HUMAN BIOMATERIALS RESOURCE CENTRE

Parent/Guardian 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 if your child donates 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 are we inviting your child to participate?

- Your child has been identified as having a condition or disease that scientists are currently researching, or which is considered rare. Scientists need lots of samples from people with diseases to carry out biomedical research. We ask many people to give us samples, in order to make sure we have enough for research now, and in the future.

What are we asking your child to do?

- We are inviting your child to donate one or more samples to the HBRC. A sample may be tissue, blood or another body fluid.
- Usually, we will ask for samples that have already been, or will be, collected as part of your child’s routine care. These samples may be ‘leftovers’ from diagnostic tests and stored within the hospital pathology laboratories, or they may be ‘waste’ samples produced during surgical or clinical procedures and then normally discarded. These ‘leftover’ and ‘waste’ samples can be extremely useful for scientists.
- On some occasions, we may ask for a small additional sample: for example, an extra blood sample, or small piece of extra tissue. Additional samples will only be collected at the same time as a routine procedure, so they should not involve any extra pain, discomfort or inconvenience. 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. **NO-ONE** should feel forced to agree to collection of additional samples on any occasion.
- 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 your child’s disease can be monitored. In these instances, we may ask your permission for a sample on more than one occasion. **NO-ONE** should feel forced to agree to collection at any time.
- We would also like permission to access your child’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 information held by, for example, the National Cancer Registry and the Office of National Statistics.
- We will ask for permission 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.

Who gives consent?

Legally, anyone under the age of 18 may give consent to the storage and use of their samples for research if they are ‘competent’. If your child is willing and able to give consent, then they can. We will usually ask you to consent as well if your child is under 16. Some children might prefer a parent/guardian to give consent, even if they are ‘competent’. Alternatively, there may be some doubt over whether they understand what is involved. If a child is not ‘competent’ to give consent, or they prefer a parent/guardian to give consent, then the parent(s) or legal guardian(s) can give consent on the child’s behalf.

What will happen if consent is given?

- When your child’s sample arrives at the HBRC, a member of staff will assign it a unique sample code. The link between the sample code and your child’s identity will be retained securely within the NHS.
- 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 your child 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 anything to you/your child, or given to other organisations except for the purposes of biomedical research.

- Scientists receiving your child’s samples will **NOT** be provided with any personal information such as their name, address or phone number. The information received will relate to your child’s disease, treatment and medical history only and **NOT** you or your child’s identity.
- Your child’s samples and associated information from their 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.
- Neither you nor your child will receive any personal financial reward for the donation, and the samples 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 request donations from your child until they (any age) or you (before their 16th or sometimes 18th birthday) withdraw consent. This does **NOT** mean that they must donate at every hospital visit – just that there is no need for re-consent every visit.
- However, if your child currently has reduced mental capacity, or it is reduced after their 16th birthday, please ensure we are informed, so that they (all ages), you (before or after their 18th birthday), or another consultee (after their 18th birthday) can advise us whether to store or retain existing samples and associated information after their 16th and/or 18th birthdays.

Do you have to agree?

NOT AT ALL. Your child does not have to donate a sample, and neither of you needs to give a reason for choosing not to. Whatever the decision, it will not affect your child’s care or treatment in any way, now or in the future.

What happens if I change my mind, my child changes their mind, or disagrees with my decision when they are older?

- You or your child can withdraw consent at any time by contacting the hospital doctor or the HBRC directly (details below). Neither of you needs to give a reason why.
- If you or your child withdraws consent, this will not affect your child’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 your child 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 consent is withdrawn 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 your child?

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

What are the risks to your child?

As far as we know there are **NO** increased risks to your child’s health associated with donating samples to the HBRC. Samples will only be collected when it is safe to do so during your child’s routine care or treatment, and this will not involve any additional visits to hospital. Your child’s 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 or your child 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 or your child can find out more generally about the types of research projects using your child’s samples by contacting us using the details below. You can also ask to visit us the same way (we will check with you, if your child asks by themself while under 18).
- If a research project using your child’s samples generates clinically important information, then a doctor, or another member of the healthcare team, will contact you about this. They may wish to discuss how the information could be used to guide treatment for your child’s current condition or for other conditions (possibly hereditary) which may affect your child and your 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).