

Human Tissue Act

- Human Tissue Act (2004)
- Upheld and regulated by the Human Tissue Authority (HTA)
- Became applicable 1 September 2006

What does the Act cover?

- Regulates removal, storage and use of human tissue – defined as material that has come from a human body and consists of or includes human cells. In practice this means:
- Storage and use of 'relevant material' from the living
- Storage of dead bodies
- **Removal** and storage of relevant material from dead bodies

What does the Act do?

Organisations that store and use human tissue for a 'scheduled purpose' must have a licence to do so.

There are 5 different types of licence:

- teaching about or studying the human body
- carrying out post-mortem examinations
- using human tissue to treat patients
- carrying out research on human tissue
- displaying human bodies or tissue in public (e.g. in a museum)

What type of licence?

The University of Cambridge is the 'licence holder' and holds two licences:

- An ***anatomy*** licence to cover removal, storage and use of human tissue for education from the deceased, with the Designated Individual as Prof Bill Harris (Department of Physiology, Development and Neuroscience)
- A ***research*** licence to cover storage and use of relevant human tissue for research with the Designated Individual as Professor Andrew Wyllie (Department of Pathology).

Downing Site hub licence

The Department of Pathology (TCR site) is currently the hub for the University's **research** licence. This hub licence covers buildings on the Downing Site which store human tissue:

- Department of Pathology
- Department of Biochemistry Hopkins Building:
- Department of PDN

There are 2 satellite licences operating within the hub licence. A satellite licence allows Departments, through their Persons Designated, to store relevant human material for research under the conditions of the licence with the Department of Pathology. The 2 satellite licences cover Old Addenbrooke's and New Museums' sites

Old Addenbrooke's satellite licence

Covers the following buildings:

- Department of Pharmacology
- WT Centre for Stem Cell Research
- Department of Biological Anthropology (Leverhulme Centre)
- Department of Chemical Engineering and Biotechnology (Institute of Biotechnology site)
- Department of Biochemistry (Sanger Building)

New Museums Satellite Licence

Covers the following buildings:

- Department of Biological Anthropology
(Pembroke Street)
- Department of Chemical Engineering and
Biotechnology (Pembroke Street)

What does the Act mean to my research?

It means that a licence is needed to store *relevant* human material (unless there is ethical approval from the local NHS Research Ethics Committee (LREC) for a specific research project) **and**,

That informed consent must be obtained for the removal, use and storage of *relevant* human material for the research, from the living and the dead.

Licence Exemption

- Licence exemption is in place only if there is ethical approval from the local NHS Research Ethics Committee (LREC) for a specific research project
- The School of Biological Sciences (SBS) Human Biology Research Ethics Committee does not give licence exemption under the Human Tissue Act

Consent

■ Consent is required if

- tissue is from a living person *and*
- samples are identifiable *and*
- the samples were obtained after 1st September 2006
or
- if tissue is from a deceased person collected post mortem (both identifiable and anonymised samples) *and*
- tissue is not imported *and*
- is not an *existing holding*,
or
- if DNA analysis is intended *and* samples are identifiable *and* were obtained after 1st September 2006.

Consent

- Consent is **not required** if
 - tissue is an *existing holding* (from living or deceased persons)
 - or
 - if tissue was obtained from a living person after 1st September 2006 *and*
 - samples are anonymised *and*
 - the project is LREC approved
 - or
 - for imported tissue (from living or deceased persons).

Relevant material

- Material that consists of or includes human cells
- Includes slides, tissue blocks
- Essentially all other material such as breast milk, urine, serum, faeces etc are considered relevant human material and, if you store this material, you need cover by the licence.
- A link to the HTA's list of Relevant Material can be found on the University's website

Existing holdings

- Refers to the material collected prior to the Act coming into force on 1 September 2006
- Consent not needed for scheduled purposes under Act
- Licence for storage will be required under same conditions as new collections

What is storage?

- If material is being STORED outside of an ethically-approved research project, storage should be regarded as anything which needs to be 'put away' at the end of a day for future use.
- The Act permits storage for up to 7 days without a licence only if the tissue is being processed for disposal or is being moved on for analysis

Governance

- The University of Cambridge is the licence holder
- Each licence must have a Designated Individual whose role is to supervise activity in relation to the Act as follows:
 - that the other persons to whom the licence applies are suitable persons to participate in the carrying on of the licensed activity
 - that suitable practices are used in the course of carrying on that activity, and;
 - that the conditions of the licence are complied with.

Governance

- Each establishment storing human tissue under the research licence must have a 'Person Designated'
- The role of Person Designated is to ensure that research is carried out in accordance with the Act and those factors by which the Authority granted the University of Cambridge a licence.

Governance

- The Person Designated must be a senior member of academic staff with responsibility for HTA activities within the relevant location
- Departmental Administrator is the point of contact for HTA administration
- HTA (Research) Committee meets annually and comprises all PDs and Departmental Administrators

Record keeping

- Records must be kept that document consent and allow traceability to the tissue stored for research
- The system of record-keeping must include the location of human tissue stored under the licence (i.e. which cupboard / fridge / freezer it is stored in) and the name of the researcher
- The records should include a description of the tissue, the project it is currently being used for and who the lead researcher is, and whether consent is specific for the project or for wider use in research.

What must an establishment consider ?

1. Practice of Informed Consent is in place
2. Storage and use of the material according to Good Laboratory Practice
3. Secure storage of material and records in a manner that preserves the material, and that back-up systems are in place should primary systems fail.
4. That the material is disposed of sensitively and in accordance with the law
5. Compliance with the University processes including participation in annual inspections and requirements for record keeping
6. Payment of the HTA Licence fee

For More Information...

- <http://www.path.cam.ac.uk/administration/policies-and-procedures/human-tissue-act.html>
- <http://www.hta.gov.uk/>
- HTA Codes of Practice
- Frances McLoughlin, HTA Licence Holder Contact, Department of Pathology fam27@cam.ac.uk ext 33693

1. SOP Checklist:

- Consent - from the living and the dead (excludes active, ethically approved research projects, anonymized and imported samples)
- Use of tissue – to be done sensitively
- Storage of samples
- Disposal of samples – from the living and the dead
- Audit - logs, risk assessments, environmental controls, back-up facilities, emergency contacts
- Use of tissue for educational purposes
- Imported Tissue

2. Staff training:

- Use, storage and disposal of human material
- RECORDS needed showing training of staff
- Risk assessments for the procedures used to undertake research with the relevant material
- Taking tissue or fluid samples
- Consent for taking tissue or fluid samples

3. **Records** showing consent, use etc need to be securely stored and backed-up.
4. **Audit trail** for intake, storage, disposal and reason for disposal (annual audit)
5. **Consent traceability**
6. **Can't store on behalf of another individual without permission of the establishment PD and DI**