



Guidance for using human tissue for research

Human Tissue Act and Human Tissue Authority

The [Human Tissue Act \(2004\)](#) and any subsequent amendments is the legislative framework which governs the removal, storage, use and disposal of human tissue defined as ‘relevant material’ from the living and the deceased for a [scheduled purpose](#).

[Relevant material](#), as defined by the Human Tissue Act, is material derived from a human body (other than gametes) which consists of or includes cells (including bodily waste products).

The following are excluded from the Act:

- Hair and nail from the body of a living person
- Embryos outside the human body¹
- Cell lines and other material created outside the human body
- Any sample that has been rendered acellular within 7 days of initial sample collection

The Human Tissue Act established the [Human Tissue Authority](#) to regulate activities concerning the removal, storage, use and disposal of human tissue for research, medical treatment, post-mortem examination, education and training, and display in public, along with giving approval for organ and bone marrow donations from living people. The Human Tissue Authority issues licenses for the storage and use of human tissue, carries out inspections on licensed premises and promotes good practice on all aspects of the handling, use, storage and disposal of human tissue. The University does not hold a Human Tissue Authority Licence.

You should bear in mind that transfer of human tissue between organisations, including a research site and the University, will need to be covered by a material transfer agreement (MTA) and you must contact the REO Contracts Team (reo-contracts@essex.ac.uk) either to review an MTA if you have been sent one or to draft one. MTAs must be signed by an authorised institutional signatory.

¹ Regulated by [Human Fertilisation and Embryology Act 1990](#)

Ethics review requirement

All research involving human tissue whether undertaken by the University's staff or students, must undergo an appropriate ethics review and ethical approval must be obtained before it commences. The authorised ethics review body and the ethical approval required, will depend on the type of tissue being used and from where it has been obtained.

Projects using human tissue defined as 'relevant material' need project-specific NHS REC approval unless the tissue has been obtained from a REC-approved bank with broad ethical approval for research and the project falls within the specified remit of the approved research. Once you have received a favourable ethical opinion from an NHS Research Ethics Committee, you must register the external approval with the University of Essex using [ERAMS](#).

Projects using tissue taken from consenting healthy volunteers, who have not been identified because of their use of NHS services, which is rendered acellular within 7 days but normally within a matter of hours can be submitted for University ethics review and approval.

Storage of human tissue at the University of Essex

The University of Essex does not hold a Human Tissue Authority Licence to store human tissue so, in accordance with the [Human Tissue Authority's Code of Practice and Standards-Appendix B](#), researchers cannot store human tissue unless one of the following exemptions apply:

- the human tissue is for a specific project approved by a recognised research ethics committee (e.g. NRES REC). The University of Essex Ethics Committee is not a recognised research ethics committee for this purpose.

or

- the human tissue is received from a Human Tissue Authority-licensed research tissue bank (RTB) with generic ethical approval from a 'recognised' research ethics committee. The University of Essex Ethics Committee is not a recognised research ethics committee for this purpose.

or

- the storage of human tissue is 'incidental to transportation'. This means that the storage of tissue while it is being conveyed from one place to another does not need to be licensed. This would normally be for a matter of hours or days and no longer than a week. The transportation must be covered by a Material Transfer Agreement (MTA).

or

- there is no intention to use or store human cellular material for research, and the holding of cellular material is temporary and for the purpose of obtaining material which does not contain cells. This would normally be a matter of hours or days and no longer than a week.

Acquisition and importation of human tissue samples at the University of Essex

New human tissue samples may be acquired as part of an NHS REC-approved project or from a REC-approved Research Tissue Bank. Where a project is led by another institution, the University of Essex is not the research sponsor and you are using human tissue as a collaborator, it is a requirement that you are aware of the content of any ethics application submitted to an external REC and that you register the approval from the external REC with the University of Essex using [ERAMS](#). If you are a collaborator on a project which has received approval from an external REC and you wish to transfer human tissue samples to University of Essex, you will need to upload an MTA to your University of Essex [ERAMS](#) application registering the external REC approval.

Imported relevant material (meaning samples that have been imported into England, Wales or Northern Ireland from a place outside England, Wales and Northern Ireland), may be licensable once it is imported if this is for a scheduled purpose, such as research within the scope of the Human Tissue Act. In such a situation, imported relevant material for research should be treated in the same way as relevant material originating from England, Wales or Northern Ireland and the same exceptions to licensing apply. In some cases, a licence may not be needed to store such material if it is being kept for use in a research project that already has approval from a recognised Research Ethics Committee.

E-learning modules

- [Research and human tissue legislation e-learning](#)
- [Research and human tissue legislation assessment – England, Wales and N. Ireland](#)
- [Research and human tissue legislation assessment – Scotland.](#)
- [Research involving human tissue](#)

Useful reading resources

- [UK Policy Framework for Health and Social Care Research](#)
- [Human tissue and biological samples for use in research](#)
- [Framework on the feedback of health-related findings in research](#)
- [Good research resource hub](#)