Inspection report on compliance with HTA licensing standards
Inspection date: **05 and 06 August 2025**

Leicester Royal Infirmary
HTA licensing number 12337

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 Leicester Royal Infirmary	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Satellite Site Leicester General Hospital	Not licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*Carried out*
Satellite Site Glenfield Hospital	Licensed	Licensed	Licensed
Mortuary	*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 Leicester Royal Infirmary (‘the establishment’) had met the majority of the HTA’s standards, six major and two minor shortfalls were found against standards for Consent, Governance and quality systems 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
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	Whilst there is a documented policy in place and this gives procedural information to staff; the most recent previous review was undertaken in 2020. This is not in line with the establishment policy for the review of policies and procedures every 24 months. Furthermore, the document contains out of date information and references the previous Designated Individual (DI) as a point of contact for staff.	**Major (cumulative)**
b) There is a documented standard operating procedure (SOP) detailing the consent process		
c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice	There is no agreed and ratified information available to those being asked to give consent. Written information provided to the inspection team was in draft.	

f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds	Whilst staff are aware of the need for a cooling off period; guidance for staff to follow outlining the minimum timeframe for families to change their minds is not documented in the Policy, SOP or consent form guidance note.	
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.	Whilst policies and SOPs cover all mortuary procedures, the SOP in place for the viewing of bodies lacks detail regarding the process bereavement staff should follow when facilitating a viewing. To fully address this shortfall the establishment should review all procedures relating to mortuary activities to ensure that they contain sufficient detail and are reflective of staff practice.	**Major**
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	The Inspection team were not assured all staff who undertake activities under the licence are appropriately trained. No training records were available for review to indicate the bereavement support team, who facilitate viewings, have received training.	**Major (cumulative)**

c) Staff are assessed as competent for the tasks they perform	The Inspection team were not assured all staff who undertake activities under the licence have received a competency assessment. No documents were available for review to indicate the bereavement support team, who facilitate viewings, have been assessed as competent. Furthermore, whilst mortuary staff have received an initial competency assessment the establishment competency tracker indicated some staff had not been reassessed as competent for all mortuary duties carried out.	
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	The Inspection team were not assured all procedures relating to the licensed activity had been risk assessed on a regular basis. Some risk assessments had not received a documented review since 2022. These include but are not limited to the risk assessments for - Post Mortem Examinations - Reception, Release and Accommodation of patients and specimens This is not an exhaustive list of risk assessments required. To fully address this shortfall the establishment should review all risks relating to mortuary activities to ensure that they contain sufficient detail to mitigate and reduce risks to staff, bodies and the undertaking of licensed activities.	**Major (cumulative)**
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	Risk assessments lack detail regarding actions taken to mitigate risks to bodies. To fully address this shortfall the establishment should review all risks relating to mortuary activities to ensure that they contain sufficient detail to mitigate and reduce risks to bodies and the undertaking of licensed activities.	

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	There are significant areas of damage to the fabric of the building at Glenfield Hospital, including breaches in the plaster wall in the body store exposing the structure beneath. There were small areas of exposed plaster in the body store and PM suite at Leicester Royal Infirmary, and damage to a plug socket meaning it was no longer safe to use. At Leicester General Hospital there was a significant crack in the wall exposing the plaster in an area used to undertake care of the deceased. This poses a risk of ineffective cleaning and decontamination. *The establishment submitted sufficient evidence to partially address this shortfall before the report was finalised.*	**Major**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	Whilst post mortem examinations are carried out infrequently at Glenfield Hospital, air flow within the post mortem room was recorded as 9.25 air changes per hour in the most recent ventilation report dated September 2024. This poses a risk to staff if there are undiagnosed infections.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

d) Fridge and freezer units are in good working condition and well maintained	Whilst fridge and freezer units receive regular maintenance, the door seals of some of the fridges at Glenfield Hospital had perished.	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	Whilst there is a plan of works to rectify the rusting of hydraulic trolleys, some trolleys used for the transfer of the deceased were still waiting for work to be carried out to address significant areas of rust and exposed metal. Additionally, the post mortem table stands at Glenfield Hospital had small areas of rust. This poses the risk of ineffective decontamination.	**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.	GQ1(d)	Whilst there are policies in place detailing the legal responsibilities of the NHS Trust relating to Duty of Candour and requests under the Freedom of Information Act and Environmental Impact Regulations, these were overdue a review by the relevant document owners. The DI is advised to escalate this to the relevant committees who are tasked with reviewing the document. This will ensure the information within these documents remain relevant and is reflective of current legislation.

2.	GQ6(b)	The DI is advised to risk assess the windows between the funeral director entrance and the adjacent offices at Glenfield Hospital to ensure the window film in place is sufficient to prevent the oversight of activity being undertaken within the mortuary loading bay.
3.	GQ6(c)	The DI is advised to undertake a review of the current staffing levels, to ensure the system is resilient and there are enough staff in place to manage the volume and complexity of work, including the oversight and maintenance of systems in place for the traceability of tissue taken at post mortem.
4.	PFE1(a)	The DI is advised to continue with the existing plans in place for the refurbishment of the mortuary at Glenfield Hospital. Furthermore, the DI is advised to review the following document Health Building Note 16-01: Facilities for mortuaries, including body stores and post-mortem services as part of the refurbishment plan; which may be helpful.
5.	PFE2(d)	The DI is advised to continue with existing plans to undertake remedial work on the freezer units at Leicester Royal Infirmary to ensure they can maintain the set temperature range.
6.	PFE3(f)	The systems and equipment within the mortuary are subject to regular testing and servicing. However, records are not kept within the mortuary and are only available upon request. The DI is advised to request copies of all maintenance, servicing and repair reports so that they are easily accessible to mortuary staff for review and monitoring purposes.

Background

Leicester Royal Infirmary has been licensed by the HTA since 2007. This unannounced inspection was the fifth inspection of the establishment; the most recent previous inspection took place in January 2023.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence.
The inspection team reviewed the establishment plans in place for a major refurbishment of the mortuary facilities at Glenfield Hospital; the funding had been secured as a result of the findings during the most recent previous inspection.

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 included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records for the mortuary, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and training records for staff.

Visual inspection
The inspection included a visual assessment of all mortuary body storage areas at all three sites, the post mortem rooms at Leicester Royal Infirmary and Glenfield hospitals, viewing rooms and tissue storage areas. The inspection teams observed the processes for admission, release and viewing of bodies within the mortuaries and on the maternity units at Leicester Royal Infirmary and Leicester General Hospital.

Audit of records
Leicester Royal Infirmary (Hub site)
Audits were conducted for three bodies from refrigerated storage and one from freezer storage. Identification details on bodies were crosschecked against the information recorded in the mortuary electronic register and associated paperwork. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides from four coroners consented cases. These included audits of the consent documentation for the retention of these tissues. No discrepancies were identified.

Leicester General Hospital (Satellite site)

Audits were conducted for four bodies from refrigerated storage. Identification details on bodies were crosschecked against the information recorded in the mortuary electronic register and associated paperwork. No discrepancies were identified.
An audit was conducted for the release of one body into the care of Funeral Directors, identification details on the body were cross checked against the information recorded in the mortuary electronic register and the paperwork provided by the Funeral Directors. No discrepancies were identified.

Glenfield Hospital (Satellite site)
Audits were conducted for three bodies from refrigerated storage. Identification details on bodies were crosschecked against the information recorded in the mortuary electronic register and associated paperwork. No discrepancies were identified. An audit was conducted for the release of one body into the care of Funeral Directors, identification details on the body were cross checked against the information recorded in the mortuary electronic register and the paperwork provided by the Funeral Directors. No discrepancies were identified.

Meetings with establishment staff
The Inspection team met with staff carrying out processes under the licence at the hub and satellite sites including; the DI, mortuary manager, the mortuary operations manager, APT, assistant technical officer, pathologist, mortuary porter, transport operative and bereavement midwifes

Report sent to DI for factual accuracy: 26 August 2025

Report returned from DI: 16 September 2025

Final report issued: 17 September 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.