

TISSUE BANK

DONATION FOR THE COLLECTION AND STORAGE OF HUMAN BIOLOGICAL MATERIAL FOR RESEARCH

Patient Information

Invitation

You are being invited to donate biological materials for research purposes.

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).

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?

Your consultant will have already informed you of the need to visit the hospital to have an operation, a test procedure or an outpatient appointment. During your visit it may be necessary to remove samples of biological material from your body as part of the diagnosis or treatment of your condition.

Any residual (left over) material is usually discarded. If you agree, 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 you directly.

If you wish to, you may also give your permission for additional samples to be collected during your procedure or during your follow-up care, provided that such removal is safe and does not require you to have any additional procedures. Additional samples could include additional blood, small samples of skin or fat taken when an incision is made, or additional biopsy material, and the risks associated with this are the same as the diagnostic procedure. If you are donating blood we will collect a maximum of 30 ml (about 6 teaspoons) at any one time 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 your blood.

Some research studies may also obtain information from your donated biological material by reading (sequencing) your DNA or RNA – your genetic code. Your genetic information defines you 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 all of your 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 or your doctor.

Some of your biological material may also be used to isolate and grow cells to produce a ‘cell line’ which can be used for future academic or commercial studies.

To further understand the disease processes it is important to collect some routine clinical data (such as age, sex and medical history) and link this with your donated samples. Only fully anonymised samples and clinical data will be released to researchers and their findings will not be linked back to you or your clinician.

Why have I been invited?

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

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 will happen to me if I take part?

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

During your operation, test procedure or follow up appointment samples of biological material may be removed and sent to the Department of Pathology for diagnostic tests and to confirm whether any further treatment is going to be necessary. This is a standard part of treatment.

When all the routine procedures are completed, any remaining samples could be used for research to help us learn more about the causes of diseases and how they can be treated or prevented.

Furthermore, subject to your specific consent, additional samples of biological material (blood, skin, fat, additional biopsy material, as outlined above) may be collected during your routine care, provided that such removal is safe and does not require an additional procedure.

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 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 any remaining material, once your diagnostics tests are completed, 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 Papworth Hospital NHS Foundation Trust, and any material you have donated that remains in the Tissue Bank will be disposed of according to standard practices and your details will be 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 to you 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 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.

Will my taking part be kept confidential?

All information that is collected about you will be kept strictly confidential according to the Data Protection Act 1998. If samples of biological material are stored, routine clinical information about your case will also be kept on a secure computer database for the Tissue Bank. This is to help us understand what your illness was like and relate this to what we find in the laboratory and to what happens to patients.

By signing the consent form you agree to allow your anonymised 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 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. This includes the results of any genetic testing.

Papworth Hospital's Research and Development Department, research organisations using the service and regulatory authorities will request access to the tissue bank database for audit and monitoring purposes to ensure accuracy of data collection and Tissue Bank processes. 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 PALS@papworth.nhs.uk).

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?

Our 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?

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

For further information contact:

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