Inspection report on compliance with HTA licensing standards
Inspection date: **14 August 2024**

Alder Hey Children's Hospital

HTA licensing number 12213

Licensed under the Human Tissue Act 2004

Licensed activities

The table below shows the activities this establishment is licensed for and the activities currently undertaken at the establishment.

Area	Making of a post-mortem 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 the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose
Hub site Alder Hey Children's Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab			*Carried out*
A&E		*Carried out*	

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 Alder Hey Children's Hospital ('the establishment') had met the majority of the HTA's standards, five major and three minor shortfalls were found against standards for Consent, 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

Major shortfall

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice	Whilst staff receive consent training and this has been refreshed. The Consent Policy lacks detail regarding the frequency of staff consent training and an assessment of competency.	**Major (cumulative)**
b) There is a documented standard operating procedure (SOP) detailing the consent process	The consent SOP lacks detail regarding the amount of time offered to those giving consent to a post-mortem examination to change their mind.	

f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds	Whilst staff identified the timeframe for those giving consent to change their minds. Information regarding who should be contacted, their contact details and the timeframe for those giving consent to change their minds, had not been completed in the consent form reviewed by the inspection team. A copy of the consent form is given to families to provide written guidance. This poses the risk of families not knowing who to contact should they wish to withdraw consent to a post-mortem examination.	
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual	The Inspection team were not assured untrained staff involved in consent seeking are always accompanied by a trained individual.	**Major (cumulative)**
d) Competency is assessed and maintained	There were no records to review indicating consent trained staff had received a competency assessment after they had undertaken consent training.	
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	Family members provide three identifiers when attending the mortuary for a viewing. These do not correspond with information held on the ID bands. This poses the risk of a viewing of the wrong body. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Major**

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	During the tissue traceability audit, two cases were identified where the number of tissue blocks in storage did not match the number indicated in associated records. One case had one tissue block in storage that had not been accounted for in storage at the time of the inspection. *See Advice item 2.*	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Whilst swipe card access lists are reviewed and updated regularly. There is no regular audit of CCTV footage to ensure adherence with relevant policies and procedures.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed	Risk assessments pertaining to lone working in the mortuary and security lack detail of the mitigating controls used by staff. See Advice item 1	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	Whilst fridge and freezer alarms are regularly tested, a test of the lower set range is not undertaken. *See Advice item 3.*	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The inspection team were not assured the ventilation system provides the necessary ten air changes per hour and is checked and maintained annually. The ventilation report provided for review was from routine servicing carried out in 2021.There was no information pertaining to the number of air changes per hour documented in the report.	**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 practice:

Number	Standard	Advice
1.	GQ6(b)	The DI is advised to risk assess the windows between the funeral director entrance and the mortuary to ensure the window film in place is sufficient to prevent the oversight of activity being undertaken within the mortuary.
2.	T1(g)	The DI is advised to undertake an audit of all tissue in storage against associated records before it is transferred to the offsite storage facility.

3.	PFE2(e)	The DI is advised to consider the introduction of an out of hours test into the programme of routine fridge testing. This will provide additional assurance the staff alerting system is effective in the event of a fridge temperature excursion out of hours.
4.	PFE3(f)	The equipment used in the mortuary including hydraulic trolleys and post-mortem tables, is subject to regular testing and servicing. However, records are not kept within the mortuary and are only available upon request. The DI is advised to request copies of all maintenance, servicing and repair reports so they are easily accessible to the mortuary management team for review and monitoring purposes.

Background

Alder Hey Children's Hospital has been licensed by the HTA since 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in December 2021

Since the previous inspection, there has been a change to the Corporate Licence Holder Contact (CLHc) in 2023, there have been no changes to the activity undertaken under the licence.

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

Review of governance documentation

The inspection included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records for the mortuary, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and training records for mortuary staff and the bereavement team.

Visual inspection
The inspection included a visual assessment of the mortuary body storage areas including the PM room and viewing suite. The inspection teams observed the processes for admission and viewing of bodies within the mortuary.

Audit of records
Audits were conducted for three bodies from refrigerated storage, and the admission of one body transferred from a third party establishment. Identification details on bodies were crosschecked against the information recorded in the mortuary electronic register and associated paperwork. No discrepancies were identified.
An audit of one consent form for a hospital post-mortem examination was undertaken, this was cross referenced against staff training records, a discrepancy was identified between the list of consent seekers and the person who had obtained consent. Furthermore, the consent form was incorrectly completed with some information not documented. (See shortfalls against C1(f) and C2(c) for further information).
Audits of tissue traceability were undertaken for eight histology cases, discrepancies between written records and physical holdings were identified for two cases, and one tissue block had not been disposed of in line with the family wishes. (see shortfall against T1(g) for further information).

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, Histopathology Manager and Governance and Quality Lead for Pathology**,** Pathologist, lead APT, APT, tissue lead, consent seeker, and a member of the Snowdrop bereavement team.

Report sent to DI for factual accuracy: 22/08/2024

Report returned from DI: 06/09/2024

Final report issued: 06/09/2024

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: 28 March 2025

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 both the draft and 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.