for a small additional sample: for example, an extra blood sample, or a small piece of extra tissue during surgery. We will only ever ask to collect additional samples if it is safe and easy to do so, and there is a specific research need.
- Sometimes research projects require serial blood or urine samples, or for samples to be taken at a certain time point, so that the progress of disease can be monitored. In these instances, we may ask to collect samples on more than one occasion.
- The HBRC would also like to access the patient’s health records. This is because information about their medical conditions and treatments (now, and in the longer term) is scientifically useful in research. This includes long-term follow up information held by, for example, the Office of National Statistics.

What will happen to the samples and data?

- When a sample arrives at the HBRC, a member of staff will assign it a unique sample code. The link between the sample code and the patient’s identity will be retained securely within the NHS.
- Samples will only be released to projects where the research is related to condition causing the patient’s capacity problems and where it is not practical to use patients who are able to give consent themselves.
- 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 researchers 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 the patient 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 the patient anything, or given to other organisations except for the purposes of biomedical research.

- Researchers receiving the patient's samples will **NOT** be provided with any personal information such as the patient's name, address or phone number. The information received will relate to the patient's disease, treatment and medical history only and **NOT** their identity.
- The patient's samples and associated information from health records will be used mainly by local researchers, but they may also be made available to researchers outside of Birmingham, elsewhere in the UK or overseas. Researchers 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.
- The patient will not receive any personal financial reward for their donation, and the samples they have gifted will never be 'sold' for profit. However, we will ask researchers to cover some of the costs incurred in sample collection and storage.
- Participation in the HBRC is 'enduring', i.e. we can request donations from the patient until you or they withdraw. This does **NOT** mean that they must donate at every hospital visit – just that there is no need for re-consent every visit.

What happens if you change your mind, or if the patient regains capacity?

- While the patient has reduced capacity, you can withdraw your advice at any time by contacting the HBRC directly (details below). You do not have to give a reason why.
- If the patient regains capacity, we expect staff to invite them to give informed consent themselves. This will override any advice that you have given. The patient does not have to give a reason for not consenting.
- If you tell us you have changed your mind (while the patient has reduced capacity), or if the patient regains capacity and declines to consent, it will not affect the patient's 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 the patient will be deleted (apart from records allowing us to trace the samples' history). We will contact any research groups and ensure that any unused samples and associated information are destroyed.
- If you change your mind after a long period of time, or if the patient regains capacity and declines to consent after samples have already been used in research, unfortunately, we cannot recall those samples or information associated with them.

What are the benefits to the patient?

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

What are the risks to the patient?

As far as we know there are **NO** increased risks to the patient's health associated with donating samples to the HBRC. Samples will only be collected when it is safe to do so. The patient's identity will remain confidential, and when we provide samples to researchers, 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.

Will anyone find out the results?

- The development of reliable new clinical tests takes many years, so the HBRC will not routinely report individual research results. Both the patient and you can find out more generally about the types of research projects using the donated samples by contacting us as detailed below. You can also ask to visit us the same way.
- If a research project using the patient's samples generates clinically important information, then a doctor, or another member of the healthcare team, will make contact. They may wish to discuss how the information could guide treatment for the patient's current condition or for other conditions (possibly hereditary) which may affect them and their family.

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).

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).