

Research and the Human Tissue Act 2004 Licensing

Produced in
consultation with
the Human Tissue
Authority

Terms are defined
on page 4

The Human Tissue Authority (HTA)¹ was established to regulate the removal, storage and use of human tissue for a range of activities, including *'research in connection with disorders, or the functioning, of the human body'*. The HTA licenses and inspects organisations involved in these activities. **The licensing requirements of the Human Tissue Act 2004² (HT Act) in relation to research are summarised here.**

When is a licence required for research?

The HTA licenses the removal and storage of 'relevant material' for research in England, Wales and Northern Ireland. The HTA license premises, such as Research Tissue Banks, which store tissue from the living and deceased for research. The HTA also licenses post mortem establishments, which may remove and store tissues from the deceased for research or other purposes covered by the HT Act. The HT Act's licensing requirement does not apply in Scotland (please see our Scotland summary for more detail)³.

The HTA does not license the 'use' of tissue for research nor does it have a role in approving individual research projects. However, it works in partnership with others to ensure that the regulatory environment is easy for researchers to navigate and understand.

Tissues or cells, including cell lines, which may be used in humans (i.e. human application), are covered by the licensing requirements of the Q&S Regulations (as amended). This applies UK wide (including Scotland) and will not be covered here. For further guidance please see the HTA website⁴.

Licensing requirements under the HT Act

Under the HT Act, a licence is required to store *'relevant material' for research in connection with disorders, or the functioning of, the human body*. There are exemptions (detailed in the chart on page 2).

How the HTA licenses

The HTA operates a continuous licensing system with an annual licensing fee⁵. Licences are provided to named premises and one licence can cover numerous licensed activities (e.g. storage for multiple research projects and researchers).

What are considered 'premises'?

Premises are where the licensable activities will take place. The HT Act restricts licensable activities to the premises named on a licence. On a case-by-case basis, the HTA can advise how different places – possibly on the same site – should be licensed. (Please see *Satellite licensing* overleaf as this may apply).

Satellite licensing

Satellite sites are premises under the same governance processes as a larger site or 'hub'; supervised by the same Designated Individual (DI). The DI must have systems that ensure the same governance framework is in place at each site. Satellite licences are offered at a reduced annual fee⁶.

What are the key roles in licensing?

Designated Individual (DI)

The DI is the person authorised to supervise the licensed activity. The DI is crucial to the successful implementation of the HTA's licensing system. It is the DI's legal duty to ensure that:

- persons involved in the licensed activity are suitable;
- suitable practices are used in the licensed activity; and
- the conditions of the licence are complied with.

The HT Act does not define characteristics of a DI. However, the HTA does state that they should be in a position to ensure that the above duties are carried out e.g. head of department, clinician, scientist or manager. For more details on the role of the DI or licence conditions please see the HTA's guidance⁸.

Licence Holder (LH)

This is the individual or corporate body e.g. University or NHS organisation, which applies for the licence and becomes the holder of the licence when granted. The Licence Holder must have the permission of the DI to apply for the licence.

Person Designated (PD)

The DI can formally nominate individuals (notifying the HTA) to help them carry out their duties. These 'Persons Designated' (PDs) do not have statutory duties (these reside with the DI). However the DI can delegate tasks and activities to the PDs to ensure compliance.

Other persons working under direction of the DI or PD

This term applies to anyone carrying out licensed activity on licensed premises. They do not need to be named in the notification to the HTA but are still considered as 'a person to whom the licence applies'.

Is a storage licence required under the HT Act?

Are you storing tissue for **research**? (see the HTA licensing flowchart⁷ for details). NO → No licence required.

YES ↓

Is the tissue '**relevant material**'? Includes **existing holdings & imported material**. NO → No licence required.

YES ↓

Is 'relevant material' only going to be held on your premises **pending transfer*** or whilst **processed to make it acellular***? YES → No licence required.

NO ↓

Is the 'relevant material' from people **who died over 100 years ago**? YES → No licence required.

NO ↓

Is the 'relevant material' being accessed from a HTA-licensed **Research Tissue Bank (RTB)** with **generic RTB ethical approval** that will cover your intended research activity? YES → No licence required.

NO ↓

Are you storing 'relevant material' for research with project-specific **NHS REC** ethical approval? YES → No licence required.

NO ↓

A licence **IS REQUIRED**, unless an exemption can be applied (e.g. apply for NHS REC ethical approval).

Note: Diagnostic archives do not need a licence as long as the primary purpose for storing samples is diagnosis. Where a diagnostic archive acts as a research resource (i.e. by inviting applications to release samples for research, and/or in any way advertising the archive as a resource for researchers) it is functioning as a research tissue bank and the licensing requirement applies (to both the archive itself, and to those accessing 'relevant material' from the archive).

**Where 'relevant material' is held for hours or days and no longer than a week, pending transfer elsewhere, the HTA takes the view that the storage is incidental to transportation and an HTA licence is not required. The HTA views storage whilst rendering tissue acellular as analogous to this exception.*

Applying for a licence

The HTA require an application from a potential Licence Holder or DI before they can grant a licence. The application must specify the premises at which the licensable activities will take place and name the proposed DI. Where an establishment has multiple sites, such as a main site (or hub) with remote satellite sites where 'relevant material' is stored, the HTA can accept a single application, provided:

- the same Designated Individual is appointed for all sites; and
- all sites work to the same procedures and governance arrangements

Licence application forms and guides to completion are available from the HTA website⁹. Each guide includes a list of documentation which must be provided in any application.

The HTA expects applicants to demonstrate compliance with their Codes of Practice and appropriate Standards¹⁰ in any application.

HTA Research Standards

The HTA expects licensed research establishments to meet the HTA's Research Standards¹¹. The Research Standards are grouped under four headings:

Consent (C)

Obtaining consent for research is legally required; unless an exemption applies. Consent should be *valid and appropriate* and in line with the HT Act (see Consent summary³). To meet the consent standards, the HTA expects establishments to demonstrate that:

- their processes for seeking and gaining consent, and any documents supporting the process, comply with the HT Act and the HTA's Codes of Practice;
- staff who seek consent are suitably trained; and
- where applicable, there are agreements with other parties to ensure consent is valid and appropriate.

Governance and quality systems (GQ)

Suitable quality systems and an overarching governance structure should be in place. This will be underpinned by:

- documented policies and procedures as part of the overall governance process e.g. Standard Operating Procedures (SOPs) to cover relevant activities;
- routine audits which are completed to improve practice (these should be documented);
- staff who are appropriately qualified and trained for their role and ensure their skills are kept up to date;
- management of records is planned and systematic;
- adverse events are investigated promptly. Adverse events may include: lost samples, missing or incorrect documentation, deviations in storage temperature, etc;
- risk assessments which are completed regularly, recorded and monitored. Appropriate management strategies should be put in place to mitigate any significant risks.

A quality management system can help achieve this standard. To learn how to develop a risk-based quality system, see the RQA Quality Systems Guide¹².

Traceability (T)

Establishments should be able to demonstrate full traceability for their samples, from receipt to final disposal/disposition. HTA inspectors will test this through traceability audits carried out on site. There should also be a well-established disposal policy, which is in line with the HTA's Codes of Practice (please see our Disposal summary for further guidance)³.

Premises, facilities and equipment (PFE)

Premises, facilities and equipment must be appropriate for the licensed activities. A major consideration is ensuring the quality and integrity of samples, so they are fit for the intended use. This requires establishments to have systems in place for on-going monitoring (e.g. temperature monitoring of freezers), which are regularly tested. DIs are encouraged to work with Health and Safety colleagues to ensure all statutory requirements are met.

Granting a licence

When offering a licence, the HTA may include a number of actions which must be achieved to reach satisfactory standards. These will be specific to the licence and are designed to help achieve compliance with the licensing requirements and improve standards.

Will my establishment be inspected?

The HTA takes a risk-based approach to discharging its duties, and carries out both desk-based assessments and site visits¹³. The HTA publishes reports from inspections on its website¹⁴.

Definitions

EXISTING HOLDING: Material from the living or deceased that was already held for a scheduled purpose(s) when the Human Tissue Act 2004 came into force; e.g. samples held prior to 1st September 2006 for research.

IMPORTED MATERIAL: 'Relevant material' imported into England, Wales or Northern Ireland from a place outside England, Wales and Northern Ireland. Again, these are not exempt from the licensing requirements.

NHS REC: Ethical approval which qualifies for exemptions under the HT Act can only be given by:

- a) an NHS (or HSC in Northern Ireland) Research Ethics Committee listed on the Health Research Authority's website, or
- b) a REC recognised by the United Kingdom Ethics Committee Authority (UKECA) to review CTIMPs.

RELEVANT MATERIAL: Any tissue or sample that contains human cells (from the living or deceased). It **excludes:** gametes, embryos outside the body, nails and hair from the living, cells manufactured outside of the human body (e.g. cell lines once established) and any sample that has been processed to render it acellular. The HTA website¹⁵ has more information on relevant material.

References

1. Human Tissue Authority (HTA) website <https://www.hta.gov.uk>
2. Human Tissue Act 2004 <http://www.legislation.gov.uk/ukpga/2004/30/contents>
3. MRC Research and Human Tissue Legislation Series: available from mrc.ukri.org/regulatorysupportcentre
4. HTA Licensing under the Quality and Safety Regulations <https://www.hta.gov.uk/policies/licensing-under-quality-and-safety-regulations>
5. HTA Fees and Payment <https://www.hta.gov.uk/guidance-professionals/hta-fees>
6. HTA Satellite premises <https://www.hta.gov.uk/policies/satellite-premises>
7. HTA Do I need a storage licence under the HT Act 2004? https://www.hta.gov.uk/sites/default/files/HT_Act_Licensing_flowchart_FINAL_201305210156.pdf
8. HTA A guide to licensing for Designated Individuals and Licence Holders, March 2006 https://www.hta.gov.uk/sites/default/files/2006-03-01_Guide_to_licensing_for_DIs_and_LHs_final_PDF.pdf
9. HTA Licence application forms and guidance documents <https://www.hta.gov.uk/application-forms-and-guidance>
10. HTA Codes of Practice and Standards <https://www.hta.gov.uk/hta-codes-practice-and-standards-0>
11. HTA Research Standards and Guidance <https://www.hta.gov.uk/sites/default/files/Code%20E%20Research%20Standards%20and%20Guidance.pdf>
12. Research Quality Association (RQA)– Quality Systems Guide https://www.therqa.com/resources/publications/booklets/Quality_Systems_Guide/
13. HTA Inspections <https://www.hta.gov.uk/policies/inspections>
14. HTA Inspection Reports <https://www.hta.gov.uk/establishments/report>
15. HTA definition of relevant material <https://www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004>