

The Human Tissue Act (HT Act) 2004¹ establishes the Human Tissue Authority² (HTA) as the regulatory body for all matters concerning the removal, storage, use and disposal of human tissue (excluding gametes and embryos). They issue licences for a number of activities, e.g. storage of relevant material for research or for human application; and public display of a body or material from a deceased person. The HTA are also responsible for carrying out inspections to ensure licence conditions are being met.

This page summarises the licensing requirements for storage of tissue for research.

When is a licence required for research?

A licence will allow a specified activity to take place at a specified premise(s) under the supervision of a Designated Individual named on the licence.

A licence IS REQUIRED for:

- Storage of human samples, that consist of or contain whole cells, for research in connection with disorders or the functioning of the human body (this includes existing collections and imported material), with the exemptions outlined below.
- All tissue establishments (definition below), storing relevant material that is not for a specific NHS REC approved project, e.g. tissue banks that distribute tissue to researchers require a licence, even though the bank itself may have NHS REC approval.

Exemptions for Research:

A licence IS NOT REQUIRED to store human tissue for research if:

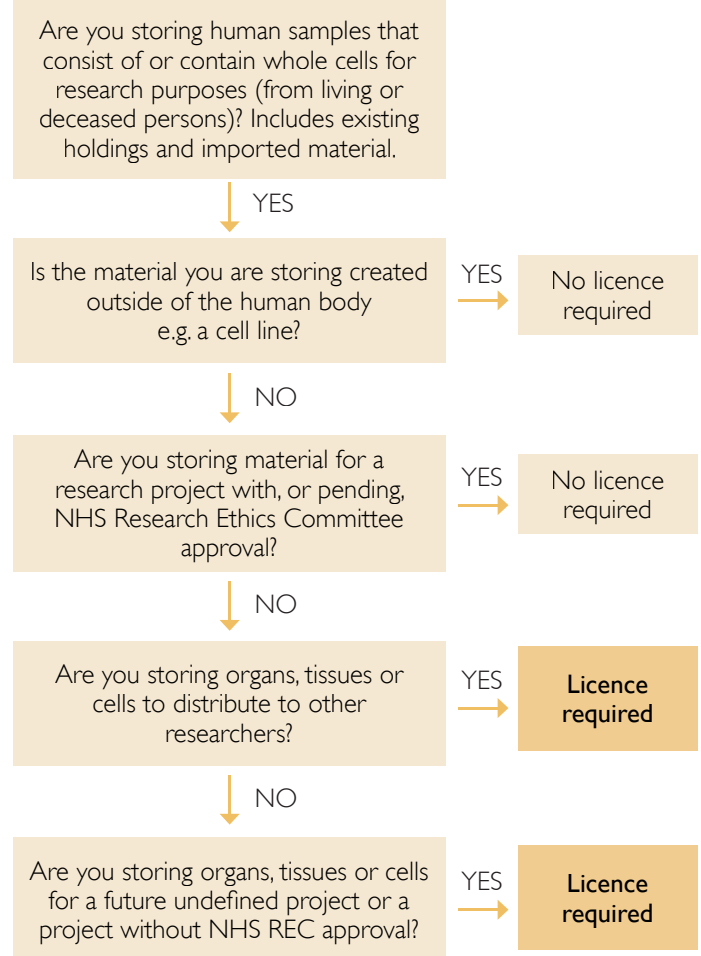
- The tissue(s) is stored for a research project, which has been approved by (or is pending approval from) an NHS Research Ethics Committee. However, if you continue to store the tissue after the research project has ended then a licence IS REQUIRED for storage.
- The research involves bodies or tissues of people who died before the licensing provisions took effect and at least 100 years have passed since the date of death.
- The samples are being stored in establishments in Scotland (Scotland is exempt from the licensing provisions apart from storing tissue for human application).

Note: A licence is not required if the purpose of storing tissue is for diagnostic purposes. However, if the primary purpose for storing the samples changes to research, a licence WILL be required unless one of the above exemptions applies.

DEFINITION

TISSUE ESTABLISHMENT A tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissue and cells are undertaken. It may also be responsible for procurement or testing of tissue and cells.

Flowchart: Is a licence required for research?*



*Adapted from HTA application guidance³.

DEFINITION

RELEVANT MATERIAL: Material other than gametes, which consists of or includes human cells (does not include embryos). Please see the HTA website for more details on relevant material⁴.

EXISTING HOLDING: Body of a deceased person or relevant material which has come from a human body held immediately prior to the commencement of section 1 of the Human Tissue Act 2004 for use for a scheduled purpose, i.e. prior to 1 September 2006.

What are considered 'premises' for a licence?

A licence is required for each premise. If the licensed activity takes place in premises at more than one place, a separate licence will be required. Premises in different streets or with different postcodes will be considered as being in different places, but buildings on a hospital site could be considered the same place. The HTA will deal with any uncertainties regarding premises on a case-by-case basis.

A single application will be accepted for multiple licences (two or more) if:

- All sites share the same governance structure and standard operating procedures (see definition), and
- All sites are supervised by the same Designated Individual (DI).

For a single application for multiple licences there should be a main site and satellite site(s). Satellite sites are those establishments which are smaller and store material on behalf of a parent organisation (main site) and will have their own licences at a reduced fee (see HTA website for guidance³).

What are the key roles in licensing?

There are 4 key roles defined by the HTA³:

1. Designated Individual (DI)

This is the person under whose supervision the licensed activity is authorised to be carried on. It is the DI's legal duty to ensure any other persons involved in the licensed activity are suitable; practices used in that activity are suitable; and the conditions of the licence are complied with. The DI does not need to be medically qualified but should be the person who is in a position to ensure that the above duties can be carried out e.g. head of department, clinician, scientist or manager.

2. Licence Holder (LH)

This is the individual or corporate body e.g. NHS Trust, who applies for the licence and becomes the holder of the licence when granted. The LH and DI can be the same person. If they are different, the LH must have the consent of the DI to apply for the licence.

3. Person Designated (PD)

The DI can designate particular individuals in a Notice to the HTA, who will then be regarded as 'a person to whom the licence applies'. These persons do not have a legal duty comparable to the DI but must be able to 'direct' others in relation to the HT Act 2004.

4. Other persons designated by DI

This term applies to anyone acting under the direction of a DI or PD. They do not need to be named in the Notice to HTA but are still considered as 'a person to whom the licence applies'.

What should I have in place to meet licensing requirements?

The licensing standards outlined by HTA and evaluated via the compliance report during application are separated into four themes:

1. Consent

All those licensed under the HT Act must demonstrate implementation of the provisions for informed consent. Consent must be obtained in accordance with the requirement of the HT Act and as set out in the HTA Code of Practice on Consent⁵. The MRC has produced a summary of these requirements⁶.

2. Governance and quality systems

Establishments should demonstrate systems to ensure the provision of safe tissue with reliable quality, including the following:

- Ratified, documented policies and procedures.
- Documented system of quality management and audit.
- Staff who are appropriately qualified and trained, and continuously update their skills.
- Systematic and planned approach to management of records.
- Documented procedures for distribution of material.
- Coding and record system to facilitate traceability of material – ensuring robust audit trail.
- Systems to ensure all adverse events are investigated promptly.
- Regular risk assessments of practices and procedures, recorded appropriately.

3. Premises, facilities and equipment

The premises, facilities and equipment must be suitable for the licensed activity undertaken including the following:

- Premises are fit for purpose.
- Environmental controls are in place to avoid potential contamination.
- Appropriate facilities are in place for storage of material, consumables and records.
- Systems are in place to protect quality and integrity of material during transport and delivery.

4. Disposal

Establishments should develop a clear and sensitive disposal policy. More information is available on disposal in the HTA Code of Practice on the removal, storage and disposal of human organs and tissue⁷. For a summary of requirements please see MRC Research and Human Tissue Legislation Series: 'Disposal'⁸.

How do I apply for a licence?

Licence applications are made by submitting an application form via the HTA website: www.hta.gov.uk/licensing.cfm.

A login ID will be required to apply online.

The application form consists of three sections:

- 1) Information about the DI and LH.
- 2) Information on the establishment.
- 3) Compliance report.

How much does a licence cost?

The HTA is required to charge a fee to cover costs incurred in the licensing and inspection process. It is the Designated Individual's responsibility to ensure the appropriate fee is paid by the Licence Holder.

The licences issued by the HTA will normally be for a period of three years. The charge for this licence will cover all the work in connection with licensing, including any site visits.

The fee structure (which may be subject to change) for licences in the research sector can be found on the HTA website⁹.

DEFINITION

STANDARD OPERATING PROCEDURES: Procedures to be followed when carrying out a specific task e.g. consent or tissue collection.

What are licence conditions?

Licence conditions are actions which must be achieved to reach the required standard.

Statutory Conditions: There are a number of statutory conditions set out in the HT Act, which apply to all licences e.g. the licensed activity shall only be carried out on the premises specified in the licence.

Standard Conditions: The HTA will also develop standard conditions that apply to all licences (or a sub-set of them), which are applied and varied at their discretion e.g. conditions relevant to HTA education and training.

Additional conditions: These may be applied by the HTA and are specific to a licence. These additional conditions are designed to help achieve compliance with the licensing requirements and improve standards.

Will my establishment be inspected?

The HTA will conduct site visits according to risk, apparent from the licence application or randomly to assess compliance with the HT Act. A licence may be revoked if necessary (with an appeals process available).

References

1. Human Tissue Act 2004, www.opsi.gov.uk/acts/acts2004/20040030.htm
2. Human Tissue Authority (HTA) website www.hta.gov.uk
3. Human Tissue Authority – A guide to licensing for Designated Individuals and Licence Holders, March 2006 www.hta.gov.uk/regulation/guidance
4. Definition of Relevant Material http://www.hta.gov.uk/guidance/licensing_guidance/definition_of_relevant_material.cfm
5. HTA Code of Practice: Consent http://www.hta.gov.uk/guidance/codes_of_practice.cfm
6. MRC Research and Human Tissue Legislation Series: 'Consent'. www.rsc.mrc.ac.uk
7. HTA Code of Practice: The removal, storage and disposal of human organs and tissue http://www.hta.gov.uk/guidance/codes_of_practice.cfm
8. MRC Research and Human Tissue Legislation Series: 'Disposal'. www.rsc.mrc.ac.uk
9. HTA Fees and Payment http://www.hta.gov.uk/licensing/guide_to_licensing_and_application/fees_and_payment.cfm