Licence application assessment visit inspection report on compliance with HTA licensing standards

Brighton & Sussex Medical School

HTA reference number 12687

Application for a licence under the Human Tissue Act 2004 for the

- **Storage of the body of a deceased person or relevant material for use for a scheduled purpose, and**
- **Use, for the purpose of public display, of the body of a deceased person, or relevant material which has come from the body of a deceased person.**

02 May 2019

Summary of inspection findings

The HTA found the proposed Designated Individual (DI), the Licence Holder (LH), the premises and the practices to be suitable in accordance with the requirements of the legislation.

Although Brighton & Sussex Medical School (the establishment) was found to have met the majority of the HTA standards, two minor shortfalls were found relating to competency assessments of staff and risk assessments.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

Background to the establishment

The establishment holds HTA licences for the anatomy and research sectors (licence numbers 12098 and 12561, respectively). The establishment has applied for a HTA licence for storage and use of a body of deceased person or relevant material for the scheduled purpose of public display. This report describes the licence application assessment visit.

The proposed DI is the Head of Anatomy, the LH is the University of Sussex and the Licence Holder named contact is the Pro-Vice Chancellor. The proposed DI has nominated several Persons Designate (PD) to oversee activities relating to public display.

The establishment has 177 potted pathology specimens and a large quantity of osteological material. Two potted specimens are tissue from the living, and all other specimens are from the deceased. Most specimens were gifted to the medical school at its inception in 2003, predominantly from Hospital Trusts. The remaining specimens were gifted through the Institute of Anatomical Sciences (IAS) pot reclamation scheme. Occasionally, material may be gifted to the establishment by members of the public (see *Advice*, item 1).

The specimens are stored in the anatomy laboratory under the establishment's anatomy sector licence, and are not currently used for public display.

The establishment holds regular learning and awareness events for both students and the public in which animal material is used to teach anatomy, physiology and pathology. These events are held both on and off site. The department wishes to display human potted specimens and osteological material at future events, subject to appropriate licensing arrangements being in place (see *Advice*, item 3). These events may also be open to other groups of individuals, such as physiotherapists and artists.

The establishment has developed risk assessments and standard operating procedures (SOPs) covering licensable activities, including the receipt, handling, security and safety of specimens both on and off site (see shortfall against GQ6(b)).

All potted specimens are anonymised, allocated a unique identification code and stored in specific locations in the anatomy laboratory. Potted specimens are also labelled using a red, amber and green (RAG) rating system to provide a visual indication of status of the specimen, where: material cannot be publically displayed because it does not have consent for public display – red; material is of a sensitive nature but can be publically displayed – amber; or, material can be publically displayed – green. Osteological material is individually numbered and kept collectively in watertight containers which are assigned a box number. The unique identification code / box number, description of material and storage location are logged in specimen registers and details recorded on an electronic database.

The prosection team from the anatomy laboratory have received training in the maintenance of potted specimens and are responsible for their upkeep (see shortfall against GQ3(b)). There is a dedicated area in the laboratory for maintenance of specimens to be performed.

All staff are allocated entry system bracelets which are required for all doors into and out of the anatomy laboratory. There is CCTV covering all areas and the building and department is alarmed. An introductory video for visitors explains rules in relation to health, safety and security. Mobile phones are not permitted in the department.

Before the display of any material, all staff involved will receive information and training regarding SOPs and processes for dealing with any incidents or concerns from the public.

Description of inspection activities undertaken

The timetable for the site visit was developed in consideration of information submitted upon application for the licence and pre-inspection discussions with the proposed DI. The inspection team undertook a visual inspection of the premises, review of documentation and traceability records and conducted roundtable discussions with establishment staff.

Inspection findings

The HTA found the proposed Licence Holder, Designated Individual and the premises to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
b) There is documented induction and training for staff, which includes the handling of human remains; attendance at training is recorded.	Whilst there is a process to ensure staff are trained in the requirements of SOPs, there is no procedure for ongoing competency assessment.	**Minor**

GQ6 Risks associated with the establishment's practices and processes in relation to the storage and display of human material are assessed and monitored		
b) Risk assessments set out steps taken to mitigate risks	Risk assessments do not include sufficient detail of control measures in place to mitigate the risks of storage and use of potted specimens of a sensitive nature.	**Minor**

Advice

The HTA advises the proposed DI to consider the following to further improve practices:

No.	Standard	Advice
1.	C1(a)	The DI is advised to update the form used for accepting specimens gifted to the establishment to record the consent status for storage and use of the samples for public display. The DI is advised to refer to the flow chart in HTA Code of Practice D (Annex C) when considering the consent requirements for public display of specimens.
2.	N/A	The DI is reminded that public display of human specimens at off site events can only take place on premises licensed for this scheduled purpose, or where the specimens are exempt from the licensing requirements of the HT Act 2004. The DI is advised to refer to the flow chart in HTA Code of Practice D (Annex C) when determining the licensing requirements for public display of specimens.

Concluding comments

This report describes the licence application assessment of the suitability of Brighton & Sussex Medical School to be licensed under the HT Act for storage and use of human specimens for the scheduled purpose of public display.

Some areas of good practice were identified during the inspection. There is a dedicated entrance for the public where they will be given information regarding the event before entering. This includes a detailed introduction video stating the rules for visitors.

The HTA found the proposed DI and Licence Holder to be suitable. Two minor shortfalls against the HTA standards were identified. The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Prior to issue of this report, the establishment submitted evidence that corrective and preventative actions have been taken to address the shortfalls.

Report sent to DI for factual accuracy: 30/05/2019

Report returned from DI: 31/05/2019

Final report issued: 03/06/2019

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; Individual standards which are not applicable have been excluded.

HTA licensing Standards: Public Display sector

Consent

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 systems

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 (whistle-blowing).

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

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

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.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
   - has the potential to become a critical shortfall unless addressed

   or

   A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

   In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.