

The Human Tissue Act 2004 - consent, ethical review and licensing

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The FAQs below relate to the application of the Human Tissue Act 2004 to issues of consent, ethical review and licensing. The Act generally applies only in England, Wales and Northern Ireland.

In addition to the FAQs below, Question-Specific Guidance (QSG) can be accessed throughout the Integrated Research Application System (IRAS) by clicking on the information button next to each question. Alternatively, you can download collated QSG for:

Part B: Section 4 - Use of residual or existing stored human tissue (or other human biological materials)

Part B: Section 5 - Use of newly obtained human tissue (or other human biological materials) for research purposes)

<https://www.myresearchproject.org.uk/Help/Information.aspx>

If you cannot find an answer to your question, please email queries@nres.npsa.nhs.uk .

For further guidance on licensing for storage of tissue for research in England, Wales and Northern Ireland, please refer to (or contact) the Human Tissue Authority (external website: www.hta.gov.uk).

For the Human Tissue (Scotland) Act 2006, please refer to [http://www.hta.gov.uk/db/documents/Information_about_HT_\(Scotland\)_Act.pdf](http://www.hta.gov.uk/db/documents/Information_about_HT_(Scotland)_Act.pdf) (external website).

Consent

Is consent always legally required to store and use tissue for research?

No. There are a number of exceptions under the Human Tissue Act. The most important of these are:

- Tissue which is an "existing holding", i.e. it was already held before 1 September 2006
- Tissue which has been taken from a living person AND the researcher is not able to identify the person AND the research is ethically approved by a REC
- Imported tissue.

Should consent be obtained if it is not legally required?

Applicants should consider whether it is ethically appropriate to obtain consent. Advice may be sought from ethics committees.

In the case of *existing holdings*, the [HTA Code of Practice on Consent](#) (external website) includes specific guidance on whether consent should be sought to use of tissue in research (see paragraphs 114-115). Considerations include whether other sources of tissue are available, the feasibility of tracing and contacting donors, the potential for the research to discover information of clinical significance for donors, or to cause them unnecessary further distress.

In the case of new tissue from the living, it is good practice to obtain prospective consent to use the tissue in research where practicable.

Is consent always required to remove tissue for research?

Appropriate consent is always required under the Human Tissue Act to remove tissue from the deceased for research purposes.

Consent is always required under the common law to remove tissue from the living.

However, consent from the living may be given for diagnostic or therapeutic purposes. If it is also intended to store and use part of the tissue for research, it is good practice to seek specific consent for research at the same time but this is not a legal requirement. Tissue from the living may be stored and used for research without consent provided the research is ethically approved and the researcher cannot identify the donors.

Recognised RECs under the Human Tissue Act

Which Research Ethics Committees are recognised to give ethical approval under the Human Tissue Act?

Under the Regulations made under the Human Tissue Act, ethical approval can be given by a "research ethics authority", i.e. any ethics committee recognised by the United

Kingdom Ethics Committee Authority (UKECA) under the Clinical Trials Regulations, or any REC recognised by the health departments in England, Wales or Northern Ireland to advise on the ethics of research involving human tissue. The health departments recognise all RECs operating under the framework of its Governance Arrangements for Research Ethics Committees (GAfREC). This means all RECs within the NHS or Health and Social Care in Northern Ireland are recognised for the purpose of the Human Tissue Act.

Research involving tissue not from NHS patients - can it be reviewed by a NHS REC?

Yes. NHS RECs will accept applications under the Human Tissue Act not involving NHS patients.

Can university ethics committees be recognised under the Regulations?

This is a matter for the health departments in each country. In England, the Department of Health has said that it does not intend to introduce a new process under the Act to recognise ethics committees other than those operating under the framework of its Governance Arrangements for Research Ethics Committees (GAfREC).

Are NHS RECs in Scotland able to give ethical approval for the purpose of the Human Tissue Act?

Yes. All NHS RECs in Scotland are recognised by the health departments in the other countries of the UK for the purposes of the Human Tissue Act. This means that a Scottish REC can give UK-wide approval for research involving human tissue.

Are RECs outside the UK are recognised for the purposes of the Human Tissue Act?

No RECs outside the UK are recognised for the purposes of the Human Tissue Act.

Ethical review of tissue banks

The tissue is held in a licensed tissue bank - is ethical approval required for research carried out on licensed premises?

If consent has been given to use the tissue for research, there is no legal requirement to obtain ethical approval for research carried out on licensed premises. The Licence gives authority to store the tissue for research. Any requirement for ethical approval depends on the policy of the organisation storing the tissue.

If the tissue was taken from the living after 1 September 2006 and consent for research has not been obtained, ethical approval for the research would be required. The tissue must also be anonymised to the researchers.

A tissue bank holds a HTA Licence for research - is ethical review required?

No. Any application for ethical review would be voluntary.

What would be the purpose of applying for ethical review of a licensed tissue bank?

If the bank plans to distribute tissue to external researchers, it can apply to a REC for "generic ethical approval" for these research programmes. This would confer ethical approval for projects receiving tissue from the bank within the conditions agreed by the REC (for example, tissue is supplied in anonymised form and projects have received appropriate scientific critique). NRES has published [model approval conditions for tissue banks](#). RECs have the discretion to vary these conditions in discussion with applicants.

The REC is also a source of ethical advice to the bank on its arrangements for collecting, managing and distributing tissue. In particular, the REC can advise on informed consent procedures.

Ethical approval for a tissue bank offers additional assurance to end user researchers, donors and the public that its operations meet the highest ethical standards.

One HTA Licence covering a number of distinct tissue collections - can a single application made for ethical review?

Yes. The application should however include relevant information about each collection, in particular any differences in policy for access to tissue and distribution to external researchers. Alternatively, the applicant has discretion to submit a separate application for each bank if this would be more manageable.

Two tissue banks with separate Licences but within the same institution - can a single application be made for ethical review?

No. A separate application should be made for each licensed bank. Each bank will have a Designated Individual who is separately accountable for management of the bank in accordance with the terms of the Licence.

Definition of relevant material

What is "relevant material" for the purpose of the Act?

The Human Tissue Act defines "relevant material" as any material from a human body that consists of, or includes, cells. This includes blood (except where held for transplantation). Hair and nail from living persons are specifically excluded, as are gametes and embryos outside the body, which are covered separately by the provisions of the Human Fertilisation and Embryology Act.

The HTA ([Human Tissue Authority](#) - external link) has published detailed guidance on [what is relevant material](#) for the purposes of the Act.

Researchers should contact the HTA if they require further advice.

Temporary storage

Temporary storage of tissue - is licensing or ethical approval required?

Under section 16(7) of the Human Tissue Act, "storage" does not include storage incidental to transportation. The HTA ([Human Tissue Authority](#) - external link) defines storage as incidental to transportation if tissue is held for a matter of hours or days (but never weeks) pending transfer to a licensed establishment. Where this applies, a Licence is not required.

However, where a researcher holds tissue for a short period for the purpose of a project (e.g. to conduct analysis prior to discarding the tissue), this is storage for a scheduled purpose (i.e. research). Such storage requires either a Licence from the HTA or ethical approval for the project.

Duration of ethical approval

Collecting new tissue for a specific project but also planning storage for future projects - what approvals are required?

You should apply to a REC for ethical review of the initial project, using IRAS. Ethical approval will give authority to store the tissue for the duration of this project only.

At the end of the project, if the tissue has continuing value you will need to do one of the following to make it lawful to store the tissue for further research use:

- Apply for ethical approval of a new project, *or*
- Set up a tissue bank and obtain a HTA Licence, *or*
- Transfer the tissue to a licensed establishment.

Diagnostic archives

Researchers approach NHS diagnostic archive on an ad hoc basis for release of tissue - what approvals are required?

The diagnostic archive does not require a storage Licence for research. The licensing requirement would apply only where an archive planned systematically to store tissue for research use.

Researchers sourcing tissue from diagnostic archives require specific project approval from a REC.

NHS diagnostic archive plans to supply tissue systematically for research - can it apply for ethical review as a research tissue bank?

Yes, provided it also obtains a Licence from the HTA ([Human Tissue Authority](#) - external link) to store tissue for prospective research use. It could then seek generic ethical approval for projects to which it releases tissue.

Import and export of tissue

Research using imported tissue - is licensing or ethical approval required and can the research be reviewed by a NHS REC?

The import or export of tissue is not in itself a licensable activity under the Human Tissue Act 2004. However, once tissue is imported, its storage or use for a scheduled purpose (including research) is subject to licensing by the Human Tissue Authority unless it is for a specific research project with ethical approval from a NHS Research Ethics Committee.

It is preferable for imported tissue to be stored in a licensed establishment where possible, and if so there is no requirement for NHS REC approval to undertake research. However, if the premises where the tissue will be held are not covered by a HTA licence, each research project using the tissue will require NHS REC approval to comply with the Act.

The HTA has issued a Code of Practice on the Import and Export of Human Bodies, Body Parts and Tissue that provides best practice guidelines for individuals and establishments involved in import and export. This is available at <http://www.hta.gov.uk/guidance/codesofpractice.cfm>

If an application to a REC is required, the researcher should provide assurances to the REC that the tissue has been obtained ethically and in accordance with the legal requirements of the donor country, including specific consent for research if appropriate. NRES guidance to RECs is to confine its review to the research activities to be conducted in the UK. Provided appropriate assurances are given, no further detailed review will be undertaken of the consent arrangements in the donor country.

Exporting tissue for research overseas - is licensing or ethical approval required?

There is no legal requirement for licensing or ethical approval. However, applications may be made voluntarily to a NHS REC. The REC will confine its review to the activities to be conducted in the UK, in particular the arrangements for informed consent. It will not undertake detailed scrutiny of overseas research projects. Where appropriate these should be ethically reviewed in the host country.

When seeking consent from donors it is good practice to inform them of plans to export their tissue outside the UK for use in valid scientific research by overseas collaborators.

The [Human Tissue Authority \(HTA\)](#) (external link) has published a [Code of Practice on the Import and Export of Human Tissue](#) (external link).

DNA analysis

Research involving DNA analysis – is ethical approval required?

Under the Human Tissue Act, the only circumstances where ethical approval is legally required in relation to DNA research is where cellular material from the living (e.g. blood) is stored with the intention of conducting DNA analysis without consent from the person whose body manufactured the DNA. In these circumstances ethical approval from a NHS REC is required under Schedule 4 Paragraph 10 of the Act. The material must be non-identifiable to the researcher. Where consent is in place for DNA analysis, no requirement for ethical approval would arise. In some cases consent is only given to

analyse the DNA for the specific study - in these circumstances, further ethical approval would need to be sought to analyse DNA in further projects. Researchers may anticipate this by seeking broad consent at the outset.

Under NHS research governance systems, ethical approval is not required for research involving anonymised extracted DNA, as the research involves neither tissue (i.e. cellular material) nor data of NHS patients. Ethical approval would only be required where identifying data is held with the DNA sample. However, it would be open to researchers using anonymised DNA to seek ethical review on a voluntary basis, e.g. if required by their funder/sponsor, or if the project raised unusual issues on which they needed ethical advice.

Voluntary applications may be made for review of DNA banks ("genetic databases") using the research tissue bank application process, and this could provide generic approval for future projects using identifiable or non-identifiable DNA. The RTB process may be used for any stored biological material, not only where it is relevant material under the HTA.

Cell lines

Cell lines – is licensing or ethical approval required?

Cell lines are not relevant material under the Human Tissue Act.(although primary cell cultures are). Storage of cell lines for research does not require a Licence.

However, cell lines are subject to the Quality and Safety Regulations, which deal with the storage and use of tissue for human application/therapeutic use.

Research using cell lines does not require ethical review either under the Human Tissue Act or NHS research governance systems.

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