Inspection report on compliance with HTA licensing standards
Inspection date: **27 and 29 March 2023**

Birmingham Women's Hospital
HTA licensing number 12565

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 Women's Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*

Summary of inspection findings

Whilst the HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation, the LH is advised to consider a change of DI as part of the organisational restructure with another

HTA licensed establishment. The extensive clinical and governance role of the current DI, both internal and external to the organisation, could pose a risk to the DIs ability to have full oversight of licensable activity.

Although the HTA found that Birmingham Women's Hospital ('the establishment') had met the majority of the HTA's standards, two major and four minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities, and equipment. These related to reporting of incidents to the HTA, security of external fridge components, standard operating procedures, errors in written records and accurate recording of tissue slides in the laboratory database.

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**
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	The inspection team identified two incidents in the internal reporting system that should have been reported to the HTA. One related to the temporary closure of the establishment to undertake post mortem examination and the second incident related to a complaint from a family arising because of the first incident. The establishment, however, have completed thorough investigations into the incidents and have implemented corrective and preventative actions to mitigate risk of similar incidents.	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		

d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	The external components of the fridge units are accessible outside of the mortuary. This leaves a risk of the external components being tampered with. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Major**

Minor 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.	Some standard Operating Procedures (SOPs) do not include sufficient detail of the identification checks performed relating to traceability of bodies or describe current practice. These include but are not limited to: • Whilst bodies are regularly checked to ensure the condition of the body is being maintained, these checks are not recorded or detailed within an SOP. • The SOP for the viewing of the deceased is not clear how the identifiers received from visitors at the time of a viewing are checked against the body to confirm the correct visitors have arrived to view the correct body. To fully address this shortfall the establishment should review all SOPs relating to traceability of bodies to ensure they contain sufficient details of identification checks performed and are reflective of current practice.	**Minor**

d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	Some SOPs have been authored and authorised by the same person.	**Minor**
GQ4 There is a systematic and planned approach to the management of records		
b) There are documented SOPs for record management which include how errors in written records should be corrected	Whilst there is an SOP in place on how errors in written records should be corrected, the inspection team identified some instances where errors had been corrected in manner which made the record illegible. This poses a risk of documents not being fully auditable.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
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 slides in storage did not match the number of slides recorded in the laboratory database. This was due to the creation of more slides for analysis that were not subsequently added to the total in the database.	**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(b)	Whilst the SOP for seeking consent includes reference that consent seekers must be trained and competent in the seeking of consent, the DI is advised to ensure information leaflets for consent seekers also include this detail, so the requirements are clear.
2.	C1(g)	The DI is advised to ensure that all establishments who refer the deceased for PM examination have the latest copy of the perinatal consent seeking form.
3.	GQ1(h)	HTA governance meetings were suspended during the Covid pandemic and have recently been reinstated. The DI is advised to ensure the meetings are now held regularly going forward.
4.	GQ3(a)	Whilst staff involved in licensable activities are trained and competency assessed, the DI may wish to consider extending awareness of requirements of procedures to ward staff who may be involved to support trained individuals in activities out-of-hours such as viewing of the deceased.
5.	GQ6(b)	The DI is advised to review the HTARI risk assessment in place for assurance that control measures to mitigate the risk of an incident also extend to activities that may occur out-of-hours.
6.	T2(a)	The DI is advised to complete and return the PACE self-assessment form to the HTA as soon as review of police holdings has been completed.
7.	T2(c)	The DI is advised to liaise with the Coroner's service regarding the family wishes forms in use. The form has grouped together all the scheduled purposes for which consent can be obtained to retain material. This means those giving consent must consent to retention for all scheduled purposes or to none. Families may not wish to consent to some of the scheduled purposes listed and should be given the option of which scheduled purposes they would like to give consent for.
8.	PFE2(e)	The DI is advised to review the upper alarm trigger points for the refrigerated unit which is currently set at 10 degrees Celsius. This may pose a risk to bodies being stored at suboptimal temperatures for prolonged periods of time prior to the alarm sounding.

Background

Birmingham Women's Hospital has been licensed by the HTA since May 2010. This was the fourth inspection of the establishment; the most recent previous inspection took place in September 2018.

Since the previous inspection, a change to the list of Persons Designate named under the licence was made in September 2019 and a change to the Corporate Licence Holder contact was made in December 2022.

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

71 out of 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017). Standard PFE3(b) is not applicable to this establishment as the establishment does not routinely receive bariatric bodies.

Review of governance documentation

The inspection team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. This included cleaning records for the mortuary and post-mortem room, mortuary visitor logs, records of servicing of equipment, fridge and freezer alarm testing records, ventilation reports, body and tissue traceability audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training and competency records. Consent seeking policies and procedures, information for relatives giving consent and current consent forms in use for both adult and perinatal PM examination were also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the premises which included the mortuary body storage area, the PM room, the viewing room, and the laboratory where tissue retained at PM is processed and stored.

Audit of records
The inspection team undertook audits of traceability for three bodies in storage. Traceability details were crosschecked between the identification bands on the body, information on the mortuary whiteboard, the mortuary register, associated paperwork, and the electronic mortuary database. A minor discrepancy was identified with the recording of a digit of an NHS number between mortuary records, however, this was corrected at the time of the inspection.

The inspection team observed the release of bodies from the mortuary, and it was noted that funeral directors arrive with release forms which contain three identifiers of the deceased. This form is physically crosschecked against the information on the identification bands of the body. No discrepancies with the release procedure were noted.

Audits were conducted of tissue taken at PM examination for seven cases. Information was crosschecked between the mortuary traceability documentation, Coroner's paperwork, family wishes forms, and the tissue blocks and slides being stored. Four cases were identified as being stored for a scheduled purpose with appropriate consent, one case was being stored for analysis purposes following PM examination, and two cases had been disposed of in line with the wishes of the family. Two minor discrepancies were identified with the accurate recording of the number of slides created in the laboratory database (see shortfall against standard T1(g)).

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence, including the mortuary manager, mortuary staff and portering staff, staff involved in the consent seeking process for perinatal PM examination and the DI.

Report sent to DI for factual accuracy: 25 April 2023

Report returned from DI: 05 May 2023

Final report issued: 16 May 2023

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: 6 June 2023

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.