Inspection report on compliance with HTA licensing standards
Inspection date: **28 October 2025**

Birmingham Children's Hospital

HTA licensing number 12132

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
Birmingham Children's Hospital	Licensed	Licensed	Licensed
Mortuary	*Not carried out*	*Carried out*	*Carried out*
Pathology laboratory	-	-	*Carried out*
Paediatric ward	-	*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 Birmingham Children's Hospital ('the establishment') had met the majority of the HTA's standards, three major and four 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

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	Risk assessment documentation is inconsistent and not reviewed on a regular basis. HTA reportable incident classifications were last risk assessed in 2022 on a template that includes risk scoring, mitigations actions, timeframes of	**Major (Cumulative)**

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	completion, and responsible individuals. However, the remaining risk assessments of licensed activities were of a poor quality and out of date. This includes: • No template for recording mitigation actions, or timeframe of completion. • Unclear risk scoring. • Absence of mitigation actions that were observed on site, such as CCTV reviews and checking of identification labels. • No evidence of regular reviews, a number of risk assessments had not been reviewed since 2008. These therefore included out of date HTA guidance and establishment procedures.	
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	The inspection team are not assured that three identifiers are used to identify bodies when activities are carried out by non-mortuary staff. The inspection team were told that when releases and viewings were carried out by ward staff, only two identifiers were given verbally, as the families were often known to the staff. This combined with no acknowledgement of SOPs (see shortfall GQ1e) poses a risk of the incorrect body being released or viewed, with no documented evidence that any identification checks had taken place.	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		

a) The premises are clean and well maintained	The post mortem room is currently being used as a store room for 'existing holdings' of tissue retained for the purpose of teaching. As the room is still used for the removal of tissue, and the establishment is licensed for conducting post mortem examinations, the inspection team were concerned that the room is no longer fit for its designated purpose. The room is currently shared by two departments, with no staff group having overall responsibility for its cleanliness and maintenance. Whilst traceable, tissue samples cover all surfaces within the room. The inspection team could therefore not assess against all standards relating to post mortem activity. *See advice PFE1(a).* Further, the fridge room is predominantly used as a store room for mortuary equipment and consumables, some of which are stored on the floor, this poses a risk of ineffective cleaning and decontamination. The collection area for funeral services is also poorly maintained, and used as an area for storing waste and condemned equipment.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	Whilst checked on a regular basis, condition of bodies is not recorded. The inspection team were informed that condition of bodies would be recorded if there were deterioration or signs of change. However, there were no evidence that this had been completed.	**Minor**

e) There is a system for recording that staff have read and understood the latest versions of these documents	Bereavement staff and site-coordinators, responsible for regulated activities such as viewings, are sent updated SOPs on the procedures. However, there was no mechanism to record that they had read and acknowledged the latest versions of these documents.	**Minor**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	Whilst all mortuary areas appeared clean, the schedule of cleaning had not been signed since September 2025. On review there were gaps of up to three months where there was no evidence cleaning had taken place. Further, the post mortem room did not form part of the schedule of cleaning.	**Minor**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The mortuary access audits require strengthening. This includes ensuring the mortuary visitor book includes full names, job roles, and time spent in the mortuary. The records currently only include visitors using their initials and not entering a time out of the mortuary.	**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.	GQ1(a)	The mortuary manager is advised to complete a comprehensive review of all SOPs to ensure they contain up to date hyperlinks to guidance and activities.
2.	T1(b)	The mortuary manager is advised to record the fridge location of bodies to further strengthen traceability processes and audits.
3.	PFE1(a)	The designated individual is advised to review the use of the post mortem room and the necessity of having the licensed activity of 'conducting a post mortem examination' on the HTA licence. The room currently requires non-mortuary staff to have access to the mortuary and occupies much needed space for the storage of mortuary equipment and consumables.
4.	PFE2(c)	The mortuary manager is advised to relocate, or lock, the freezer unit within the body store to mitigate the risk of it accidently being used for the storage of bodies.
5.	PFE3c	The ventilation service report in 2025 deemed the post mortem room air handling unit to be in a poor condition. The designated individual is advised to take remedial actions to prevent further deterioration of the equipment. This will help mitigate against the risk of the ventilation system falling below the required 10 air changes per hour.

Background
Birmingham Children's Hospital has been licensed by the HTA since August 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in July 2024.

Since the previous inspection, there have been no 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 inspection team covered the following areas during the inspection:

Standards assessed against during inspection

70 out of the 72 licensed standards were covered during the inspection (standards published 3 April 2017). Standards GQ1(b) and PFE3(e) were not assessed as the establishment no longer carries out post mortem examinations.

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, cleaning records for the mortuary, records of servicing equipment, audits, risk assessments, meeting minutes, reported incidents, and training records for staff.

Visual inspection

The inspection included an unannounced visual assessment of the regulated areas of Birmingham Children's Hospital including the mortuary access points, the mortuary fridge room, postmortem room, viewing facilities, Peadiatric ward, and tissue storage areas. The inspection team observed the processes for admission, release, and viewing of bodies within the mortuary.

Audit of records

A limited audit was conducted of a small number of bodies in refrigerated storage. Identification details on bodies were cross-checked against the information recorded in the mortuary register and associated paperwork. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides from six consented postmortem cases. These included audits of the consent documentation for the retention of these tissues. No discrepancies were identified.

Meetings with establishment staff

Staff conducting processes under the licence were interviewed including the DI, Mortuary Manager, Quality Lead, Mortuary Porter, and Bereavement Coordinator.

Report sent to DI for factual accuracy: 05 December 2025

Report returned from DI: 11 December 2025

Final report issued: 12 December 2025

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 January 2026

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.