The Human Tissue Authority (HTA)\(^1\) was established by the Human Tissue Act 2004 (HT Act)\(^2\) 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. This document summarises the licensing requirements of the HT Act in relation to research.

WHEN IS A LICENCE REQUIRED FOR RESEARCH?

The HTA licenses organisations removing and storing ‘relevant material’ for research in England, Wales and Northern Ireland. This requirement does not apply in Scotland (for further details please see our Scotland summary)\(^3\). The HTA’s licensing role in research is limited to licensing premises, such as Research Tissue Banks, which store tissue from the living and deceased. The HTA also licenses establishments, including post mortem establishments, where tissue is removed and stored from the deceased for research or other purposes covered by the HT Act.

The HTA does not license the ‘use’ of tissue for research nor does it have a role in approving individual research projects. It does, however, work 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\(^4\). This applies UK wide (including Scotland) and will not be covered here. Please also see the HTA website\(^5\).

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; these are detailed in the flowchart opposite.

HOW THE HTA LICENSES:

The HTA operates a continuous licensing system with an annual licensing fee\(^6\). Licences are provided to cover named premises and one licence can cover numerous activities.

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 also see Satellite licensing, below, as this may also apply.

SATELLITE LICENSING

Satellite sites are premises under the same governance processes as a larger site or ‘hub’; supervised by the same Designated Individual. The DI must have systems in place to ensure that the governance framework is properly implemented and maintained at each site. Satellite licences are offered at a reduced annual fee\(^7\).

\*Adapted from HTA application guidance\(^8\).

\*Where ‘relevant material’ is held for a matter of hours or days, 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.

Note: Diagnostic archives do not need a licence, as long as all samples are being stored for diagnostic purposes. Where a diagnostic archive functions as a resource for researchers (i.e. by inviting applications to release samples, and/or in any way advertising the archive as a research resource) it is functioning as a research tissue bank. If samples are also being stored for research, then a licence IS REQUIRED.

Definitions

**Relevant Material:** Any tissue or sample containing human cells. **Excludes:** gametes, embryos outside the body, nails and hair (removed from the living), cells manufactured outside of the human body (e.g. cell lines once established) and any sample processed to render it acellular.

**Existing Holding:** ‘Relevant material’ held or stored prior to the enforcement of the HT Act i.e. prior to 1 Sept 2006. These are not exempt from the licensing requirements.

**Imported Material:** ‘Relevant material’ imported into England, Wales or Northern Ireland from a place outside England, Wales or Northern Ireland. Again, these are not exempt from the licensing requirements.

### IS A LICENCE REQUIRED UNDER THE HT ACT?*

- **Are you storing ‘relevant material’ for research? NB Includes existing holdings and imported material.**
  - YES: No licence required
  - NO: No licence required

- **Will ‘relevant material’ be held on your premises for research only pending transfer**\(^\star\) elsewhere or while it is processed to make it acellular**\(^\star\)?
  - YES: No licence required
  - NO: No licence required

- **Does your research involve ‘relevant material’ from people who died over 100 years ago?**
  - YES: No licence required
  - NO: No licence required

- **Are you accessing ‘relevant material’ from a Research Tissue Bank (RTB) which has a generic RTB ethical approval that covers your intended activity?**
  - YES: No licence required
  - NO: No licence required

- **Are you storing ‘relevant material’ for research with/pending project-specific ethical approval from an NHS REC?**
  - YES: No licence required
  - NO: No licence required

A licence IS REQUIRED, unless an exemption can be applied (e.g. applying for project-specific ethical approval)

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Produced in consultation with the Human Tissue Authority

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\(^1\) The HTA is the regulatory authority for the HT Act for England, Wales and Northern Ireland. See the HTA website for more information.

\(^2\) The HT Act 2004 (HT Act) was passed on 7/7/2004.

\(^3\) The HTA website provides information on what the HT Act covers. For further information on HTA summary please see our Scotland summary.

\(^4\) The Q&S Regulations provide for the licensing of procedures involving the use of human tissue. The Q&S Regulations provide for the licensing of procedures involving the use of human tissue. These are not exempt from the licensing requirements.

\(^5\) The HTA website provides information on HTA licensing requirements. For further details please see our Scotland summary.

\(^6\) The HT Act allows the HTA to charge an annual fee for licences. The fee is currently £400 for an annual licence. This fee is reviewed annually and may be increased. The HTA can advise if a licence is required.

\(^7\) The HT Act allows the HTA to charge a reduced fee for licences for satellite premises. The fee is currently £200 for a satellite licence. This fee is reviewed annually and may be increased. The HTA can advise if a licence is required.

\(^8\) The HTA website provides information on HTA licensing requirements. For further details please see our Scotland summary.

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What are the key roles in licensing?

1. DESIGNATED INDIVIDUAL (DI)

The DI is the person under whose supervision the licensed activity is authorised to be carried out. The role of 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 guidance10.

2. 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 LH and DI can be the same person, though this is not the HTA's preferred arrangement. 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 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 with the licence.

4. OTHER PERSONS WORKING UNDER THE 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’.

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 (DI) is appointed for all sites; and
- All sites work to the same procedures and governance arrangements

Guidance and licence application forms are available from the HTA website8.

The application has three sections:
1. Information about the establishment.
2. Information about the DI and the LH
3. Evidence of how the HTA licensing standards are met.

What should we have in place to meet licensing requirements?

The HTA expects you to be able to demonstrate how you comply with their codes of practice11 and meet their licensing standards. Here are some examples:

1. CONSENT

Although the HT Act provides legal exemptions from the need for consent, obtaining consent is considered best practice and should be obtained wherever practicable. Consent should be:

- ‘valid’ – given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question (and in practice, indicated);
- ‘appropriate’ – given by an appropriate person, i.e. the person themselves or someone else who is legally appropriate (see Consent summary3); and
- obtained by an appropriately trained member of staff.

2. GOVERNANCE AND QUALITY SYSTEMS

The HTA expects licensed establishments to have:

- documented policies and procedures to cover all aspects of sample use e.g. having a documented process to ensure all samples are tracked from receipt through to exhaustion or disposal.
- identified the risks associated with their activities. For example of not meeting donor expectations. This includes the risk of not knowing what donors have agreed their samples could be used for, as well as the risk that samples are not used at all (e.g. due to freezer failure, samples being left on ice for too long during transport, samples being lost etc.)
- appropriate management strategies in place to mitigate risks. For example, if invalid consent has been identified as a risk, the process for seeking / obtaining consent should be reviewed; all those who seek consent should be trained in the process and aware of their responsibilities; and routine audits undertaken.
- routine audits or other processes in place, to enable the DI to determine how practice can be improved. For example; are all policies and processes fully implemented, is there a need to review any specific aspects, are there outstanding training needs etc?
- appropriate governance structures in place to ensure that everyone is aware of their responsibilities and appropriate committees / personnel are accountable.

All of this can be achieved with an appropriate quality system. To learn how to develop a risk-based quality system, see the RQA Quality Systems Workbook12

3. PREMISES, FACILITIES AND EQUIPMENT

These must be fit for purpose and suitable to support the licensed activity. A major consideration here is how to ensure that samples are looked after appropriately to maintain integrity, and meet donors’ expectations (i.e. that their samples will be used). This may include freezer monitoring and ensuring appropriate systems are in place to handle any significant temperature deviations quickly, without compromising the samples.

DIs are encouraged to work with Health and Safety colleagues to ensure all statutory requirements are met.

4. DISPOSAL

Establishments should develop a clear and sensitive disposal policy. This should describe when disposal is appropriate; how it should be done and include taking any specific wishes of the donor into consideration. For further details please see our Disposal summary3
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 visits\(^\text{13}\). The HTA publishes reports from inspections on its website\(^\text{14}\).

References

1. Human Tissue Authority (HTA) website https://www.hta.gov.uk
3. MRC Research and Human Tissue Legislation Series: available from the ‘Human Tissue’ link (from menu on left) at http://www.mrc.ac.uk/regulatorysupportcentre
5. HTA - Licensing under the Quality and Safety Regulations: https://www.hta.gov.uk/policies/licensing-under-quality-and-safety-regulations
6. HTA - Fees and Payment: https://www.hta.gov.uk/policies/licence-fees-and-payments-201415
7. HTA - Satellite premises: https://www.hta.gov.uk/policies/satellite-premises
8. HTA - Licence application forms and guidance documents: https://www.hta.gov.uk/policies/licence-application-guidance
11. HTA Codes of Practice: https://www.hta.gov.uk/codes-practice
13. HTA - Inspections: https://www.hta.gov.uk/policies/inspections

Other guidance available from www.mrc.ac.uk/regulatorysupportcentre

- Tool Kits - help you navigate your way through requirements
- MRC Ethics Series - Human Tissue and Biological Samples for Use in Research
- e-Learning - freely available to all

Research and Human Tissue Legislation Series
MRC Regulatory Support Centre, V2 April 2014.
www.mrc.ac.uk/regulatorysupportcentre
Links updated February 2015
Supersedes V1, March 2007