Inspection report on compliance with HTA licensing standards
Inspection date: **16&17 October 2024**

University Hospital Lewisham

HTA licensing number 12266

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 University Hospital Lewisham	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	-	-
A&E	-	-	-
Satellite site Queen Elizabeth Hospital	Licensed	Licensed	Licensed
Mortuary (satellite site)	*Carried out*	*Carried out*	*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 University Hospital Lewisham ('the establishment') had met the majority of the HTA's standards, one major shortfall was found against standards for Traceability. 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
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete	The inspection team tissue audit at the hub site identified one case where the tissue had not been disposed of as soon as reasonably possible. *The establishment provided confirmation that this tissue was sensitively disposed of prior to the publication of this report.*	**Major**

Advice

The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	GQ6b	Whilst risk assessments are in place, the DI is advised to further review these in order to differentiate between risks relating to staff and those relating to HTA standards.
2.	PFE1d	CCTV is in operation at both sites. At the hub site, the DI is advised to review the effectiveness of the internal CCTV system which has been in operation for many years and may require updating. At the satellite site the DI is advised to review the positioning of the camera relating to the internal corridor leading to the mortuary office entrance.
3.	PFE2b	At the time of the inspection there was sufficient storage for bodies. However, despite improvements at the hub site, the establishment regularly has insufficient fridge storage to meet demand across the joint facility. Off-site contracted contingency measures are used regularly which requires bodies to be transferred to a contracted storage facility in East London. Bodies are returned to the establishment for release to funeral directors at a later date. This increases the risk of loss of traceability and of deterioration of the condition of bodies and raises the risk of accidental damage to bodies due to being moved more frequently. The DI is advised to ensure that this is added to the trust risk register and mitigation progressed.

Background

University Hospital Lewisham has been licensed by the HTA since 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in January 2023. This was a targeted inspection to review corrective and preventative actions taken to address shortfalls identified at the last HTA inspection.

Since the previous inspection, there has been a change to Designated Individual in April 2023. The establishment does not currently undertake post mortem examinations.

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

Licensing Standards C2c, C2d, GQ6b, PFE1a, PFE2d, PFE2g, PFE3b, T1a, T1g, T1h, T2g were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

The inspection included a review of the establishment's documentation relating to risk assessments, training and competency records for both the mortuary staff and porters and other support staff.

Visual inspection

The inspection included a visual assessment of both establishments including body storage areas in the mortuaries and tissue storage areas. The inspection teams observed the processes for release of bodies within the mortuary.

Audit of records

Hub Site

Audits were conducted onsite of five bodies from refrigerated storage, and one body stored in long term frozen storage. Identification details on bodies were crosschecked against the information recorded in the register, electronic records and associated paperwork. No discrepancies were found.

Audits of traceability were conducted for tissue blocks and slides from seven cases, these included audits of the consent documentation for the retention of these tissues. One discrepancy was identified where the tissue had not been disposed of as soon as reasonably possible. See shortfall T2(a) above. The establishment provided confirmation that this tissue was sensitively disposed of prior to the publication of this report.

Satellite Site

Audits were conducted onsite of four bodies from refrigerated storage and one body stored in long term frozen storage. The release of one body to funeral directors was observed. Identification details on bodies were crosschecked against the information recorded in the register, electronic records and associated paperwork. No discrepancies were identified.

Report sent to DI for factual accuracy: 8 November 2024

Report returned from DI: 25 November 2024

Final report issued: 26 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.