Inspection report on compliance with HTA licensing standards
Inspection date: **17 July 2024**

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
Hub site **Birmingham Children's Hospital**	Licensed	Licensed	Licensed
Mortuary		*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 Birmingham Children's Hospital ('the establishment') had met the majority of the HTA's standards, five major and two 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**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	Whilst all staff involved in mortuary duties receive initial training, porters, bereavement officers and site co-ordinators who undertake activity under the licence do not receive refresher training. *See Advice item one*	**Major (cumulative)**

c) Staff are assessed as competent for the tasks they perform	Whilst all staff involved in mortuary duties are assessed as competent, porters, bereavement officers and site co-ordinators who undertake activity under the licence do not have their competency reassessed regularly. *See advice, item one*	
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	Whilst there are processes in place for staff to follow when undertaking a viewing, the inspection team were not assured information provided by families is checked against the information obtained on booking a viewing and ID bands on the body prior to being shown into the viewing room. This poses the risk of the viewing of the wrong body.	**Major**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	Whilst there are systems and processes in place to maintain the traceability of organs and tissue removed during post mortem (PM) examination, the establishment does not obtain confirmation of receipt of tissue transferred to the third party establishment undertaking research. Furthermore, there are two cataloguing systems in place for the existing holdings. This could cause confusion during the audit process. This poses the risk of a loss of tissue traceability.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
d) Fridge and freezer units are in good working condition and well maintained	The histology -80°C freezers used to store tissue are not included in the routine equipment servicing and maintenance schedule. This poses the risk of damage to tissue due to a major equipment failure.	**Major**

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 fridges and freezers are centrally monitored, the temperature monitoring system for one of the -80°C freezers used for the storage of histology tissue is faulty and does not record the temperature or alert personnel in the event of a temperature excursion out of hours. This poses the risk of damage to tissue due to a major equipment failure.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Whilst there is a documented schedule of audits, the audit schedule does not include the security audits which are undertaken on a monthly basis. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
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.	**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.	GQ3(a)(c)	The DI is advised to expedite existing plans in place for link workers to deliver refresher training and reassess staff competency for non mortuary staff who undertake activity under the licence.
2.	PFE1(d)(e)	The DI is advised to risk assess the plans in place for the installation of additional CCTV cameras, to ensure the dignity of the deceased is maintained. Additionally, a review of staff authorised to access the CCTV feed should be undertaken in response to security audit findings. Should additional personnel be granted access, suitable training should be provided and access for all authorised personnel should be risk assessed. Furthermore, the DI is advised to introduce regular testing of the panic alarm for use by staff when lone working to provide assurance the process in place is effective.
3.	PFE2(e)	Whilst fridge alarms are regularly tested, there is no testing of alarms out of hours. The DI is advised to consider adding the testing of alarms out of hours to the existing fridge testing schedule. Additionally, the DI should consider reducing the 60 minute delay in the alarm alerting staff of a temperature excursion. This will help to mitigate the risk of accidental damage to a body.
4.	PFE3(a)	Whilst the mortuary ventilation system is subject to regular testing and maintenance, the sound level measurements exceed the recommended safe volume. The DI is advised to expedite the remedial work needed to address this issue.

5.	N/A	Consideration should be given to the revocation of the activity of the Making of a post mortem examination from the establishment licence, as there have been no post mortem examinations undertaken for several years.

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 January 2022.

Since the previous inspection, there has been a change to the Corporate Licence Holder Contact (CLHc) in December 2022. There have been no changes to the activity undertaken under the licence. At the time of the inspection there were no bodies in storage.

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

69 out of the 72 post mortem standards were covered during the inspection. Three standards (GQ1(b), T1(f) and PFE3(b)) are not applicable. The establishment has not undertaken a PM examination for over four years and do not store bodies long-term or receive bariatric bodies.

Review of governance documentation

Policies and procedural documents relating to licensed activities were reviewed. The inspection team reviewed records relating to equipment servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training. Consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection
The inspection team inspected the premises, including the mortuary body storage area, PM room and viewing suite, and the area for storage of relevant material held within the pathology department. A visual inspection of the freezers used for storage of tissue retained for research purposes was undertaken.

Audit of records
The inspection team were unable to undertake an audit of bodies as there were no bodies in storage at the time of the site visit. However, the inspection team did review the paperwork in place to document the care delivered to bodies from admission to release.
Audits were conducted of tissue taken at PM examination for three cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, consent for PM examination forms (where relevant), the laboratory database, and tissue blocks and slides being stored. No discrepancies were identified.

Audits were conducted of tissue held for research purposes for three cases. Sample identifiers were crosschecked between consent forms held, laboratory records, detail of location of samples in laboratory records and actual sample location. No discrepancies were identified.

There is a small collection of existing holdings held in the mortuary store. Audits were conducted on five cases. Information was crosschecked between information on the container and laboratory records. No discrepancies were identified.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence, including the DI, Mortuary Manager, Quality Lead, staff involved in the consent seeking process and a Porter.

Report sent to DI for factual accuracy: 31 July 2024

Report returned from DI: 06 August 2024

Final report issued: 06 August 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: 3 October 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 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.