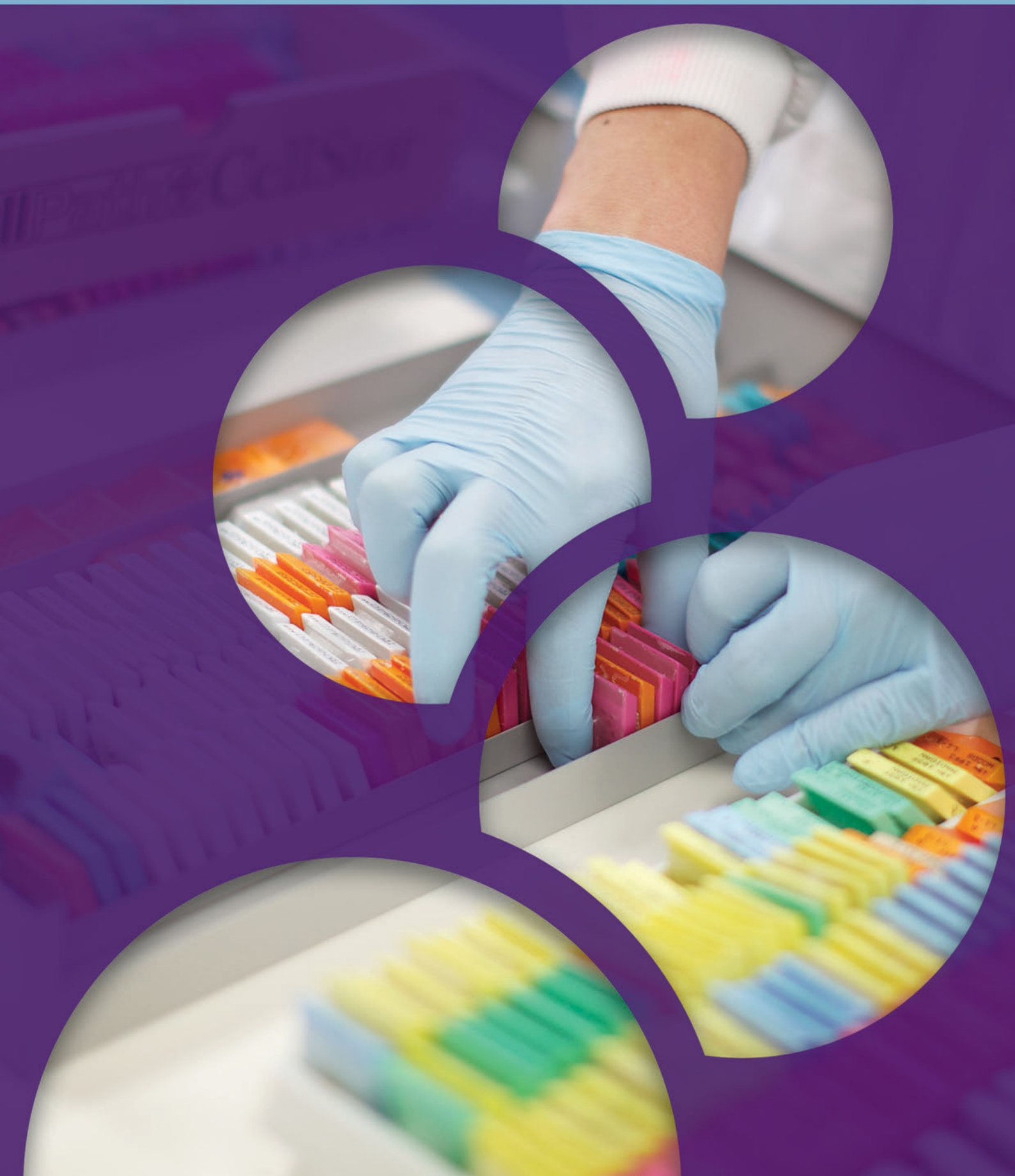
E Research

HTA Human Tissue Authority

Guide for the general public to Code of Practice E



Public guide to Code of Practice E: Research

What is research?

The type of research regulated by the HTA under the HT 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.

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. Alternatively, if you have a disease or condition, you may give consent to donate tissue after your death.

As a general rule, consent is required for research using human tissue from deceased people. There are limited exceptions. If you give consent for your tissues to be used after your death, this will be respected. Alternatively, if you make it clear you do not wish to give consent, this will also be respected.

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.

This cannot happen if you have made it known that you do not consent during your lifetime. Someone close to you cannot give consent on your behalf if you have expressed a wish not to donate.

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. The information should include the practicalities of withdrawing consent at different stages. For example, you would not be able to withdraw your consent to use your tissue after it has been used.

Information you should receive

To give consent you should have enough information to understand what you are agreeing to and make an informed decision. You should receive this information whenever you are giving consent. This includes consent for the use of your own tissue and tissue taken from a deceased person with whom you had a qualifying relationship (see above). You should be informed 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;
- who your tissue will be supplied to e.g. local researchers, commercial sector organisations or researchers abroad; and
- if your tissue will or is likely to be used:
    - for genetic testing; or
    - with animals or animal tissue.

Material risks include risks which you think are significant, as well as those which your clinician would reasonably think are significant to your decision.

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 our Codes of Practice.

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.

Generic or broad consent

You can give consent for your tissue to be used in a particular project. Alternatively, 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 can't be met or guaranteed, then your donation may not be accepted.

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 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.

As a general 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 researchers must meet while making sure human tissue is used lawfully.

The Department of Health has produced a guide to the health and care system. For more information about how we and other organisations fit into the system, please refer to the Department of Health website.

Research Tissue Banks

Research tissue banks collect and store tissue for research. If you donate to 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, 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. 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.

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 is 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 it has come from; and
- 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 the donor has given valid consent for.

Disposal

As part of the consent process, you should be given information about how your tissue will 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.