Inspection report on compliance with HTA licensing standards
Inspection date: **16 August 2023 (site visit)**

University of Manchester
HTA licensing number 12111

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 Manchester	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.

University of Manchester ('the establishment') was found to have met all HTA standards.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Compliance with HTA standards
All applicable HTA standards have been assessed as fully met.

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

Number	Standard	Advice
1.	GQ1(a)	The establishment's fridge spaces are not large enough for some bariatric bodies. The establishment has developed a procedure for storing bariatric bodies on trolleys in the mortuary and, at the time of the inspection, there was a bariatric body in the mortuary. To ensure consistency of practices, the DI is advised to document the process for storing bariatric bodies.
2.	GQ1(a)	The establishment has developed a suite of SOPs and risk assessments for imported fresh frozen material. The DI is advised to review the establishment documentation to ensure it incorporates the advice and guidance provided in the HTA Codes of Practice, such as ensuring that donors who have tested positive for tuberculosis, a transmissible spongiform encephalopathy, and meningitis have been excluded from donation by the supplier in the source country.
3.	GQ1(b)	The establishment has a process in place for notifying staff when changes are made to Standard Operating Procedures (SOPs). The DI is advised to implement a process to ensure that staff remain competent for procedures that are unchanged.
4.	GQ2(a)	Rather than label individual bones, the majority of the skeletal collection is stored in communal boxes, each box containing a specific type of bone used for teaching. The DI is advised to implement a process for

		periodically auditing the number of bones in each box to provide an assurance that none have been misplaced.
5.	GQ2(a)	To provide greater assurance on security, the DI is advised to expand the scope of internal audits to include audits of security measures and facility access records.
6.	GQ4(b)	The establishment records body donations in a mortuary logbook. The DI is advised to ensure that the mortuary logbook is regularly scanned to provide a back-up provision to avoid loss of records, especially for older donations that may not have corresponding electronic records.
7.	GQ6(a)	To provide assurances that the risks associated with dignity of the deceased and traceability have been considered and addressed, the DI is advised to document a risk assessment for the procedure for storing bariatric bodies in the mortuary.
8.	PFE2(b)	The MSSSC unit has a fridge that is not in continuous use and is not alarmed or on the remote monitoring system. As the fridge is located outside the main storage area, the DI Is advised to either include the fridge on the remote monitoring and alarm system, or to document this in a risk assessment.

Background

The establishment is licensed for the full suite of anatomy sector activities and forms part of the Faculty of Biology Medicine and Health, University of Manchester. The establishment receives bodies donated through its bequethal service, which are either embalmed on site for use for anatomical examination as part of teaching anatomy to undergraduate medical, dental and life-science students, or may be frozen for surgical skills training at the Manchester Surgical Skills and Simulation Centre (MSSSC). The MSSSC is a facility for training surgeons, using fresh frozen cadaveric material. Fresh frozen cadaveric material may also be sourced from another HTA-licensed establishment or imported from suppliers in Europe or the United States. The establishment also stores prosections, with appropriate consent, and has a collection of potted specimens and skeletal material used for training purposes.

University of Manchester has been licensed by the HTA since July 2007. This was the second inspection of the establishment; the most recent previous inspection took place in September 2013.

The establishment has appointed and replaced two DIs since the last inspection.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection

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

Review of governance documentation

Policies and procedural documents relating to licensed activities, cleaning records for the storage areas and dissection room, contracts for servicing of equipment and records of servicing, audits, meeting minutes, risk assessments, temperature logs for the storage units, reported incidents, staff training records, and visitor management policies and visitor codes of conduct were reviewed.

Visual inspection

The inspection included a visual inspection of the anatomy suite including the areas where staff receive and store bodies, the establishment mortuary, the embalming area, the storage areas for prosections and other relevant material, and the areas where anatomical examination, dissection, and surgical skills training are undertaken.

Audit of records

An audit was undertaken of records and labelling for two embalmed and three frozen bodies, one prosection, three prosections stored in fluid at ambient temperature, and one potted specimen. There was full traceability for all material.

Meetings with establishment staff
The inspection included discussion with the DI, the Corporate Licence Holder contact, Persons Designated, and other staff working under the licence including two surgical skills team members and other staff carrying out processes under the licence.

Report sent to DI for factual accuracy: 12 September 2023

Report returned from DI: 13 September 2023

Final report issued: 13 September 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 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 inspection.

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 inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

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