Inspection report on compliance with HTA licensing standards
Inspection dates: **13 and 16 December 2021**

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
Hub site **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*	-

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 The Royal London 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 consent training, PM suite maintenance, audits, viewing procedures, security, and bariatric facilities.

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

Standards	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice	There is no formalised process for the consent training of clinicians who seek consent for adult (hospital) PM examinations.	**Major (cumulative)**

b) Records demonstrate up-to-date training	There are no accessible records held by the DI to determine who is appropriately trained to seek consent for adult (hospital) PM examinations. Staff self-certify that they have read consent documentation and the HTA's Code of Practice A. Although there is a declaration on consent forms for clinicians to confirm that they have read the relevant training documentation, this is not always completed.	
d) Competency is assessed and maintained	Staff competency in seeking consent for adult PM examination is not assessed. During the inspection multiple errors were identified in the completion of consent forms by clinicians for adult (hospital) PM examinations.	
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	Areas of the mortuary premises are showing signs of wear and require maintenance to ensure decontamination procedures are effective: • The paint on the walls of the PM suite is flaking exposing porous plaster. • Door frames between the PM suites are chipped exposing porous wood. • The X-ray table has extensive areas of rusting. • The plugs on the PM tables have extensive areas of rusting. • An area of flooring of the PM suite has come away from the wall leaving a gap and exposed porous plaster.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	Routine audits are carried out as part of the establishment's audit schedule however there is no documented procedure detailing what is covered in the audits, who is responsible for follow-up actions and the timeframes for completing these.	**Minor**
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 procedure for viewing of the deceased does not include a final check using a minimum of three points of identification of the deceased with the visitors prior to them entering the viewing room.	**Minor**
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	The establishment does not have a system in place to formally review records of swipe card access to the mortuary to ensure that it is limited to those with legitimate right of access. Furthermore, the establishment does not have a register to record visitors and contractors that come into the mortuary.	**Minor**
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	Although contingency arrangements are in place, there is insufficient refrigerated bariatric storage and there are no bariatric freezer spaces.	**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.

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 Hospital Post-Mortem Consent policy (CP-SOP-M020), to remove references to Next of Kin.
2.	C1(c)	The DI is advised to review the baby PM consent form for references to previous versions of HTA Codes of Practice.
3.	GQ1(b)	During a PM the external examination is carried out by the pathologist prior to evisceration however this is not detailed within the Adult PM SOP (CP-MORT-PM-SOP7). The DI is advised to include this detail.
4.	GQ1(g)	The DI is advised to nominate HTA representatives (Persons Designated) in all areas that carry out licensable activity including the Accident & Emergency departments and Neonatal and Paediatric wards. The DI is advised to extend the invitation to the HTA governance meetings to these representatives.
5.	GQ2(a)	The DI is advised to include audits of bodies in long-term storage in the audit schedule to ensure that any discrepancies which arise within internal paperwork (such as transcription errors or updates to patient identifiers) are identified and managed appropriately. Whilst the audit conducted on traceability

		of bodies in the body store demonstrated full traceability, the inspection team identified a minor transcription error on the wrist band against the mortuary register for one body.
6.	GQ5(a)	Staff carrying out licensable activity know how to identify and report incidents however the DI is advised to document procedures within an SOP.
7.	GQ6(b)	The establishment has a comprehensive suite of risk assessments however the DI is advised to review the mitigating factors to ensure that all are detailed against the relevant risk.
8.	PFE2(a)	Although there are separate arrangements for the storage of foetuses under 24 weeks awaiting burial or cremation, the DI is advised to use opaque containers to further strengthen the establishment's practices for ensuring the dignity of the deceased.
9.	PFE2(c)	The DI is advised to record the condition checks of bodies. This should include the date of the check, the condition of the body and include sufficient detail of actions taken in relation to expediting release from the mortuary and/or actions taken to prevent deterioration to the body.
10.	PFE2(e)	Whilst fridge alarm tests are undertaken as part of an internal monitoring system, the DI is advised to implement regular unannounced fridge alarm tests from within the mortuary. This will provide robust challenge procedure to ensure the call out procedures work as expected in the event of a unit failure.
11.	PFE2(f)	The DI is advised to record and review trends in storage temperatures on a regular basis. This may help to identify trends and the extent of any variations in storage temperatures.

Background

The Royal London 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 September 2016.

Since the previous inspection, there has been some significant changes to the licence arrangements including a change of Designated Individual (DI) in October 2021 and change of Corporate Licence Holder contact (CLHc) in January 2017.

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 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

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 standard operating procedures, records of servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training records. 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, freezer room, PM rooms and viewing rooms. Storage arrangements for relevant material held within the pathology department was also visited.

Audit of records
The inspection team undertook audits of traceability for four bodies in storage. This included a paediatric case, bodies with same / similar name and a body in long term 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. One minor discrepancy was found relating to the hospital number.

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 and tissue blocks and slides being stored. One case reviewed demonstrated disposal of tissue had been completed in line with the wishes of the family. Full traceability of tissues was demonstrated for all four cases.

Meetings with establishment staff

The assessment team met with staff carrying out activities under the licence, including mortuary staff, a pathologist who conducts PM examinations, a portering staff member, staff involved in the consent seeking process and the DI.

Report sent to DI for factual accuracy: 31 December 2021

Report returned from DI: No response

Final report issued: 19 January 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: 8 February 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.