Inspection report on compliance with HTA licensing standards
Inspection date: **19 September 2024 (Unannounced)**

The Royal London Hospital

HTA licensing number 12187

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
The Royal London Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
A&E	-	*Carried out*	-
Neonatal and Paediatric wards	-	*Carried out*	-
Maternity	-	-	*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 legislationThe HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although The Royal London Hospital ('the establishment') had met the majority of the HTA's standards, one cumulative critical, seven major and one minor shortfall was found against standards for Consent, Governance and Quality, 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

Critical Shortfalls

Standard	Inspection findings	Level of shortfall
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).	<u>Funeral director's entrance</u> The roller shutter door at the funeral director's entrance contains a pedestrian access door which has an automatic closing device fitted. Upon inspection, the closing device did not consistently close the pedestrian door. This area is in constant use by pedestrians, there is no CCTV that monitors the area and doors are not locked between the garage and the body store. *The DI informed the inspection team that they have implemented interim mitigating actions prior to the publication of this report.*	**Critical (cumulative)**

	Body store There are automatic doors that open into the mortuary body store from the staff corridor and can open when mortuary staff are accessing bodies from the fridge. This poses a risk of oversight of mortuary activities by non-mortuary staff. Viewing rooms The viewing room entrance, which is next to the funeral director's entrance, does not have CCTV and the additional shutter door into the viewing room area is not used. Freezer room The door in the freezer room has a manual lock which relies on the individual remembering to lock the door. In addition, freezer doors are not locked when not in use. Specimen room within the post mortem room The room that contains specimens within the examination room is not locked out of hours. Staff informed the inspection team that in case of an emergency, contractors may attend the mortuary unsupervised. The above pose a risk to the safety and dignity of the deceased.	
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.	During the inspection, the inspection team observed that the roller shutter door was left open after funeral directors collected a body. Staff informed the inspection team that it is left to the funeral director to close the shutter door when they leave. Therefore, staff do not have oversight of the activities and there is potential of unauthorised access to the mortuary. *The DI informed the inspection team that they have implemented interim mitigating actions prior to the publication of this report.*	

Major Shortfalls

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	There is a documented schedule of audits, however they do not include the following: • Consent forms for hospital PM examinations (adult, paediatric and perinatal) • Material held for research (*see advice, items 3 and 4)*	**Major**

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.	The risk assessment for viewings does not detail control measures to mitigate the risk of viewing of the wrong body.	**Major**

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.	Establishment staff informed the inspection team that they do not confirm with relatives a minimum of three identifiers of the deceased when organising a viewing. In addition, the SOP for viewings does not detail what identifiers are confirmed with the family when making an appointment.	**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	Although the premises were clean at the time of inspection, the following areas were showing signs of wear and tear: • Significant amounts of limescale on the floor and PM tables • Some areas of rust on the PM tables, trollies and other equipment used to assist with positioning of body trays • The floor covering on the inspection hole cover in the body store was peeling • Skirting damage in the corner of the room exposing plaster in the freezer room	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	At the time of the inspection, the freezers were at capacity., There is a risk that bodies could be in refrigerated storage for over 30 days. This poses a risk to the dignity of the deceased.	**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	**Body store** The trigger point for the lower fridge temperature is set at 0 degrees Celsius and the upper temperature is set at +12 degrees Celsius which is outside the acceptable range to mitigate the risk of accidental damage to a body. This poses a risk to the dignity of the deceased should the temperatures go out of range.	**Major**
f) Temperatures of fridges and freezers are monitored on a regular basis	**Maternity fridge** The fridge in maternity for paediatric storage is used short-term prior to transfer to the mortuary. The inspection team observed gaps in the recording of the fridge temperatures. In addition, establishment staff could not confirm if the fridge was alarmed, and staff would be alerted in the event of a deviation in temperatures.	**Major**

Minor shortfalls

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased.	Mortuary freezers have been utilised by the establishment to store specimens removed during surgery from living patients awaiting disposal. These storage arrangements impact the dignity of the deceased.	**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 (a)	The DI is advised to review the PM consent forms to remove the references to Next of Kin and align this with the wording further down the form that refers to the qualifying relationship hierarchy.
2.	C1 (d)	The DI is advised to update the post mortem consent form for babies to include a separate section for organs to mitigate the risk of user error.
3.	C1 (e)	The establishment should undertake a full audit of tissue stored for research within the PM room to determine if it is being stored for its intended purpose. If research cannot be identified, the tissue should be sensitively disposed of in line with the consent given. The form should reflect that where suitable use for research cannot be identified, the tissue will be sensitively disposed of.
4.	C2 (b)	The establishment is advised to formalise the process for monitoring clinicians and other relevant staff who have completed refresher training for seeking consent (e.g. keep a list of consent seekers who have completed the training).
5.	GQ1 (a)	Mortuary records are all paper based. The establishment is advised to consider the use of an electronic system to save time and mitigate the risk of transcription and traceability errors.
6.	GQ5 (b)	Staff carrying out licensable activity know how to identify and report incidents and categories of HTA reportable incidents are detailed in the incident reporting procedure. The DI is advised to update this procedure to also include details of who can report incidents to the HTA (e.g. DI and PDs) and the required timeframe for reporting.

7.	GQ2 (a)	Mortuary staff are advised to undertake regular audits of hospital consented PM forms to identify any errors in completing the forms and implement any follow up actions. In addition, the DI is advised to review tissue in storage to see if it is consistently being used for its intended use (e.g. research).
8.	PFE1 (a)	The DI is advised to risk assess the blind spots within the establishment and give consideration to additional CCTV.

Background

The establishment has been licensed by the HTA since September 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in December 2021.

The establishment is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes. 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

All HTA licensing standards under the overarching standards for Traceability, Governance and Quality Systems, Traceability and Premises, facilities and equipment were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

A review was also carried out on: the policies and procedural documents relating to licensed activities for the mortuary; audits; risk assessments; training records for staff, meeting minutes and HTA reportable incidents.

Visual inspection

The inspection included a visual inspection of the mortuary body store, freezer room, PM rooms, histology, viewing rooms and the fridge in maternity.

Audit of records

Audits were conducted for four bodies in refrigerated storage and one body in freezer storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and relevant documentation. No discrepancies were found. Audits were also conducted for consented PM cases and crosschecked with relevant documentation and location of tissue in histology.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI (a Pathologist), Mortuary Services Manager, staff who seek consent for PM examinations, staff who are involved in arranging viewings out of hours and a porter.

Report sent to DI for factual accuracy: 16 October 2024

Report returned from DI: 31 October 2024

Final report issued: 04 November 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.