NHS
Royal Papworth Hospital
NHS Foundation Trust

TISSUE BANK

DONATION FOR THE COLLECTION AND STORAGE OF HUMAN BIOLOGICAL MATERIAL AND ROUTINELY COLLECTED CLINICAL DATA FOR RESEARCH

Patient Information

Donation of material after an emergency procedure

Invitation

You are being invited to donate biological materials and routine clinical data to our Tissue Bank for research purposes.

Why have I been invited?

All patients requiring an appointment (including an operation, test procedure or follow up appointment) at Royal Papworth can be invited to donate samples of biological material.

You have been invited because you attended Royal Papworth Hospital for an emergency procedure.

The biological material removed as part of your emergency procedure was not discarded and we ask your permission to donate this to the Tissue Bank for research purposes. Because of the nature of the emergency it was not possible to discuss this donation to the Tissue Bank before your procedure. *If you do not wish to give consent the material will be immediately disposed of.*

During your emergency procedure biological material may have been removed to undertake various tests to better understand your condition and we ask your permission to donate these to the Tissue Bank for research purposes. *If you do not wish to give consent the material will remain in the hospital Pathology Department.*

Do I have to take part?

Your participation is entirely voluntary. If you do decide to take part you will be given this information sheet to keep and we will ask for your written permission (consent). You are under no pressure to take part and if you decide not to, this will in no way affect the standard of care you receive.

What is Biological Material?

For the purposes of the Tissue Bank, human **biological materials** include blood, sputum, tissues such as samples taken from your heart or lungs, urine and any other cell containing samples defined as ‘relevant material’ in the Human Tissue Act (2004).

What is anonymised routine clinical data?

For the purpose of the Tissue Bank it includes any data that is collected routinely for your clinical care.

Before you make your decision, it is important for you to understand why we are asking you to make this donation and what it will involve. Please take time to read the following information carefully and discuss it with your relatives or friends. Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

What is the purpose of a Tissue Bank?

During a visit to the hospital to have an operation, a test procedure, or an outpatient appointment it may be necessary to remove samples of biological material as part of the diagnosis or treatment of a condition.

Any residual (left over) material is usually discarded. However if a patient agrees, this material can be stored in a Tissue Bank for use by researchers locally or from other centres around the world, at a later date. The purpose of this research is the development of new treatments for the benefit of future patient care, although this research will not benefit the patient directly.

If you wish to you can also give your permission for additional samples to be collected during follow-up care, provided that such removal is safe and **does not** require a patient to have any additional procedures. For the purpose of Tissue Bank additional samples are blood, and other bodily fluids (e.g. urine) and the risks associated with this donation are the same as your routine procedure. If blood is being donated a maximum of 30 ml (about 6 teaspoons) at any one time will be collected for the Tissue Bank.

Your donation will help in the study of disease processes. Researchers are increasingly interested in studying markers of disease in peripheral blood to develop new monitoring techniques, assess response to treatments and to understand the changes taking place in the abnormal cells by comparing them to normal cells present in blood.

Some research studies may also obtain information from donated biological material by reading (sequencing) DNA or RNA – our genetic code. This genetic information defines a person and genetic differences in people can help researchers to diagnose or treat diseases in the future. This may include studies which will ‘sequence’ part or whole of the genome (your entire genetic information). However, as the samples stored in Tissue Bank are released anonymised the results of the genetic research will not be known to you and if the results are published the findings cannot be linked back to you.

Some your biological material may also be used to produce a ‘cell line’. Researchers can isolate cells from tissue, grow and multiply (culture) them to create a cell line. Most cells have a limited lifespan even as cell lines, but some cells can be kept indefinitely. These anonymised cultured cells/cell lines could be used in future work to study new drugs, therapies or diagnostic tests.

In addition, with your optional consent your tissue may be used in research with animal models of disease in order to understand disease processes and for the development of new treatments.

The majority of research supported by the Tissue Bank is based in the United Kingdom, although the Tissue Bank will supply researchers from Europe and outside of Europe, including Canada and the USA. Before Tissue Bank agrees to supply researchers outside of the EU, we check that the country has sufficient data protection regulations and the researcher signs an agreement agreeing to handle the tissue/data in line with our regulatory requirements.

To further understand the disease processes, it is important to collect some routine clinical data (such as age, sex, diagnosis and medical history). This routine clinical data is stored in your medical records at Royal Papworth and other health-related records, including those held by organisations such as UK Health Security Agency and NHS England. Tissue Bank will only collect the data relevant to the research project and will keep it confidential at all times. Only fully anonymised samples and/or fully anonymised clinical data will be released to researchers and their findings cannot be linked back to you or your clinician.

Material collected for research could be stored for many years before it is used, and your samples and data may be stored indefinitely. The tissue bank where your samples are stored is licensed by the Human Tissue Authority and is strictly regulated and the ethical approval for the tissue bank is reviewed every 5 years. When Tissue Bank provides samples to researchers, they are obliged to use the samples only for the research they said they would do. Researchers are bound by a strict agreement to ensure this, including agreeing not to store unused material and data supplied once the project is completed. If they wish to use any remaining material for further work, they have to apply to Tissue Bank for a new approval.

What will happen to me if I take part?

If you choose to take part we will ask you to sign a consent form. Please keep this information sheet and consent form to remind you of what you were asked to do and what you have given consent for.

Furthermore, if you agree you can donate additional samples of biological material (as outlined above) which may be collected during your routine follow up care after your emergency procedure and in connection with any future care in our hospital, provided that such removal is safe and does not require an additional procedure. This request for future donations is optional, you can still donate the material from your emergency procedure even if you do not wish to donate future material.

You will never be asked to have additional procedures (operations or tests) solely for the purpose of collecting samples for the Tissue Bank. Samples will only be taken during your routine treatment or follow up care and with your specific consent.

What do I have to do?

Taking part does not require you to do anything different, but you will be asked to sign a consent form saying that you have read and understood this information.

When you sign this form you will hand over the custodianship of the samples of biological material to Royal Papworth Hospital NHS Foundation Trust, who will decide how they should be used for research.

If you do not want your samples to be stored in the Tissue Bank please tell us and DO NOT sign the consent form. If you do not sign this form the material collected during your procedure, surplus to diagnostic material, will be disposed of and not used for research purposes.

You may withdraw your consent at any time by writing to the Tissue Bank at Royal Papworth Hospital NHS Foundation Trust, and any material you have donated which remains in the Tissue Bank will be disposed of according to standard practices and your details will deleted from the Tissue Bank computer database. However, because samples and data are fully anonymised before being provided to researchers, once samples have left the Tissue Bank it will no longer be possible to identify them and withdraw the material or the data.

What are the side effects of taking part?

There will be no additional side effects if you decide to donate your residual samples of biological material taken during routine procedures. There is a very small risk associated with donating the optional additional samples for research. However, additional samples will only be taken by your doctor if it is felt to be safe and appropriate to do so. If at any stage during the procedure your doctor feels it is unsafe for you to donate additional samples, they will not be taken.

Donation of extra blood during routine blood taking carries no more risk than giving any routine blood sample.

What are the possible benefits of taking part?

There is no intended clinical benefit to you from donating your samples of biological material. The purpose of the research to which you would donate such samples is to benefit future patients.

What if I change my mind?

You may withdraw your consent at any time by writing to the Research Tissue Bank at:

Royal Papworth Hospital NHS Foundation Trust
Research & Development Department,
The Heart & Lung Research Institute,
Papworth Road,
Cambridge Biomedical Campus,
CB2 0BB

You do not need to say why you have changed your mind. Any material you have donated which remains in the Tissue Bank will be disposed of according to standard practices and your details will deleted from the Tissue Bank computer database in accordance with the General Data Protection Regulations 2018. However, because samples and data are fully anonymised before being provided to researchers, once samples have left the Tissue Bank it will no longer be possible to identify them and withdraw the material or the data.

Will my taking part be kept confidential?

All information collected about you will be kept strictly confidential according to the General data Protection Regulations 2018. If samples of biological material are donated to Tissue Bank, routine clinical information from your medical records will also be kept on a secure computer database for the Tissue Bank to supply projects. This is to help researchers understand your illness and relate this to the laboratory findings and to what happens to patients. The Research Tissue Bank will act as the data controller for this purpose. This means that we are responsible for looking after your information and using it properly. To safeguard your rights, we will use the minimum personally-identifiable information possible.

By signing the consent form you agree to allow your **anonymized** genetic and routine clinical information to be released to other medical, academic, government and commercial databases.

To maintain confidentiality we will fully anonymise the collected samples and the corresponding information by removing anything that could identify you (name, date of birth, address, hospital number) and allocate a tissue bank number before the samples are used for research studies. When samples are released to a researcher for a study a further level of anonymisation will take place as each sample will be given a unique study number.

Consequently researchers who are given samples of your biological material and/or data will not be able to find out anything about you personally from the anonymised information that they receive and will not be able to provide you with the results of their research.

However, there is a very small possibility that when conducting a genetic sequencing project, the researcher could identify something of potential health importance and notify Tissue Bank. In this event Tissue Bank will be able to link the unique study number of the sample used by the researcher back to your clinician who is looking after you at Papworth. They will be informed of the potential finding. Tissue bank will not have any direct contact with you. Your clinician will be responsible for reviewing the finding and feeding back to you if it is felt to be clinically important and in your best interest. You can decide if you do not wish to be informed of an incidental finding.

Royal Papworth Hospital's Research & Development Department, research organisations using the service and regulatory authorities will have access to the tissue bank database for audit and monitoring purposes to ensure accuracy of data collection and that the tissue bank is being properly managed. All staff have a duty of confidentiality to you.

What if there is a problem?

If you are concerned about any aspect of this donation you should ask to speak to one of the Tissue Bank staff who will do their best to answer your questions.

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the Patient Advice and Liaison Service (PALS) (01480 364896 or email papworth.pals@nhs.net).

If something goes wrong and you are harmed during the donation due to someone's negligence then you may have grounds for legal action and compensation against the hospital involved, but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

Who is organising and funding the research?

Royal Papworth Hospital NHS Foundation Trust is responsible for the management of the Research Tissue Bank. The Research Tissue Bank's primary objective is to supply NHS and University research scientists with the biological materials they need to undertake their research. This research is usually funded either by the government, by research councils or by major charitable organisations. We also provide samples of human biological materials to commercial organisations such as pharmaceutical companies to use in their research, the purpose of which is the improvement of patient care. The hospital will charge the companies involved a reasonable fee to cover the provision of this service. Some of the research undertaken by companies could lead to the development of new products and processes, which may be sold commercially. You as an individual will not receive a share of any profits that might ensue from such commercial enterprises. The hospital may benefit financially from exploitation of intellectual property arising from research using Tissue Bank biological material. Any such income will be invested in future research or patient care by the hospital.

Who has reviewed these arrangements?

Royal Papworth Hospital Research Tissue Bank policy and procedures have been reviewed by the Cambridgeshire East – East of England Research Ethics Committee. Royal Papworth Hospital Research and Pathology facilities are also fully licensed by the Human Tissue Authority (http://www.hta.gov.uk).

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