



Human Tissue Act Guidance

1. What is the Human Tissue Act 2004?

The Human Tissue Act originated in response to the unauthorised removal and storage of children's organs between 1988-1995. The scandal led to the Human Tissue Act 2004.

It makes consent the fundamental principle underpinning the lawful storage and use of human bodies, body parts, organs and tissue and the removal of material from the bodies of deceased persons.

The intention behind the Act is to achieve a balance between the rights and expectations of individuals and families, and broader considerations, such as the importance of research, education, training, pathology and public health surveillance to the population as a whole.

In the Act, "relevant material" means material, which consists of or includes human cells. e.g. organs, tissues, blood, but does **not** include the following:

- a) embryos outside the human body
- b) hair and nail from the body of a living person
- c) gametes
- d) cell lines (cells manufactured outside the body)
- e) 'cells' that have been treated, processed or 'lysed' through a process intended to render them 'a-cellular'.

Guidance on relevant material with a list of materials and their classification can be found here:

http://www.hta.gov.uk/db/documents/Supplementary_list_of_materials_200811252407.pdf

2. What is the Human Tissue Authority?

The **Human Tissue Authority (HTA)** is a watchdog that supports public confidence by licensing organisations that store and use **human tissue** for purposes such as research. The aim of the HTA is to set standards that are clear and reasonable, and in which both the public and professionals can have confidence.

The HTA was established on 1 April 2005 under the Human Tissue Act 2004 (the Act) which extends to England, Wales and Northern Ireland (there is separate legislation for Scotland that should be observed if necessary). The HTA is an Executive Non-Departmental Public Body (ENDPB) sponsored by the Department of Health.

The HTA licenses a number of activities relating to human tissue. They are also responsible for carrying out inspections to ensure licence conditions are being met. These activities are laid out in the Human Tissue Act and associated Regulations.

The activities licensed by the HTA are:

- Carrying out of an anatomical examination
- Making of a post-mortem examination
- Removal of relevant material from a deceased person
- Storage of relevant material from a deceased person (other than for a specific ethically approved project)
- Storage of anatomical specimens
- Public display of a body or material from a deceased person, and
- Storage of relevant material from a living person for research (other than for a specific ethically approved project) or for human application.

3. Do I need a licence from the Human Tissue Authority (HTA) to store tissue for research purposes?

Yes if the tissue is not covered under an ethically approved study.

A licence is required to store any relevant material or research if it is not being collected and stored as part of an ethically approved study

No if the tissue is for a research study with current-study specific ethics and governance approval.

If Human study samples are to be collected in the UK then ethics approval must have been granted by a recognised Research Ethics Committee. These are:

- A National Research Ethics Service Research Ethics Committee (NRES REC) - (or Health and Social Care in Northern Ireland)
- 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; i.e. a suitably flagged NRES REC.
- **NB** University of Cambridge Faculty Research Committees are **NOT** recognised Research Ethics Committee under the HTA and cannot approve storage of tissue for research purposes.

If the study samples are to be collected outside of the UK then approval only needs to come from the University Faculty Research Ethics Committee

Yes if the samples are 'existing holdings' i.e. collected before 1st September 2006 when the legislation was enacted. Evidence of consent is not required for these samples as long as they are protected by anonymisation.

NB Best practice is to have consent for all human tissue samples.

4. I have NRES REC approval for a current study. Can I retain samples I collect for future studies?

Yes they can be kept if the following conditions are met.

- a. if the terms of donor consent allow; the original ethics approval is still 'live' – i.e. the final report has not been submitted to the NRES REC to close the study;
- b. another, 'overlapping' ethics approval for another study will be submitted;

5. Are blood samples 'relevant material'?

Yes.

- Whole blood contains cells so it is relevant material. However, if it is processed within 7 days, to either plasma or serum, or cells that have been treated, processed or lysed through a process intended to render them a-cellular it is no longer relevant material and does not require a licence for storage.
- However, a-cellular human material can only be used in NRES REC approved studies that also have University of Cambridge Governance approval.

6. Does the University of Cambridge have a HTA licence?

Yes.

The University of Cambridge has a licence for: "Storage of relevant material which has come from a human body for scheduled purposes". These scheduled purposes are listed on the license and include 'Research in connection with disorders or functioning of the human body', 'Obtaining Scientific information about a living or deceased person' and 'Education and training relating to Human health'

Licence number: 12196.

Licence Holder: University of Cambridge

Designated Individual: Dr Martin Vinnell

In the Department of Archaeology and Anthropology, there is an "HTA Person Designated", which for the year 2015-16 is Dr Sue Hakenbeck (Oct-Dec 2015) and Dr Toomas Kivisild (Jan 2016 onwards)

7. When are samples considered to be under licence?

- The only premises licensed in the Department of Archaeology and Anthropology are the Pembroke Street and Fitzwilliam Street sites. Only samples reported and stored using the quality management system are covered by the license.
- All human tissue samples stored under HTA licence are in secured locations (either locked freezers or secured laboratories), with keys held by the Lab Technicians looking after those areas
- A copy of the HTA licence should be displayed at the premises where the storage activity is taking place.

- Any laboratory used for storage must meet the standards required for compliance with the terms of the licence before being allowed to store samples.
- Traceability of all samples must be recorded on an electronic database
- Any researchers wishing to store samples under the HTA licence must contact the 'Person Designate' on the HTA licence at least 24 hours in advance in order for their suitability and compliance to be assessed. This also applies to samples being retained at the end of an ethically approved study.

8. Can I use samples from overseas?

You can use samples from overseas if the following conditions are met:

- a) Although consent is not required for imported tissue, it is good practice to ensure that where possible consent is obtained when using imported samples.
- b) the work has either project specific NRES REC approval, or
- c) the work is part of a NRES REC approved programme of work;

What is a Materials Transfer Agreement (MTA)?

MTAs for human tissues are required to provide a robust audit trail whenever human tissue is transferred in or out of University of Cambridge laboratories

- An MTA is a contract that governs the transfer of tangible research materials between two organizations when the recipient intends to use them for their own research purposes.
- It defines the rights of the parties in respect to scope of use of material, confidentiality, publication, and ownership of Intellectual Property.
- Importantly it provides evidence in case of inspection of effective management of human tissues in and out of the University of Cambridge laboratories a requirement under the HTA.
- These agreements should not include payment for the material, other than reimbursement of transport costs.
- Usually the supplier of the samples raises the MTA.

There are two types of MTA:

1. An **MTA-out** covers the transfer of materials owned, controlled or managed by the University of Cambridge to another university, company or other external body for research purposes.
2. An **MTA-in** covers the transfer of materials to the University of Cambridge from another university, a company or other external body.

The University Research Operations Office deal with these agreements and more information and requests can be found here:

<http://www.research-operations.admin.cam.ac.uk/research-contracts/types-contracts/materials-transfer-agreement>

9. When do I need an MTA?

- For all samples being transferred in or out of the University to Overseas Countries for research purposes.
- For all samples being transferred in/out of the University to other UK sites, for research purposes, if this material movement has not been adequately detailed in either the protocol or NRES REC submission (usually a Sponsor decision).

10. Does the University have policy documents and SOPs on the use of tissues for research? What other guidance is available?

Yes.

Please see the University Health & Safety website for more information.

<http://www.safety.admin.cam.ac.uk/subjects/biologicals/human-tissue-act>

Please use the University's HTA decision tree to assess whether work falls under the HTA legislation:

http://www.safety.admin.cam.ac.uk/files/hta_decisiontree_oct15.pdf

The Department has policies and guidelines concerning consent, storage and analyses of HTA-regulated material:

<http://www.archanth.cam.ac.uk/safety.html>

Who can I contact if I have more questions?

- In the first instance, the Departmental laboratory technicians.
- The Department of Archaeology and Anthropology's "HTA Person Designated": Dr Sue Hakenbeck (Oct-Dec 2015) and Dr Toomas Kivisild (Jan 2016 onwards)