Inspection report on compliance with HTA licensing standards
Inspection dates: **22 February (remote) and 27 February (site visit) 2024**

University of Southampton Faculty of Medicine
HTA licensing number 12555

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 Southampton Faculty of Medicine	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 University of Southampton Faculty of Medicine ('the establishment') had met the majority of the HTA's standards, two minor shortfalls were found against standards for Governance and quality systems and Premises, facilities and equipment.

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 shortfalls identified during the inspection.

Compliance with HTA standards

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
b) There is a document control system	The establishment did not have system in place for governance documents, to include revision history, version number, 'effective from' and next review dates.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
d) There are documented contingency plans in place in case of failure in storage area.	There was no contingency plan in place in case of failure in storage area	**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.	GQ2(a)	To provide greater assurance on security, the DI is advised to expand the range of internal audits to include audits of security measures and facility access records.
2.	GQ3(b)	As part of the induction programme, new staff are provided with HTA's Code of Practice C: Anatomical Examination and are expected to familiarise themselves with the regulatory and legal requiirements and expectations relating to their work. To strengthen training, the DI is advised to consider developing materials that help to direct new staff to the key requirements and consolidate their knowledge.

3.	GQ5(b)	The incident log book referenced two incidents related to use of mobile phones. The DI is advised to review the details of these incidents and consider whether any further actions should be taken to prevent similar future incidents; for example, actions relating to procedure/s or policy.
4.	PFE2(c)	The temperature ranges for fridges and freezers are documented in standard operating documents (SOPs). To improve awareness and monitoring in practice, the DI is advised to consider displaying these temperature ranges on the fridges and freezers.

Background

University of Southampton Faculty of Medicine is a facility that provides teaching of human anatomy to undergraduate and postgraduate students, and provides surgical training. University of Southampton Faculty of Medicine has been licensed by the HTA since 2009. This was the second inspection of the establishment; the most recent being a site visit in June 2013. Since the previous inspection, the Corporate Licence Holder contact (CLHc), DI and Persons Designated (PDs) have changed and there have been no other significant changes to the licence arrangements or the activities carried out under the licence

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 inspection:

Standards assessed against during inspection

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

Review of governance documentation

Policies and procedural documents relating to all licensed activities, including standard operating procedures and traceability systems, were assessed. Documents detailing staff training, adverse events, incidents, governance meetings, risk assessments and audits were also reviewed.

Visual inspection
The inspection included a visual inspection of the anatomy suite including the areas where staff receive and store embalmed bodies, prosections and relevant material, and the areas where relevant material and anatomical specimens are used for training and anatomical examination.

Audit of records
An audit was undertaken of records and labelling for two embalmed bodies, seven prosections, one plastinated specimen and three potted specimens in the storage area. There was full traceability for all material.

Meetings with establishment staff
The inspection included discussions with the DI, PD, teaching fellows and technicians carrying out processes under the licence.

Report sent to DI for factual accuracy: 14 March 2024

Report returned from DI: 03 April 2024

Final report issued: 04 April 2024

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: 25 June 2024

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.