

# Guide to Completion of the Public Display Licence Application

The following activities can only take place under the authority of a licence from the Human Tissue Authority:

- The use, for the purpose of public display, of the body of a deceased person, or relevant material<sup>1</sup> which has come from a human body
- The storage of the body of a deceased person, or relevant material which has come from a human body for use for a scheduled purpose<sup>2</sup>

This document outlines the legal framework of the licensing system, explains the application process and provides guidance on how to complete the application form.

Our [Code of Practice D](#) and the [Public Display licensing standards and guidance](#) provide additional guidance on the licensing requirements for the Public Display sector.

## General

1. The Human Tissue Authority (HTA) was established under the Human Tissue Act 2004 (HT Act). The HTA licenses a number of activities and undertakes inspections of establishments carrying out these activities to ensure the requirements of the HT Act are being met.
2. We operate a continuous licensing system, with an annual [licensing fee](#), although in some circumstances we can issue fixed-term licences.
3. The HTA must receive an application before it can grant a licence. The application must specify the premises at which the licensable activities will take place. Where the establishment has multiple sites, such as a main site with remote satellite sites where bodies, body parts or tissue samples are stored, we 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.
4. We issue separate licences for the hub and for each satellite site, under the same licensing number. Satellite sites are eligible for a reduced licence fee.

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<sup>1</sup> Go to <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm> for more information on relevant material

<sup>2</sup> See Schedule 1 of the HT Act (Scheduled Purposes) Part 1 and Part 2

## Completing and submitting a licence application

5. Licence applications must be downloaded from the HTA website and submitted by email to [licensing.enquiries@hta.gov.uk](mailto:licensing.enquiries@hta.gov.uk).
6. The application form has four sections:
  - Information about the establishment
  - Information about the DI and the Licence Holder
  - Information about how the [HTA licensing standards](#) are met
  - List of documents to be submitted as part of the application
7. The licensing standards section contains four sets of standards that applicants must assess and evaluate their performance against. These are:
  - Consent
  - Governance and Quality Systems
  - Traceability
  - Premises, Facilities and Equipment
8. The HTA will assess the information provided in the application form and the mandatory documents that must be submitted before the application can be assessed, taking this as evidence on which to base an informed and proportionate licensing decision.
9. Where we have considered it to be helpful, we have included guidance under individual standards to help you assess whether you meet them. You should include details of what procedures you have in place to meet each standard, or if the standard is not being fully met, what you are doing in order to achieve the standard. Key strengths or areas identified for improvement can also be given. For each applicable standard, the establishment should consider the evidence it has to demonstrate whether the standard is not met or met.
10. Where a standard is not applicable please select 'N/A' and provide an explanation of why the standard is not applicable to your establishment.
11. We may contact applicants and undertake a site visit to obtain any additional information or evidence required. This could be at any stage in the application process.
12. Where applications are complete and demonstrate a satisfactory level of compliance with standards we will aim to issue a licence offer within 20 working days of receipt of the application.
13. Any incorrect or misleading information provided in an application could lead to the revocation of any licence granted.

14. Applicants will need to complete their application and submit all relevant information before the application can be assessed. If an application is not completed due to delays at the establishment within three months from the start of assessment, the applicant(s) will need to repay the licence application fee before their application is further assessed.
15. If an application is rejected following assessment, the applicant(s) will need to repay the licence application fee if they wish to submit a new application.

## **Granting a licence**

16. A licence will be granted when we receive written acknowledgement of the licence offer from the proposed DI and the Licence Holder.
17. If a licence application is refused or granted with conditions and the applicant chooses to challenge this decision, the proposed Licence Holder and/or the proposed DI must give notice of their intention to make representations within 28 days from the date that notice of the proposed licensing decision was given by the HTA (i.e. the date on the Licence Offer/Notice of Proposal letter). This is a strict time limit laid down by statute.
18. Notification of the intention to make representations may be given to the HTA either orally or in writing by the person entitled to make representations. If the request is given orally, it must be made to the Authority's Director of Regulation, one of the Regulation Managers or one of the Heads of Regulation only. The person receiving the oral request to make representations will record the request and confirm this in writing to the person proposing to make representations.
19. The person entitled to make representations must after any oral request then confirm their intention to make representations in writing to the HTA. This may be by letter, email and/or fax to the Director of Regulation.
20. The following section gives specific help on completing the Application Form. Please contact us by emailing [licensing.enquiries@hta.gov.uk](mailto:licensing.enquiries@hta.gov.uk) if you need further information about any part of the application form or our process for considering licence applications.

## **How to complete the application form**

### **Establishment Information**

21. Establishment name

Please provide the name of the organisation on whose premises the activities will take place. Careful consideration should be given to where the licensed activities are going to take place and whether they extend to more than one area within the premises. Include the department name if applicable.

## 22. Establishment address

A licence application must specify the premises where the activities are to take place. The address of the main site should be stated in this section. Where the licensed activity will take place at more than one premises, such as a main site with satellite sites, a separate satellite licence would be needed for each site, however a single application for multiple licences may be made. Details of satellite sites should be recorded in the relevant section.

## 23. Names of person(s) who have consented to be designated on the licence (where the establishment is applying for a licence(s) on single premises)

The HT Act allows the DI to designate persons on the licence, with their agreement. Persons Designated can support a DI in overseeing licensable activities.

## **Satellite Sites**

### 24. Address of satellite site premises and activities to be licensed

Satellite sites are premises under the same governance arrangements as the main site (hub) and are supervised by the same DI. Each satellite site will have its own licence.

### 25. Names of person(s) who have consented to be designated on the licence at the satellite premises.

There should be a primary Person Designated at each satellite site who can direct licensable activities at the site and is accountable to the DI. Please provide the name of the primary Person(s) Designated on the licence for the satellite premises and any additional persons to be designated on the licence of the satellite premises.

## **Application to be Designated Individual (DI)**

### 26. Information about the role of the DI is available on our [website](#).

### 27. With regard to the organisational structure of the establishment, please indicate the lines of responsibility between the DI and any persons engaged in licensed activities.

We must be satisfied the DI is able and willing to supervise the licensed activities. The relationship between the DI and those working under the licence should be described here, as well as the DI's position in the overall governance structure.

### 28. Please explain how the DI ensures that staff, who will be working under the licence, are appropriately qualified and trained in techniques relevant to their work and continuously update their skills.

The DI must ensure that suitable practices are carried out by those undertaking the licensed activities; staff training is an important part of this. The DI's role in ensuring that staff working under a licence are suitably qualified and trained should be described here.

## 29. Declaration

The DI must read and acknowledge each statement in this section.

### **Application to be Licence Holder/Corporate Licence Holder**

30. The applicant can be a person or a corporate body and must be suitable to hold the position of Licence Holder. If the applicant is a corporate body, the application to be a Corporate Licence Holder must be completed by a person suitable to act as Licence Holder contact.

## 31. Declaration

The Licence Holder or Corporate Licence Holder contact must read and acknowledge each statement in this section.

### **Licensing Standards**

32. The licensing standards are separated into four main themes: consent; governance and quality systems; traceability and premises, facilities and equipment. Each of these four sections must be completed.

33. It is important for establishments to demonstrate how they meet HTA quality standards.

### **List of mandatory documents to be submitted as part of the application**

34. You will need to submit all documents in the following checklist, together with the completed application form, before your application can be assessed.

35. Please note that these do not need to be separate documents, they may be embedded within other governance documents (e.g. the Quality Manual). If that is the case, please provide the relevant document and indicate the page numbers or section where the mandatory document can be found in the relevant 'Further information on documentation' section of the application form.

## Application Checklist – Mandatory documents

### Governance and Quality Systems

- Collection management policy (if applicable)
- Risk assessments relevant to licensable activities (please note that these must be developed in line with the guidance provided in relation to standard GQ6)

### Traceability

- List of material to be displayed or stored under the licence

### Premises, Facilities and Equipment

- Risk assessment of premises
- Site plan, indicating where display/storage of relevant material will take place
- Information on the site and environment where public display will take place

## HTA Licensing Standards

### Consent standards

#### **C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in its codes of practice**

- a) If the establishment is required to seek consent, a process is in place which is in accordance with the requirements of the HT Act and the HTA's Codes of Practice, and records of consent are maintained.
- b) If relevant, there is training for staff on how to seek consent for the public display of human material, which addresses the requirements of the HT Act and the HTA's Codes of Practice and records demonstrate attendance.
- c) Where applicable, there are agreements with other parties to ensure that consent is sought in accordance with the requirements of the HT Act and the HTA's Codes of Practice.

#### *Guidance*

*Establishments should seek to receive written assurance that, for imported specimens, the donor's consent was sought in line with that country's requirements.*

#### **C2 Information about the consent process and the activity for which consent is sought is provided**

- a) There is written information about the consent process for those giving consent, which reflects the requirements of the HT Act and its codes of practice.
- b) Standard operating procedures (SOPs) specify how information on consent is provided.

## Governance and quality system standards

### GQ1 All aspects of the establishment's work are governed by documented policies and procedures

a) There are collections management policies and procedures, or equivalent, governing the storage and public display of bodies and human tissue which give due regard to the dignity of the deceased. These should include, as relevant to the establishment's activities:

- i. an overarching policy on the care and treatment of exhibits containing human tissue;
- ii. seeking consent for donation of bodies and human tissue for public display;
- iii. specimen acquisition e.g. by bequest, exchange, loan or purchase from another individual or organisation nationally or internationally;
- iv. specimen preservation, monitoring and conservation;
- v. control of environmental conditions;
- vi. the management of sensitive material, such as fetal remains;
- vii. transportation of specimens e.g. on loan to or return to other collections;
- viii. the disposal/deaccession of specimens;
- ix. storage contingency arrangements;
- x. the creation, amendment, retention and destruction of records;
- xi. the management of incidents and complaints.

#### *Guidance*

*Individual SOPs for each activity are not required; some SOPs will cover more than one activity. Where appropriate, procedures should be developed in consideration of potential risks. For example, where staff undertake cleaning of material on public display, the procedure should be based on the assessment of risk to staff from contamination and the cleaning materials they will be exposed to, as well as the potential risk of damage to the item being cleaned.*

b) There are procedures that govern the work of temporary staff and contractors, which ensure that they are sensitive to the special status of human remains and exhibits consisting of human material.

c) Regular governance meetings are held; for example, health and safety and risk management committees, that have agendas and minutes.

*Guidance*

*Team meetings provide an ideal opportunity to pass on relevant information to staff working under the licence, as well as allowing them to raise any issues or concerns.*

d) Policies and procedures are reviewed regularly and are version controlled.

*Guidance*

*Governance documentation should be up to date, subject to regular review and reflective of good practice, including guidance from organisations such as Arts Council England and the Department for Culture, Media and Sport (DCMS).*

**GQ2 There is a documented system of audit**

a) There is a documented system of audit, which includes records of traceability and specimens.

*Guidance*

*Audits should include compliance with documented procedures; the completion of records; and traceability*

**GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks**

a) There are clear reporting lines and accountability, and documented roles and responsibilities.

b) There is documented induction and training for staff, which includes the handling of human remains; attendance at training is recorded.

**GQ4 There is a systematic and planned approach to the management of records**

a) There are suitable systems for the creation, review, amendment, retention and destruction of records.

b) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).

**GQ5 There are systems to ensure that untoward incidents are investigated promptly**

a) There is a system for reporting and investigating serious untoward incidents.

*Guidance*

*This should include incidents relating to the safety and integrity of human material and those that may impact on the establishment's ability to meet the requirements of the HTA codes of practice and licensing Standards. Staff should understand what is meant by an incident and be familiar with the procedure to follow when such an incident occurs. Serious incidents should be reported to the HTA.*

b) Corrective and preventive actions are taken where necessary and improvements in practice are made.

**GQ6 Risks associated with the establishment's practices and processes in relation to the storage and display of human material are assessed and monitored**

a) Risk assessments are documented.

*Guidance*

*Risk assessments should consider risks to, for example: tissue traceability; storage of specimens; and dignity of the deceased. Where actions are identified to mitigate risks, these should have deadlines for completion and a person responsible for completing them.*

*For risk assessments to be meaningful, they should be undertaken by a suitably trained person, who has an objective view or who is following an established risk-assessment process. It may not be appropriate for staff working under the authority of the licence to undertake their own risk assessments. In any event, the results of risk assessments should be shared with staff so that they have an understanding of the issues identified.*

b) Risk assessments set out steps taken to mitigate risks.

c) Risk assessments are reviewed regularly.

*Guidance*

*Risk assessments should be reviewed every 1-3 years.*

d) Staff can access risk assessments and are made aware of them in training.

## Traceability standards

### T1 A coding and records system facilitates traceability of bodies and human tissue

- a) Bodies and human tissue are traceable through a unique identification number or code.

*Guidance*

*Procedures relating to indexing and record-keeping should reference the establishment's system of labelling bodies and body parts.*

- b) The system of record-keeping should include the location of material at the establishment and may include a description or photographic record and details of any specialist storage conditions, shelf-life or contamination risk.

### T2 Records of traceability are maintained

- a) Records of receipt, storage, transportation and delivery of bodies and human tissue are maintained.

- b) Disposal or de-accession records include the date, reason and method of disposal/de-accession.

*Guidance*

*If relevant material is loaned to or borrowed from another licensed establishment, consideration should be given to minimising the likelihood of theft or damage during transport. Loan agreements should define how the material is preserved and any potential contamination risks associated with it.*

*There should be clear instructions on how to deal with an untoward incident and contact details for the person responsible at the establishment loaning relevant material.*

- c) Where applicable, disposal arrangements reflect specified wishes of the donor.

## Premises, facilities and equipment standards

### **PFE1 The premises and facilities are secure and safeguard the dignity of the deceased and the integrity of human tissue**

a) Areas used for storage or public display provide an environment that is safe for staff and visitors and preserves the integrity of the material and the dignity of the deceased.

#### *Guidance*

*As advised in the DCMS Guidance for the care of human remains in museums, visitors should not come across human remains unaware. The establishment should give consideration to suitable signage, explaining the presence of bodies, body parts or other relevant material and the requirement to treat them with dignity and respect.*

b) The establishment is clean, well maintained and subject to a programme of planned preventative maintenance.

c) Staff have access to the protective clothing, materials and equipment they need.

d) A documented risk assessment has been carried out of the premises to ensure that they are appropriate for the licensed activities.

#### *Guidance*

*An assessment can cover such risks as fire, theft and vandalism.*

e) There are policies in place to review and maintain the safety of staff and visitors.

f) The premises are secure with controlled access to bodies, human tissue and records.

g) Security measures include the use of lockable display areas and alarm systems.

### **PFE2 There are appropriate facilities for the storage of bodies and human tissue**

a) Where chemicals are used for preservation, the area is adequately ventilated to control exposure.

#### *Guidance*

*Control of Substances Hazardous to Health (COSHH) regulations require the exposure of formaldehyde to be controlled as low as possible and below the maximum exposure limit (2 ppm). This may include regular monitoring of formaldehyde levels and continuous operation of extract ventilation.*

b) Critical storage conditions are monitored and recorded.

*Guidance*

*This could include, for example, temperature; humidity, dust or light levels, in storage and display areas.*

c) There are systems to deal with emergencies.

*Guidance*

*This could include, for example, fire, flood, power failure or public disturbance.*

d) There is a documented contingency plan for storage of bodies and human tissue.

*Guidance*

*For example, the establishment could have arrangements for material to be transferred to alternative licensed premises.*

## Glossary

<p><b>Adverse event</b></p>	<p>Any event that:</p> <ul style="list-style-type: none"> <li>• Caused harm or had the potential to cause harm to staff or visitors.</li> <li>• Led to, or had the potential to lead to, a breach of security of the premises and the contents contained therein.</li> <li>• Caused harm or had the potential to cause harm to stored human tissue (including loss)</li> <li>• Gave rise to an internal inquiry.</li> </ul> <p>Once an establishment is licensed, any breach of the HT Act or the codes of practice will be considered to be an adverse event.</p>
<p><b>Code of Practice</b></p>	<p>The HTA codes of practice provide guidance and lay down expected standards for each of the sectors we regulate. There are nine codes available via the HTA website  <a href="http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm">http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm</a></p>
<p><b>Designated Individual (DI)</b></p>	<p>The individual designated on the licence to supervise the licensable activities being carried out. DIs are trained by the HTA to carry out this important role and they have statutory responsibilities they must fulfil.</p>
<p><b>Existing holdings</b></p>	<p>The body of a deceased person, or any relevant material which has come from the human body, held immediately prior to 1 September 2006.</p>
<p><b>Licence Holder (LH)</b></p>	<p>The person who holds a licence and is responsible for the payment of any fees charged by the HTA. The LH can be a corporate body. Where the applicant is not the proposed DI, the HTA must be satisfied that the applicant is a suitable person to be the holder of the licence.</p>
<p><b>Person designated (PD)</b></p>	<p>A person, or persons, nominated by the DI (in writing to the HTA) who has the ability to 'direct' others in relation to the conduct of activities licensed under the Human Tissue Act 2004. There must be a Person Designated at each satellite site who can direct activities that are licensed there and who is accountable to the DI at the main hub site.</p>

<b>Relevant material</b>	<p>Defined by the HT Act as material other than gametes, which consists of, or includes, human cells. In the HT Act, references to relevant material from a human body do not include: (a) embryos outside the human body, or (b) hair and nail from the body of a living person. See policy guidance on how to apply this definition on the HTA's website:</p> <p><a href="http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm">http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm</a></p>
<b>Service Level Agreement (SLA)</b>	A formal agreement between two parties to provide a service
<b>Standard operating procedure (SOP)</b>	A document which provides detailed, written instructions to achieve uniformity of the performance of a specific operation, function or task. An SOP must be written with sufficient detail so that someone with limited experience or knowledge of the procedure can successfully reproduce it without supervision.
<b>Tissue</b>	Any and all constituent part/s of the human body formed by cells.