A guide for the public to Code of Practice E: Research

This guide is intended to be read alongside Code of Practice E: Research.

Commonly used terms

Tissue and organs

Organs
Where we use the term organ, or organs, in this guidance, it refers specifically to a whole solid organ, or organs, including:

- Kidney
- Liver
- Heart
- Brain
- Eyes

The general definition of what constitutes an organ in this context is a body part which has a specific vital purpose.

Tissue
Where we use the term tissue, this refers to all other various human materials that are not whole solid organs.

Tissue and Organs
When we refer to “tissue and organs”, this is to make it clear there is a combination of both.

The role of the HTA

The HTA licenses organisations that remove and store human tissue for research in England, Wales and Northern Ireland, under the Human Tissue Act 2004 (the Act). Our licensing role in research is limited to licensing premises, such as tissue banks, to store tissue from the living and the deceased.

We do not license the ‘use’ of tissue for research or approve individual research projects or clinical trials. Neither do we have a role in the ethical approval of research. These are the responsibilities of other organisations.

Research

The type of research regulated by the HTA under the Act usually takes the form of ‘laboratory bench’ research. HTA ensures that tissue for this type of research is removed and stored in an appropriate and well managed way.
Researchers use human tissue to improve our understanding of how diseases start and progress. They may find different ways of diagnosing diseases, monitoring their progress or developing new treatments.

**Consent**

Generally, relevant material can only be removed, used or stored for research with appropriate consent.

**Consent for donating tissues during life**

You can give consent to donate your tissues in your lifetime. For example, you may give consent for your samples to be stored and used for research when they are removed during diagnosis or treatment. For donating tissues during life, you would be required to give consent on a case-by-case basis, each time tissue is removed.

**Consent for donating tissues after death**

Alternatively, if you have a disease or condition, you may give consent to donate tissue after your death. Generally, consent is required for research using human tissue from deceased people, though there are limited exceptions. Exceptions include tissue that was obtained before the new laws in 2006 and other situations as detailed in Code of Practice E.

Your wishes will be respected, whether you have given consent for your tissues to be used, or made it clear your tissues are not to be used, for research.

If your wishes are not known, then someone close to you may be asked to give consent on your behalf. This can be either a person you nominated in your lifetime, or a person in a qualifying relationship, as described below.

**Withdrawing consent**

You can ask to withdraw your consent at any time until tissues have been used in research. You should be told how to withdraw when you are considering giving consent, including the practicalities of withdrawing consent at different stages.

If you have made it known in your lifetime that you do not consent for your tissues to be used for research, this cannot be overridden by someone else after your death.

**Qualifying relationships**

The Human Tissue Act 2004 includes a list of ‘qualifying' relationships, which are ranked. When consent is sought for any process, the person nearest the top of the list should be asked first to give consent for removal, storage or use of relevant material. Their decision has priority over someone below them on the list. The list is as follows:

1. spouse or partner (including civil or same sex partner)
2. parent or child
3. brother or sister
4. grandparent or grandchild
5. niece or nephew
6. stepfather or stepmother
7. half-brother or half-sister
8. friend of long standing

For these purposes, a person is considered a partner if they live as partners in an enduring family relationship.

While the Human Tissue Act is clear on the hierarchy of relationships, there may be situations where relatives disagree on giving consent. There are procedures and advice on dealing with these conflicts in Code A: Guiding Principles and the fundamental principle of consent, paragraphs 30-39.

We recommend that any decision on consent is sensitively discussed with other relatives of the deceased person. This may include relatives not on this list, for example, an aunt or uncle.

**Specific consent**

You may wish to give consent for specific types of research only. If this is the case, you should make this clear to the person asking for your consent. Your tissue can only be used for types of research that are in line with your consent. You can also specify which types of tissues you give consent to donate. Your wishes should be documented, normally on the consent form you have signed.

Please note that your tissue may not be able to be used at all if the consent you give is limited or restricted.

**Broad or generic consent**

You can give consent for your tissue to be used in a particular project, or you can give broad or generic consent. This means that you have given consent for a range of projects, for storage and/or for future use.

Broad or generic consent offers the widest benefit for future research. For example, you may donate your tissue to a research tissue bank, from where it may be used in a future research project. While the full details of any future research may not be known to anyone at the time of your donation, your consent must still be valid. To ensure you are able to give consent, you should be told:

- the types of research your tissue may be used for,
- how research will be approved, and
- the circumstances under which the tissue will be disposed of.

If you do not want your tissue being used for particular types of research, you should make this clear. Your wishes must be respected. In practical terms, if you place conditions on your donation that cannot be met or guaranteed, then your donation may not be accepted.
Information you should receive before you consent

To give consent you should have enough information to make an informed decision. You should receive this information whenever you are giving consent. This applies to consent for the use of your own tissue, or tissue taken from a deceased person with whom you had a qualifying relationship (see above). You should be told about:

- the activities for which they are seeking consent, such as removal, storage and/or use of tissue for research;
- any risks to you in the way the sample will be taken;
- how the tissue will be stored and/or used;
- any possible risks or implications of its use, such as genetic tests (DNA analysis);
- to whom your tissue will be supplied e.g. local researchers, commercial sector organisations or researchers abroad; and
- if your tissue will or is likely to be used:
  - for genetic testing (DNA analysis); or
  - with animals or animal tissue.

You may be given information in the form of leaflets or information sheets, as part of the consent process. This information should be used to support, not replace, discussions about consent. This documentation should include information about our role, the Human Tissue Act 2004 (the Act), and be consistent with Code of Practice E: Research.

Licensing

We license the removal and storage of tissue for research in England, Wales and Northern Ireland. Our licensing role in research is limited to licensing premises storing tissue from the living and deceased. For example, we license tissue and brain banks.

We do not:

- license the actual use of tissue for research;
- ‘approve’ individual research projects or clinical trials; or
- have any role in the ethical approval of research.

A licence is needed to lawfully remove tissue from the deceased for research falling under the Act. A licence is not needed to remove tissue from the living, but consent usually is.

As a rule, a licence is needed to store human tissue for health- or disease-related research. However, researchers do not need a licence if their research project has approval from a recognised Research Ethics Committee (REC).

A recognised REC is:

- recognised or established by, or on behalf of, the Health Research Authority under the Care Act 2014 or any other group which assesses the ethics of research involving individuals and which is recognised for that purpose by, or on behalf of, the Welsh Ministers or the Department of Health, Social Services and Public Safety in Northern Ireland; or
- an ethics committee recognised by United Kingdom Ethics Committee Authority (UKECA) to review clinical trials of investigational medicinal products under the Medicines for Human Use (Clinical Trials) Regulations 2004.

**How we work with other regulators**

Depending on the nature of the research, it may be regulated by more than one organisation. We work with the Health Research Authority (HRA), Medicines and Healthcare products Regulatory Agency (MHRA) and Human Fertilisation and Embryology Authority (HFEA) to simplify the regulatory requirements for researchers and ensure human tissue is used lawfully.

The Department of Health has produced a [guide to the health and care system](#), with information about how we and other organisations fit into the system.

**Research Tissue Banks**

Research tissue banks collect and store tissue for research. If you donate to a tissue bank, they may share your tissue with researchers in universities or other research organisations, which may be privately-owned. They may charge these researchers for providing human tissue samples. This is often to recover their running costs and ensure they are able to continue operating. If a research tissue bank charges organisations for their services, you should be told. You should be given information about how and why they charge, and to whom they will supply tissue samples.

**Diagnostic archives**

Samples used for diagnosis may be stored in an archive to benefit your medical care. These samples can also be valuable resources for health research.

There are certain circumstances set out in the Act, called scheduled purposes, where a licence is needed. If human tissue is stored for other purposes, a licence is not needed. Establishments holding tissues as part of diagnostic archives do not need a licence as licensable activities are not taking place.

If tissue is to be released regularly to researchers, then it may not be operating as a purely diagnostic archive. An archive implies long-term storage without regular moving of tissue in and out. It may instead be operating as a [research tissue bank](#) and a licence may be needed.

**DNA Analysis**

DNA is not considered ‘relevant material’ under the Act. Its storage is therefore not subject to licensing.

The Act makes it an offence to have any ‘bodily material’ with the intention to analyse the DNA in it without qualifying consent, subject to certain exceptions. Bodily material is any material which has come from a human body and which consists of or contains human cells. DNA analysis is also known as genetic testing.
In other words, anyone holding bodily material without the consent of the person/s concerned, intending to analyse the DNA and to use the results, could be breaking the law.

It is an offence to analyse DNA without qualifying consent (unless it is for an excepted purpose) and could lead to a fine, a term of imprisonment of up to three years, or both.

This offence applies to the whole of the UK.

However, the offence does not apply if the results of the analysis are to be used for ‘excepted purposes’. These are listed in Part 2 of Schedule 4. These include general purposes, such as medical treatment and criminal justice purposes.

The results of DNA analysis can be used for research without consent if:

- they are taken from bodily material that is from a living person;
- the researcher does not have, and in future is not likely to find out, the identity of the person who the tissue has come from; and
- the results are being used for a specific research project with ethical approval from a recognised REC.

**Import and Export**

It is lawful to import and export human tissue for research. Imported or exported material should only be used, handled, stored, transported and disposed of in line with the consent given.

Organisations importing or exporting tissue are responsible for making sure the donor has given consent. They are also responsible for ensuring they will be:

- treated with dignity and respect; and
- used only for the purposes for which the donor has given valid consent.

**Disposal**

As part of the consent process, you should be given information about how your tissue could be disposed of after use. There is not one set method of disposal that all organisations must use. HTA-licensed establishments can make decisions about the most suitable method of disposal in each case. You should be told about the options available and may be able to influence which is chosen.