Inspection report on compliance with HTA licensing standards
Inspection date: **6 June 2024 (remote) and 13 June 2024 (site visit)**

Robert Jones and Agnes Hunt Orthopaedic Hospital
HTA licensing number 12073

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
Robert Jones and Agnes Hunt Orthopaedic Hospital	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 Robert Jones and Agnes Hunt Orthopaedic Hospital (‘the establishment’) had met the majority of the HTA’s standards, five minor shortfalls were found against standards for Governance and quality systems, Traceability 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	Shortfall
GQ1 All aspects of the establishments work are governed by 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	The establishment's SOPs lacked detail and had not been updated in line with the changes to procedures. Examples include- • The 'Local Code of Conduct' SOP (ANAT/21) referred to the previous DI. • The 'Storage of Cadavers and Prosected Parts' SOP (ANAT/08) detailed recording the temperatures of the fridge and freezer units daily using the manual digital readout. The SOP did not reflect the remote temperature monitoring system that is in use. • The 'Receipt of Cadaver' SOP (ANAT/06) briefly detailed checking consent paperwork when a donation is received. It did not detail specifically what is checked and the identification checks for the donation. • Although the establishment does not seek consent directly from donors, no SOP detailed how any conditions made on consent are recorded; for example, whether the donor had given consent for the retention of parts. • The 'Adverse Events' SOP (ANAT/18) detailed how adverse incidents are logged and reported; however, it did not detail how incidents are to be investigated, addressed and monitored. There is an SOP for the 'Preparation of Mounting Fluid for Museum Pots' (ANAT/03); however, there was no SOP covering the routine management and maintenance of the potted specimen collection *(see linked shortfall under Standard PFE2(c)).*	**Minor**

b) There is a document control system	Some of the procedural documents have been written and approved by the same person and several of the establishment's documents are overdue for review.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities	Annual horizonal audits lack detail of what is covered and do not audit specimens and records to ensure that they are fully traceable from consent to storage. The current schedule does not cover the potted specimen collection at all.	**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 the associated products where relevant, is maintained	The establishment has a large collection of potted specimens which are existing holdings. The collection was not fully catalogued.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue		
c) Storage conditions are monitored, recorded and acted on when required	Several potted specimens require general maintenance, including the replenishment of preservative fluid.	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ1(a)	There are many shorter SOPs detailing specific procedures relating to licensable activities. The DI is advised to amalgamate the SOPs so that they cover full procedures from start to finish. This will help to streamline documentation and also reduce the time taken for staff to review the documents.
2.	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 at the site.
3.	GQ2(a)	To gain wider assurances, the DI is advised to consider extending the range of audits to include coverage of processes and procedures; for example, staff undertaking a specific task.
4.	PFE1(a)	The establishment have three fridge units and a freezer unit for the storage of cadavers and prosections. The units all look the same. The DI is advised to label the freezer to make it clear to staff, and to minimise the risk of inadvertent storage in this unit.
5.	PFE1(c)	The specimen storage area and dissection room were very clean and there are daily, weekly and monthly cleaning tasks detailed in the establishments cleaning SOP. As activity levels are very low, there were no completed schedules to view. As activity increases, the DI is advised to produce checklists where staff can sign to record the cleaning procedures being carried out.

Background

Robert Jones and Agnes Hunt Orthopaedic Hospital has been licensed by the HTA since August 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in October 2017.

Since the previous inspection, there have been significant changes to the licence including a change of DI in May 2020 and a change of the CLHc in June 2020.

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

39 out of 47 HTA licensing standards were covered during the assessment (standards published 3 April 2017).
Some standards relating to consent were not applicable as the establishment does not seek consent directly from donors (C1(a), C1(b), C1(d), C1(e), C1(f), C2(a), C2(b) and C2(c)).

Review of governance documentation

The Regulation Manager reviewed the establishment's self-assessment document provided by the DI. Policies and procedural documents relating to licensed activities were reviewed. This included standard operating procedures (SOPs), policies, risk assessments, traceability databases (paper and electronic), recent audits and governance meeting minutes.

Visual inspection

The Regulation Manager undertook a site visit inspection which included the anatomy suite and storage areas.

Audit of records

The Regulation Manager undertook traceability audits for prosections stored in the department. This included four specimens that were stored in the fridge. Traceability details were crosschecked between the identification tags on the prosections and information on the electronic and paper records through to consent documentation. Five potted specimens from the museum collection were also audited. Traceability details were crosschecked between the identification details on the specimens and information in the paper records. No discrepancies were identified.

Meetings with establishment staff

The Regulation Manager met with staff carrying out activities under the licence, including a Clinical Anatomist and Prosector, an Assistant Chief Nurse and the DI.

Report sent to DI for factual accuracy: 25 June 2024

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

Final report issued: 31 July 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.