

Information about the use of surplus tissue or body fluids for medical research, education and audit



We would like you to consider donating some of your tissues and body fluids for medical research, education and audit. This leaflet will help you decide if this is something you want to do. Please think about this and read the information carefully. You will be able to ask questions when a doctor or nurse meets with you to discuss the clinical procedure and you will be invited to record your decision on the 'Agreement to Investigation or Treatment' Consent Form 1, 2 or 3. The doctor or nurse will choose the appropriate consent form depending on the clinical procedure and whether you are being asked to consider this information on behalf of a child or young person for whom you have parental responsibility.

What is human tissue?

The human body is made up of cells that form a large number of tissues. Sometimes the tissue makes organs, such as the liver, lungs or kidneys. Other tissues do not form organs, for example teeth, bone and skin. Body fluids, such as blood and urine also contain cells.

Why are tissues or body fluids needed for medical research, education and audit?

As well as providing care and treatment, the NHS is responsible for making sure that medical students, nurses, doctors and other care providers get the training they need and that NHS processes are monitored (audited). Doctors and scientists also need human tissue and body fluids for medical research. Medical research is important to see how a particular disease or problem starts and develops, or to assess different drugs and diagnostic tests. Researchers may find new medicines and treatments or ways of diagnosing a disease earlier and thus improve healthcare in years to come.

What usually happens during a clinical procedure?

As part of your care in this hospital, doctors or other healthcare staff may take samples of tissue, blood and other body fluids from you during a clinical procedure (e.g. an operation or investigation). These samples will usually be sent to a Pathologist to find out or confirm what is wrong with you or how well a treatment is working (a Pathologist is a doctor who is an expert in examining tissue and body fluids). The Pathologist would normally keep some of your tissue as part of your medical record for many years (and even for your lifetime and beyond) so that it can be examined again as part of your medical care, now and in the future.

What will it involve if I decide to take part?

If you decide to take part, the doctor or nurse carrying out the clinical procedure will not take more tissue or body fluids than is needed for your care. However, there may be samples left over after the diagnosis is complete which would normally be stored as part of your medical record or disposed of. With your agreement, these samples could be used for medical research, education and audit. The samples will often be stored within a 'Biobank' or 'Tissue Bank'; these are facilities which are established to manage the storage and use of samples in a legal, ethical and safe manner.

Do I have to take part?

It is up to you to decide if you want to donate surplus tissue or body fluids. Your decision will not affect your treatment or care. If you decide to take part, you can change your mind at any time without giving a reason.

If you decide not to take part, any samples not required for your medical record will be disposed of respectfully and in accordance with hospital policy. If you do not want your samples to be used for research, education or audit, make this clear to the doctor / nurse who is undertaking the consent process with you and document your wishes in the appropriate section on the consent form. The doctor / nurse will show you where to write.

I want to donate... what do I do next?

When you come into the hospital or attend a clinic you will be asked if you agree to let your surplus tissue and / or body fluids be used for medical research. You will be asked to record your wishes on the consent form.

How long will my donated samples be stored?

The samples you donate will remain in storage until they are all used or you withdraw your consent. However, if you change your mind after a long period of time, some of the samples may have already been used and it will be impossible to recall those samples and information.

Who will have access to my stored tissue or body fluids?

Your samples will be used mainly by local researchers or clinical teachers but may also be used in the EU and overseas. Research may take place in hospitals, universities, non-profit institutions or commercial laboratories and must be approved by an ethics committee and meet all regulatory guidelines.

Will the researchers carry out genetic tests on my tissue or body fluids?

It may be appropriate for genetic tests to be carried out, but only for studies aimed at providing information about the nature of disease. A lot of research today focuses on the study of genetic material from normal individuals and those with known diseases. This comparison helps to reveal genetic differences, which may then be used to develop future tests and drugs.

Will my medical notes be used?

Information about your condition, other disease(s) and your past treatment is scientifically useful to clinical teachers and researchers. We must have your permission to take this information from your medical notes.

What other research is happening in the hospital?

You may also be approached to take part in clinical trials or other research studies or disease specific biobanks that have been approved by the hospital. You will usually be given an additional information sheet that explains the study and what it will involve. We will try to minimise the number of times that you are asked to give consent for sample collection or use.

Is my taking part confidential?

For teaching and training purposes, your identity may be evident to those involved, but all our staff and students are obliged to hold all medical and personal information in strict confidence in order to protect you.

For research, all information that is collected will be kept strictly confidential. Any information given to researchers will have your name and any other identifiable information removed from it so that you cannot be recognised. Data from the research will not be fed back into your medical record.

Will anyone make money from my samples?

It is illegal to sell tissue or body fluids. We may charge researchers a fee for access to your samples but this is to cover the costs of collecting and storing your samples.

If researchers develop a new test, treatment or drug, a commercial company or other research organisation may then make a profit. It will not be possible for you to make a claim for money made as a result of research involving your samples.

If you would like to find out more:

If you would like more information to help you make a decision, talk to your doctor or nurse, or contact the Patient Advice and Liaison Service **01865 221473**.

Thank you for reading this information.

Please use this page to make a note of any questions you would like to ask about the use of your tissue.

If you need an interpreter or need a document in another language, large print, Braille or audio version, please call **01865 221473** or email **PALSJR@orh.nhs.uk**

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