

The Norwich Research Park Biorepository

Information sheet for adults donating tissue – Version 2.2

Thank you for considering giving a sample and/or data for biomedical research. This information sheet provides a brief summary to help you to understand what this means and involves.

There is a consent form after the information sheet. It is important that you complete and sign it, if you decide to donate surplus (left over) and/or additional material to the Biorepository. Please complete all parts of the consent form.

There has been a Biorepository in Norfolk for many years. It collects and stores human tissue samples and information, and releases them to approved research projects. A lot of the research takes place with our partner organisations - the Norfolk and Norwich University Hospital (NNUH), the University of East Anglia (UEA) and the Quadram Institute Bioscience (QIB). Some samples may be sent to researchers outside Norwich. The purpose of research is to understand more about human health and disease. It seeks to develop new methods of prevention and new treatments, for the benefit of future patient care. We are a non-profit organisation, which is funded by public money through the BBSRC (Biotechnology and Biological Sciences Research Council) and our partner organisations.

Doctors and other health professionals often take samples (which may be blood, small biopsies, or something else) from patients to help tell us what is wrong and how best to treat it. Larger pieces of tissue or whole organs may be removed by surgeons from some patients as part of their treatment.

Quite often, some of the test sample or surgical tissue is left over at the end. The donated sample(s) and associated data can be used by other doctors or researchers in special experiments to learn more about illness, how it occurs and how to treat it. Some of these research programmes could lead to the development of new tests, products and processes, which may be developed commercially for the improvement of patient care, however, there would be no financial benefit to you.

We would like to carry out research on the left-over sample or surgical tissue, once your tests are finished. To do that, we need your permission and signed consent. If you are happy to, we would also like to store your contact details to get in touch with you at a later date with regards to future studies you may be interested in – you can record your choice on the consent form. We will never release your identity or contact information to any researcher or company.

For further information please visit our website at www.biorepository.org.uk

What are we asking you to do?

We are asking that you allow us to use;

- 1 Left over (surplus) material from your routine test(s)
- 2 Information (data) about your health/illness from your medical notes

Donating extra samples for research

In certain circumstances you may be asked by the doctor treating you (or by a doctor, research nurse or biorepository staff working with him/her) to consider donating (giving) tissue or other samples (for example; blood, urine or faecal samples) in addition to those that are removed as part of your diagnostic investigation or treatment. **Such extra samples will be taken only if you give your consent and if their removal does not cause you any harmful effects now or in the future.**

In addition, your tissue may be used in research with animals to model disease processes in order to understand disease processes and for the development of new treatments. You can record your wishes on the consent form.

Some of your biological material may also be used to isolate and grow cells which can be used for future academic or commercial studies.

The decision to participate or not is your choice and completely confidential. You can withdraw at any time by contacting the Biorepository and we will destroy all the tissue you donated which we still have in our store. However, any samples which have been passed to researchers will have been completely used.

Protecting your identity

As with all hospital records, it is of utmost importance that we protect your identity. If you consent to join the study we will give you a unique number in the Biorepository database. Our Achiever medical database is held at the hospital and has the same level of protection as all other medical information. Your Biorepository number will be linked to your NHS number, allowing us to link the samples you donate to the data we retrieve. We will never release your NHS number to others. This is a process called **linked anonymisation**, we will only ever supply your samples and data anonymously meaning no researchers will be able to identify you, this is what we mean when we use the word anonymous throughout this form. Researchers will only be able to request information relevant to their research. We will not give researchers access to your records, and any samples or data released will only show your unique Biorepository number. If researchers discover something which may have a direct effect on your health or wellbeing, they

will immediately notify the Biorepository. We will then be able to link your Biorepository number to your NHS number and report back. This will be to your hospital consultant if it relates to the disease they are treating you for, or your GP for all other illnesses.

Tissue samples

Why are they important in medical research?

The purpose of research is to understand more about human health and disease. Most disease occurs when cells or tissues in the body are not working properly. Researchers seek new methods of diagnosing and treating disease. They also look for new methods of prevention. In order to understand disease it is vital that we can look at samples to study abnormal cells and understand how they differ from normal.

If you give permission for a sample to be taken:

We will use the tissue to support research allowing us to improve our understanding of human health and disease and also to develop new treatments. Some of the points below are optional; you will be able to record your wishes on the consent form.

- The Biorepository will own the sample - The sample may be stored for an indefinite amount of time until it is used.
- The anonymous sample will be used only in research that has been independently assessed to ensure it is ethical and helps other people. Please see the section entitled 'Scientific and Ethical Approval' below to understand what we mean by *ethical*.
- Only appropriately qualified NHS staff may review your medical records.
- We will keep some facts about you on our Biorepository database.
- Samples may be included in ethically approved research.
- We will place an anonymous index of samples on an internet database. This is to enable researchers to see how we can help their research. This will be accessible by researchers working in the NHS, University sector, charitable sector and industry.

We may supply anonymous tissue to any legitimate researchers. This may include:

- Researchers working in the UK
- Researchers working overseas
- Researchers working in universities and other research organisations
- Researchers working in charities
- Researchers working in commercial organisations

Storing human tissue for research is governed by law

We need your consent to collect any of your tissue. You can withdraw at any time, we will then destroy any samples you have donated which we still have in our stores, but any samples that have been passed to researchers will have already been used. The laws governing removal and storage of human tissue for research were passed in 2004 (The Human Tissue Act 2004). It is a requirement of the Human Tissue Act that appropriate and valid informed consent in line with the Mental Capacity Act (MCA) 2005 should be given by a person donating tissue for research. The Human Tissue Authority (HTA) regulates the storage of human tissue for research. You can find out more about the Human Tissue Act on the HTA website <https://www.hta.gov.uk> or by contacting the Human Tissue Authority at HTA, 151 Buckingham Palace Road, London, SW1W 9SZ or 020 7269 1900 (Mon - Fri, 9 to 5).

Medical Data

Why is data important in medical research?

Detailed analysis of data can provide extremely important information to researchers, particularly when linked to tissue. We would like your consent to be able to collect relevant data from your medical notes associated with the sample collected for research. Only when researchers have their ethical approval, the Biorepository will arrange for the hospital data to be searched. We will **only** ever supply data required to answer the specific questions asked. The systems of linked anonymisation (described above and on the website) means that the researcher will not be able identify you. **We will not seek to collect data from any other source e.g. Facebook.**

Scientific and Ethical Approval

The Norwich Research Park Biorepository acts as a custodian of the samples it holds and has been reviewed and approved by Cambridge East Research Ethics Committee. Research using data or samples from the Biorepository will be carried out with high ethical and scientific standards. In order to ensure this happens the Biorepository requires that all medical research using its material has been approved by a National Research Ethics Committee (NREC) and the Biorepository Access Committee (BAC). The BAC committee looks particularly at whether the research is a good use of resources and ensures researchers are acting within the National Research Ethics approval we hold. These standards apply to all research, including that carried out by commercial organisations or outside the UK. Members of these committees are independent of the Biorepository or the researchers it is helping.

Your rights

If your samples are stored, information about your case will be kept on a computer in the Norfolk and Norwich University Hospital. This will help us understand what your illness was like and relate what we find in research to what happens to patients. Under the General Data Protection Regulations, you are entitled to ask to see what is recorded about you by applying to the Norwich Research Park Biorepository and/or Norfolk & Norwich University Hospital. No one other than you has the right to see these records.

Future contact

We would also like to be able to contact you to see if you will help with other research not covered by the donations we already hold in our stores. Sometimes researchers need information or samples which are not routinely collected (e.g. Faecal/Urine samples). If you agree, we will keep your contact details on our secure database which can only be accessed by authorised staff members. If a researcher asks us to provide samples we do not hold we will see if you fit the research needs, for example, age, gender, health conditions. We will send you additional information and seek specific consent for the project. You can record whether you wish to be re-contacted in the future on the consent form.

Further information and withdrawal

For further information you can visit our website www.biorepository.org.uk or contact us on the details below. If you wish to withdraw you can do so by giving your name, date of birth and NHS number either via the portal on the website, by calling this number 01603 289428 or by writing to the Biorepository at **NRP Biorepository, Bob Champion Research & Education Centre, Rosalind Franklin Road, Norwich, NR4 7UQ**. Following withdrawal we will destroy all samples and data we hold. Your medical care will not be affected.

Thank you for taking the time to read this patient information sheet and considering donating to the Norwich Research Park Biorepository.