Inspection report on compliance with HTA licensing standards
Inspection date: **3 June 2025**

**Lister Hospital**
HTA licensing number 12110

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 |
|---|---|---|---|
| **Lister Hospital** | Licensed | Licensed | Licensed |
| **Mortuary** | *Carried out* | *Carried out* | *Carried out* |
| **Pathology lab** | - | - | *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 Lister Hospital ('the establishment') had met the majority of the HTA's standards, two cumulative major, two major and eleven minor shortfalls were found against standards for Consent, Governance and quality systems, 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**

***Major shortfalls***

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| **GQ2 There is a documented system of audit** | | |
| a) There is a documented schedule of audits | Although there is a documented schedule of audits, few of these have been completed.<br>Security audits for the mortuary have not always been completed or in a timely manner to ensure CCTV footage can be reviewed before it is deleted. The last documented security audit was completed in January 2025.<br>*See Advice item 8* | **Major (Cumulative)** |
| b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these | Completed audits for body traceability from 2023 and 2024 show that where non-conformances were identified, there was not always documented follow-up of these. | |

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| c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention | No tissue traceability audits have been completed in the mortuary. The last two quarterly tissue traceability audits carried out in histopathology have not been finalised. The inspection team identified discrepancies with PM tissue blocks and slides in storage, the laboratory information management system (LIMS) and spreadsheet during the tissue traceability audit. | |
| **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 | Although staff have previously received training, this has not been regularly refreshed.<br>Not all porters who carry out mortuary activities have had refresher training. | **Major (Cumulative)** |
| c) Staff are assessed as competent for the tasks they perform | Although staff have previously been assessed as competent for the tasks they undertake, competency has not been regularly assessed.<br>Not all porters who carry out mortuary activities have been re-competency assessed. | |
| **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 | Mortuary staff do not routinely check a minimum of three identifiers on the deceased with details provided by relatives immediately before a viewing takes place. This poses a risk of viewing of a wrong body. | **Major** |
| **PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.** | | |

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| 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 CCTV cameras covering the external access points to the mortuary, the external body storage area and temporary body storage area are not monitored out of hours. | **Major** |

***Minor Shortfalls***

| **Standard** | **Inspection findings** | **Level of shortfall** |
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| **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** | | |
| a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice | The Trust has a 'Consent to examination and treatment' policy which has a section referring PM examination consent. There is no information on who can seek consent for paediatric/perinatal or adult PM examinations and who to contact should a PM examination be required.<br>*See advice item 1* | **Minor** |
| **C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent** | | |
| b) Records demonstrate up-to-date staff training | Although the training records provided for staff who seek consent for paediatric/perinatal PM examination demonstrate they have received recent training, there is no formal system in place to ensure this training is regularly refreshed. | **Minor** |

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| d) Competency is assessed and maintained | Review of the PM consent forms completed by clinicians and staff for paediatric/perinatal cases serves as an assessment of competence. However, there is no documented record to demonstrate competency is maintained.<br>*See advice item 4* | **Minor** |
| **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. | Although the following Standard Operating Procedures (SOPs) refer to checking a minimum of three points of identification at different stages of a procedure, they do not consistently state what these identifiers could be:<br>• MORTSOP-14 Toxicology taking and sending of specimens.<br>• MORTSOP-25 Monitoring of deceased patients condition/care plans and long term freezer storage.<br>• MORT SOP-20 Post mortem examination and reconstruction<br>The following SOPs do not contain accurate or clear information:<br>• MORTSOP-08 Organising coronial and hospital post mortem examinations has a flow chart at the end that does not reflect the documented procedure.<br>• MORTSOP-18 Mortuary security states hospital security monitor mortuary CCTV out of hours, which is incorrect.<br>• MORT SOP-20 Post mortem examination and reconstruction is not clear the body is examined by the pathologist before evisceration proceeds. | **Minor** |
| e) There is a system for recording that staff have read and understood the latest versions of these documents | Not all staff have read and acknowledged SOPs relevant to the activities they undertake.<br>*See Advice item 5* | **Minor** |

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| h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff | Although the DI has contact with Persons Designated, there are no formal documented meetings. | **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 | Review of the establishment's incident log identified some near-miss incidents that should have been reported to the HTA. | **Minor** |
| **GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored** | | |
| a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis | Although the establishment has a range of risk assessments, not all tasks relevant to the activities they undertake have been assessed. For example, the handling of foetuses less than and greater than 24 weeks gestation.<br>*See Advice item 9* | **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). | Samples removed from deceased children in the Emergency Department (ED) are transferred to the mortuary with the deceased for onwards transfer to the establishment where the PM examination takes place. There is currently no formal record of what samples are left in the mortuary by ED staff or a robust record of the transfer of these specimens from the mortuary to the receiving establishment. | **Minor** |
| **PFE2 There are appropriate facilities for the storage of bodies and human tissue.** | | |

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| 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 | The inspection team were not assured the upper and lower alarm trigger points for body store fridges in all areas are set at temperatures to ensure alarms will trigger at appropriate temperatures.<br>The body store alarms are not regularly tested to provide assurance they will trigger when temperatures deviate from the set range.<br>*See Advice item 12* | **Minor** |
| f) Temperatures of fridges and freezers are monitored on a regular basis | The paediatric/perinatal/specimen fridge is not linked to the remote temperature monitoring system. The temperature of the fridge is only documented by mortuary staff on working days. A failure of the fridge out of hours would not alert staff to take action in a timely manner. | **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) | Although the Trust's consent policy refers readers to the HTA's codes of practice and that there is a list of who can give consent, the DI is advised to ensure the reference to 'next of kin' is changed. |
| 2. | C1(b) | The Mortuary Manager is advised to consider having a separate SOP detailing the process for seeking consent for PM examination and who can seek consent rather than including this information in the SOP for PM examination. |

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| 3. | C2(b) | The DI is advised to ensure that staff who were trained to seek consent for adult PM examinations in 2022 complete refresher training this year. |
| 4. | C2(d) | The current process of checking paediatric/perinatal PM consent forms prior to sending them to the establishment undertaking the examination serves as an assessment of competency. Should this change, the DI is advised to ensure an alternative way to assess competence is put in place. |
| 5. | GQ1(e) | The DI is advised to ensure that distribution lists for SOPs and risk assessments on the quality management system only include staff who are required to read and acknowledge these documents. |
| 6. | GQ1(g) | The DI is advised to continue with the plan to update the PD(s) for ED and the Neonatal Intensive Care Unit, should removal of tissue from deceased babies occur in the unit. |
| 7. | GQ1(h) | The Mortuary Manager is advised to schedule formal documented staff meetings in addition to the daily 'huddle' meetings. This will help to ensure important information is formally discussed with staff and recorded. |
| 8. | GQ2(a) | The DI is advised to ensure monthly security audits are documented and include the following:<br>• Comparison of CCTV footage against swipe card access, visitor logs and any other documentation that records the attendance of staff. For example, body transfer forms from wards as both porters record their details on them.<br>• Focus on out of hours access events ensuring these correspond with legitimate purposes to access the mortuary.<br>• Follow-up of unusual patterns, times of entry and failed access attempts.<br>The DI is also advised to review the number of the 'Other' in hours and out of hours swipe access events for the mortuary as there is a significant number of these events in the last documented audit in January 2025. |
| 9. | GQ6(a) | The Mortuary Manager is advised to use the HTA Reportable Incident (HTARI) classifications to help ensure all activities in the mortuary are risk assessed. |

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| | | The DI is advised to to re-risk assess the use of the temporary body storage area and the routes of transfer of bodies requiring storage in there. This risk assessment should consider the risks to the dignity of the deceased during transport and storage. |
| 10. | GQ6(b) | When existing risk assessments are due for review, the Mortuary Manager is advised to:<br>• move the existing control measures already documented in the 'comments' column to the 'existing control measures' column.<br>• ensure staff training and competency is consistently documented as a control measure (when these are up to date).<br>• check risk ratings have considered all existing control measures. |
| 11. | PFE1(e) | The DI is advised to continue with the plans to remove the vertical frosted windows in the PM room which cannot be secured. Although they are positioned at height and located in an area which is difficult to access, this would provide assurance of security of this area. |
| 12. | PFE2(e) | When the schedule of fridge alarm testing is in place, the Mortuary Manager should ensure:<br>• testing of the upper and lower alarm trigger points is included.<br>• different fridge banks are selected for testing (within the main body store, external body store and temporary unit).<br>• tests are recorded. |
| 13. | PFE2(c) | The DI is advised to check the results of the March 2025 ventilation system test with the company who completed the testing. There is a considerable difference (improvement) in the air change rates from the previous year but no works appear to have been undertaken to account for this. |

## Background

Lister Hospital has been licensed by the HTA since November 2007. This was the sixth inspection of the establishment; the most recent previous inspection took place in February 2023. 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 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

*Review of governance documentation*
The inspection team reviewed policies and procedural documents relating to licensed activities for the mortuary. This included SOPs, risk assessments, audits, incidents, meeting minutes, training records and competency assessment documents (see shortfall against GQ3(a) and (c)). Consent seeking procedures and information for families giving consent for adult and perinatal PM examinations, servicing and maintenance records for mortuary equipment were also reviewed.

*Visual inspection*
The inspection team undertook a visual inspection of the premises which included the mortuary access points, body storage areas, including the permanent external body storage area to the rear of the mortuary and the temporary unit located in an area not close to the mortuary (see Advice item 9), the viewing room and PM room. A visual inspection of the storage areas for tissue in the histopathology laboratory were also undertaken. There are plans for PM tissue blocks and slides to be stored in the mortuary.

*Audit of records*
The inspection team undertook audits of traceability for three bodies in storage. This included a body with same/similar name and a body in long-term storage. Traceability details were crosschecked between the identification bands on the bodies, information in mortuary paperwork and the mortuary electronic record. No discrepancies were identified.

Audits were conducted of stored tissue taken at PM examination for five cases. Information was crosschecked between the mortuary documentation, relatives wishes forms and the laboratory electronic records and tissue being stored. Discrepancies were identified with three cases. The number of slides in one case did not match the LIMS, slides could not be located for a second case

and blocks and slides are being stored for a third case with conflicting information for the instructions for tissue recorded on the LIMS and the the laboratory spreadsheet (see shortfall against GQ2(c)).

*Meetings with establishment staff*
The assessment team met with staff carrying out activities under the licence, including mortuary staff, histopathology staff, a portering staff member, a pathologist, staff involved in the consent seeking processes for PM examinations, staff who are involved in the removal of relevant material in the Emergency Department and the DI.

**Report sent to DI for factual accuracy: 11 July 2025**

**Report returned from DI: 16 July 2025**

**Final report issued: 28 July 2025**

## 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.