Inspection report on compliance with HTA licensing standards
Assessment dates: **20 February (remote) and 22 February (site visit)**

University of Leicester

HTA licensing number 12399

Licensed under the Human Tissue Act 2004

Licensed activities

Area	Carrying out of an anatomical examination	Removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation	Storage of a body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose	Storage of an anatomical specimen
University of Leicester	Licensed	Licensed	Licensed	Licensed

Summary of inspection findings

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

Although the HTA found that the University of Leicester (the 'establishment') had met majority of the HTA's standards, three minor shortfalls were identified against standards relating to Governance and quality systems (risk assessments, adverse events and regular governance meetings).

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfall identified during the assessment.

Compliance with HTA standards

GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
GQ1(d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff	Regular committee meetings during which HTA-licensed activities were discussed, have not taken place since February 2022. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

GQ5 There are systems to ensure that all adverse events are investigated promptly		
GQ5(a) Staff are instructed in how to use incident reporting systems	The adverse event SOP is not comprehensive and did not provide enough details about the types of incidents and the corrective and preventative action process. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
GQ6(b) Risk assessments are reviewed regularly	Risk assessments have not been subject to regular review. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice

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

Number	Standard	Advice
1.	C2(a)	There is comprehensive training for new staff, including an oral briefing from the DI on consent and the requirements of the Human Tissue Act 2004. The DI is advised to formally document the training for new staff, and consider developing an in-house training package that could also include assessment elements.
2.	GQ1(a)	The DI should consider documenting the records retention periods within the bequest manual to ensure that this information is easily accessible to all staff.
3.	GQ1(b)	To strengthen document control, the DI is advised to review all standard operating procedures (SOPs) to ensure that they contain an issue date.
4.	GQ2(a)	Staff at the establishment undertake regular audits, covering consent and traceability of stored cadavers and parts. To widen the scope of activities covering by auditing, the DI should also consider audits tracing the receipt of cadavers through to disposal and include observational audits of staff undertaking activities against SOPs.
5.	GQ3(b)	Although all staff are given an induction, there is no system for monitoring staff competency. To strengthen the training of new staff, the DI may wish to consider adopting a competency framework that sets out clear criteria that new staff working under the licence are expected to meet during the course of their probation period.
6.	T1(c)	A bucket is kept with each cadaver in the dissection room, at a designated and numbered table. This bucket remains with the cadaver for the academic year and students are reminded that the bucket cannot be removed at any time. To strengthen traceability, the DI is advised to consider implementing a process that ensures that th bag lining the bucket is also labelled with the table number. This may help to reduce a risk that the bag is removed from the bucket and tissues from that donor are lost or mixed up.

Background

The establishment is licensed for the full suite of licensable anatomy sector activities, with students attending the dissection room as part of medical courses each week. The establishment has a Body Donation Programme Manager who oversees body donation. The establishment facilitates dissection of soft- and conventionally-embalmed bodies. The establishment does not carry out plastination of bodies and work with fresh frozen body parts for surgical skills training approximately every two to three years.

The establishment occasionally loans anatomical specimens to an unlicensed establishment, under section 30 of the Human Tissue Act 2004 and the governance of an agreement, for short and defined periods of time. All areas where bodies are received, embalmed, stored and dissected are secure areas with swipe-card access control. All students and visitors are expected to sign in and follow the establishment's guidance on conduct within the dissection room. This was the second inspection of the establishment; the last one took place in April 2012.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during the assessment:

Standards assessed against during the inspection

All 47 licensing standards were covered during the assessment (standards published 3 April 2017).

Review of governance documentation

The following documents were reviewed: policies and procedural documents relating to licensed activities, audits, risk assessments for health and safety, adverse incidents, staff training records, visitor management policies and visitor codes of conduct. Audits were also reviewed.

Visual inspection

A visual inspection was conducted during the site visit. This included the embalming area, dissection room, mortuary storage locations, parts room and wet specimen room.

Audit of records

Two forward audits were conducted for bodies in storage (location to records) and one reverse audit, from records to storage. The consent forms for each were also checked. A minor discrepancy was identified in the recording of the donor reference number, which had been entered incorrectly on the database. The donor reference number is given at the time the consent form is received. This was corrected at the time of the inspection. No other discrepancies were identified.

A forward audit was carried out of a demonstration cadaver (location to records): no discrepancies were identified.

Two existing holdings (potted specimens) were identified from the museum and traced to their associated records: no discrepancies were identified.

One body part specimen was identified from the parts store and traced to its records: no discrepancies were identified.

Meetings with establishment staff

The inspection included discussions with the Body Donation Programme Manager, Dissection Room Manager, Technicians and Designated Individual for the licence.

Report sent to DI for factual accuracy: 15 March 2023

Report returned from DI: 3 April 2023 (with comments)

Final report issued: 4 April 2023

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI 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 DI 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.

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 Human Tissue Act 2004 (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 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:

   - A notice of proposal being issued to revoke the licence
   - 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
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - 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 Codes of Practice, 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 review or at the time of the next 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 the final inspection report. Establishments 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 routine site visit inspection.

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