Inspection report on compliance with HTA licensing standards
Assessment dates: **10 November 2022 (remote) and 17 November 2022 (site visit)**

University of Sheffield

HTA licensing number 12130

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 Sheffield	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 Sheffield (the ‘establishment’) had met the most of the HTA’s standards, five minor shortfalls were identified against standards relating to Consent (staff training), Governance and quality systems (risk assessments and records management), Traceability and Premises, facilities and equipment (ventilation).

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

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a) There is suitable training and support of staff involved in seeking consent.	There was no formalised consent training, including refresher training, available for staff.	**Minor**

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	There was no records management policy that defined the retention periods for paper and electronic records.	**Minor**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.	There were no documented risk assessments for premises, practices and processes connected with licensed activities.	**Minor**

T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail		
b) A register of donated material, and associated products where relevant, is maintained	The establishment has a collection of potted pathological specimens and tissue slides transferred from another establishment. There was no record of the slides in storage. "*The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*"	**Minor**

c) An audit trail is maintained, which includes details of when and where the bodies or tissue were acquired, the consent obtained, the uses to which any material was put, when and where the material was transferred, and to whom.	Any tissues, organs or parts removed at dissection are placed in a bag that is traceable to the related body. After each bag is filled, it is removed to the assigned coffin for that particular body but there was no system to track and account for the transfer of material from the dissection table to the coffin.	**Minor**

PFE1 The premises are secure and fit for purpose		
a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose	At the time of the site visit, the dissection activities had been paused due to health and safety concerns about high formaldehyde levels and how levels had been monitored in the past. Expert advice was being sought from an Environmental Hygienist. Although formaldehyde levels had been monitored more intensively for a short period prior to the site visit and were reported to be safe, there was no evidence of the assessment of relevant risks and no documented evidence of monitoring.	**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)	The DI should ensure that audit forms clearly document what was checked during the audit; for example, what was checked and why it meets (or does not meet) a requirement. This will help ensure that all findings can be evidenced clearly for review and monitoring purposes.
3.	GQ5(a)	The DI is advised to add the Corrective and Preventative Action plan process to be followed in the event of a incident, to the Standard Operating Procedure (SOP16), Reporting of Adverse Events.

Background

The establishment is licensed for the full suite of anatomy sector activities. Each week, approximately 800- 900 students attend the Medical Teaching Unit (MTU) as part of medical courses. The establishment has a bequeathal team that manages body donation. The establishment also carries out plastination of bodies and body parts in a dedicated area of the unit. At the time of the inspection, there was no surgical skills training using fresh frozen body parts. The MTU is secure and all students and visitors are expected to sign-in and follow their Code of Conduct. This was the second inspection of the establishment; the last one took place in April 2011.

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, preparation, dissection and plastination room, storage locations for relevant material and training rooms.

Audit of records

Forward audits were conducted for bodies, body parts and relevant material (location to records). This included two bodies in the fridge room, four body parts/organs, two potted specimens and histology slides. No discrepancies were identified.

During the inspection it was identified that there were tissue slides which had not been catalogued (Minor shortfall, T1(b)).

Meetings with establishment staff

The inspection included discussions with the Bequeathal Secretary, Person Designated and Designated Individual for the licence.

Report sent to DI for factual accuracy: 14 December 2022

Report returned from DI: 16 January 2023 (with comments)

Final report issued: 24 January 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.