Inspection report on compliance with HTA licensing standards
Inspection date: **22 June 2023 (site visit)**

Faculty of Medicine and Health
HTA licensing number 12279

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
Faculty of Medicine and Health	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 Faculty of Medicine and Health (‘the establishment’) had met the majority of the HTA’s standards, one minor shortfall was found against one standard for Governance and quality systems, related to documentation of activities.

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 inspection.

Compliance with HTA standards

Minor Shortfalls

GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.	Not all practices were documented or covered by existing documents. Examples included, but were not limited to: • The staff member involved in the bequethal process had developed a checklist when accepting donations. This included confirmation that a Medical Certificate of Cause of Death (MCCD) has been seen, or confirmed that relevant clinicians had seen, or had signed, the MCCD. • When completing internal audits of specimens held at the establishment, staff routinely added a Key to the completed form to explain the terminology used. During the audit of records, it was noted that one donated body awaiting sensitive disposal, and one prosection, had appropriate consent in place but the date of the witness signature on the consent form did not match the date of the donor signature. While there was a procedure in place to check new consent forms, there was no procedure in place to address issues with older consent forms.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfall 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.	C1(a)	During the inspection it was noted that the donor consent forms for one body awaiting cremation, and one prosection, had a discrepancy where the dates of the donor and witness signature did not match. The DI is advised to consider whether similar discrepancies could be a wider issue, identifying risks that may need to be assessed and addressed.
2.	GQ1(a)	The DI and establishment staff confirmed that security staff will access the anatomy facility out of hours to investigate alarms, and that access and actions to be undertaken are detailed in an SOP held by security. The DI is advised to retain a copy of the SOP, and to periodically review it to ensure that it meets establishment expectations and requirements.
3.	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.
4.	GQ4(a)	The DI is advised to ensure that the arrangements for CCTV records are included in the establishment's records management approach.
5.	T1(c)	Thiel-embalmed bodies are stored in the ‘Thiel rack’ within the body store. When required for training, bodies are transferred to the dissection room. For a short course or training which takes place over two to three days, the location of the body is not amended in establishment records on the basis that a body recorded in the Thiel rack which is absent is understood to be in the dissection room. The DI is

		advised to amend establishment documents to reflect this procedure, to specify a maximum timeframe for this interim storage in one of the dissection rooms, and to assess any risks associated with the body not being in the location recorded in establishment records.
6.	PFE1(a)	The establishment has three dedicated dissection rooms. Two of the rooms are physically connected to the anatomy suite and the third is currently located outside of the main anatomy suite. While the third dissection room is used less often than the others, the transfer of bodies and / or specimens to dissection room three occurs outside of the main anatomy suite in an area used by non-anatomy staff and clinical trainees. The establishment has developed a procedure where bodies and specimens are transferred early in the morning, when non-anatomy staff are unlikely to be in the facility, and there is a plan to undertake building works to physically connect dissection room three to the main anatomy suite with a dedicated corridor. The DI is facilitating the building works and is advised, in the interim, to assess and document the risk/s associated with the current procedure.

Background

The establishment is licensed for the full suite of anatomy sector activities. The establishment receives bodies donated through its bequethal service, which are embalmed on site using either formalin-fixation (for conventional anatomy teaching) or Thiel fixation (for dissection and specialist training where tissue flexibility is required). The establishment also has a collection of potted specimens and skeletal material used for training purposes.

The Faculty of Medicine and Health has been licensed by the HTA since 2007. This was the third inspection of the establishment; the most recent previous inspection took place in December 2015.

Since the previous inspection, the establishment has appointed a new DI, a new Corporate Licence Holder contact, and added another Person Designated.

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, procedural documents, and records relating to licensed activities, including SOPs, risk assessments, audits, traceability systems, adverse incidents, staff training records, visitor management policies and visitor codes of conduct were assessed.

Visual inspection
The inspection included a visual inspection of the anatomy suite. This included a review of the area where funeral staff deliver and collect bodies, the temporary body storage and embalming area, the three dissection rooms where anatomical examination, dissection, and surgical skills training is undertaken, and storage areas for prosections and other relevant material.

Audit of records
An audit was undertaken of records and labelling for:

- One body undergoing Thiel fixation;
- One bariatric embalmed body in storage;
- One Thiel-embalmed body in storage;
- One dissected body awaiting transfer for cremation;
- Two Thiel-embalmed bodies in dissection room one;
- One Thiel-embalmed body in dissection room two;
- Two prosections;
- Four potted specimens; and
- One femoral head.

While evidence of appropriate consent was in place, discrepancies were noted for one body and one prosection where the date of the witness signature did not match the date of the donor signature. Oral advice was given to the establishment at the time of inspection regarding actions that could be taken regarding this issue.

Meetings with establishment staff
The inspection included discussions with the DI, the establishment's HTA manager, the anatomy facilities manager, an anatomy lecturer, the senior anatomy demonstrator, anatomical staff involved in the bequethal process, and other staff working under the licence.

Report sent to DI for factual accuracy: 18 July 2023

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 4 August 2023

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 13 November 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.