Inspection report on compliance with HTA licensing standards
Inspection date: **11-12 January 2022**

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/Not licensed	Licensed/Not licensed	Licensed/Not licensed
Mortuary	*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, six major and eight minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment. These related to standard operating procedures, risk assessments and audits, staff training and competency assessment, security arrangements in the mortuary, storage of relevant material and mortuary maintenance.

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
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	Standard Operating Procedures (SOPs) do not include sufficient detail of identification checks performed relating to traceability of bodies. These include but are not limited to: • HISMOR027 - Arranging a Viewing in the Rainbow Room (Ward and Lab Procedures) does not include sufficient information of how the three identifiers of the deceased given at the time a viewing is arranged are crosschecked to information on the body or how these identifiers are checked prior to entry of visitors to the viewing room. • HISMOR030 - Releasing a Body from the Mortuary does not make it sufficiently clear that three identifiers of the deceased will be crosschecked at the point of release of a body with funeral directors as observed by the inspection team during the inspection. To fully address this shortfall the establishment should review all SOPs relating to traceability of bodies, tissues, and organs to ensure they contain sufficient details of identification checks performed and are reflective of current practice.	**Major**
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	There is no evidence of training for portering staff, bereavement service staff, clinical site managers and ward staff involved in mortuary duties. These staff groups can be involved in admission, viewing and release of bodies, including activities undertaken out-of-hours.	**Major**

c) Staff are assessed as competent for the tasks they perform	Staff groups listed in the shortfall against HTA standard GQ3(a) have not been assessed as competent for the tasks they perform.	**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	Ward staff attend the mortuary out-of-hours to undertake viewing of the deceased with families. They are granted authorisation to enter by clinical site managers on duty however, the recording of this authorisation does not include sufficient detail of those granting access.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	The post mortem (PM) room is currently being used for the temporary storage and re-cataloguing of a collection of identifiable existing holdings for use for scheduled purposes. This storage arrangement is not currently sufficient for the number of items held in the collection to ensure dignity of the specimens is maintained. Some specimen containers were stored on the floor due to a lack of shelf space.	**Major**
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 PM room is currently not used for PM examinations however, tissue retrievals in this room may still occur. The ventilation system does not provide the necessary 10 air changes per hour. Furthermore, the unit has been described as being in poor condition in the latest service report.	**Major**

Minor Shortfalls

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		
b) There is a documented standard operating procedure (SOP) detailing the consent process	The consent policy does not detail the withdrawal of consent procedure or include detail of the timeframe in which consent can be changed or withdrawn.	**Minor**
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
d) Competency is assessed and maintained	Competency is not assessed or maintained for staff seeking consent for PM examination following initial training and sign off.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The audit schedule does not include audits of traceability of bodies within the mortuary. The risk of audits not being conducted is mitigated by the low number of bodies the establishment receive per year which is approximately 100.	**Minor**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	Not all staff involved in licensable activities were fully aware of incidents that must be reported to the HTA.	**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 do not sufficiently detail identified risks or control measures in place to mitigate risks. Furthermore, risk assessments are based on previous HTA standards.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements	The procedure for sending bodies to a referral centre for PM examination does not include confirmation of receipt of the body.	**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 the mortuary premises were clean at the time of the inspection and there are documented procedures in place, the establishment were unable to provide up-to-date records detailing the cleaning that has been completed.	**Minor**
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 -80 freezer unit used for the storage of tissue for research purposes has some excessive ice build-up which requires maintenance.	**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.	C1(c)	The DI is advised to review the PM information booklet given to parents to ensure information on where the PM will be held is accurate.
2.	GQ1(d)	Whilst the establishment have an electronic system which details when documents are reviewed, the DI is advised to include the review dates on the documents. This will provide assurance the most current printed versions are in use where relevant.
3.	GQ1(h)	The DI is advised to invite the Persons Designated (PDs) from bereavement and A&E to the HTA governance meetings and to distribute meeting minutes to PDs in other areas working under the licence.
4.	GQ2(c)	Whilst there are regular tissue traceability audits conducted of material being held for a scheduled purpose, the DI is advised to include the existing holdings held in the mortuary store in the audit schedule going forward.

5.	GQ5(a)	The DI is advised to review the incident reporting SOP and risk assessments against the most recent Guidance on HTA Reportable Incidents (HTARIs) in the Post Mortem Sector issued in 2020.
6.	T1(b)	Records relating to the deceased spanning many years following release of the body are still held in a file in the mortuary body store. The DI is advised to review the storage of these paper records and consider storage of older records in a more secure location.
7.	PFE1(a)	The DI is advised to consider alternative storage arrangements for histology consumables currently stored in the mortuary body store area.
8.	PFE2(a)	The DI is advised to find an alternative location for the freestanding fridge / freezer unit currently in use in the PM room.
9.	PFE2(a)	Whilst bodies are not stored long-term and are routinely monitored whilst in storage, the DI is advised to review the 'Guidance on body storage' recently published by the HTA for assurance that procedures on condition checking of bodies are in line with guidance provided.

Background

Birmingham Children's 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 January 2017.

Since the previous inspection, the organisation has merged with another local HTA licensed establishment. There are discussions in place to review the licensing arrangements for both establishments going forward. The establishment have stopped providing PM examination on site due to a lack of available paediatric pathologists to undertake this activity at this time. The deceased requiring PM examination are now transferred to other HTA licensed establishments.

The establishment are in the process of re-cataloguing a collection of identified existing holdings with a view to using this collection for scheduled purposes in the near future.

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

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

Review of governance documentation

The inspection team reviewed the establishments self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. The team also undertook a review of 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 undertook a visual inspection of the premises which included the mortuary body storage area, PM room and viewing room as well as 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 also undertaken.

Audit of records

The inspection team undertook audits of traceability for two bodies in storage. Traceability details were crosschecked between the identification band on the body, information on the door of the storage unit, the mortuary register and paperwork. No discrepancies were identified.

Audits were conducted of tissue taken at PM examination for four 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 five 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 four cases. Information was crosschecked between information on the container and laboratory records. Whilst the containers described the type of material being held, such as blocks and slides, there was no detail of the numbers of blocks and slides held for each of the cases. As this material is not being stored or used for a scheduled purpose as defined by the HT Act, advice and guidance regarding the management of traceability of this material was provided to establishment staff on the day of the inspection.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including laboratory staff, staff involved in the consent seeking process, staff responsible for the removal of relevant material in the Emergency Department, staff responsible for the management of the collection of the identified existing holdings and the DI.

Report sent to DI for factual accuracy: 18 February 2022

Report returned from DI: 28 February 2022

Final report issued: 04 March 2022

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: 05 September 2022

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.