Inspection report on compliance with HTA licensing standards
Inspection date: **24 and 25 July 2024**

Royal Lancaster Infirmary

HTA licensing number 12356

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 **Royal Lancaster Infirmary**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab			*Carried out*
Satellite site **Furness General 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 Hospitals of Morecambe Bay NHS Foundation Trust ('the establishment') had met the majority of the HTA's standards, one cumulative major, 11 major and eight 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
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
d) Competency is assessed and maintained	Competency assessments are not in place for those seeking consent for post mortem (PM) examinations.	**Major**
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.	Standard operating procedures (SOPs) relating to mortuary activities are not reflective of current practice or do not contain sufficient details of procedures. For example: • viewing of deceased. • release of deceased. • admittance of the deceased. This is not an exhaustive list of the amendments required to all the SOPs and, to fully address this shortfall, the establishment should review all SOPs relating to all mortuary activities to ensure that they are accurate, reflect current practice, cross reference the appropriate SOPs and contain sufficient detail of procedures.	**Major**
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	The establishment's procedure for checking and documenting the condition of the deceased does not contain sufficient detail, or at sufficiently regular intervals, to ensure the dignity of the deceased is maintained.	**Major**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Although informal governance meetings have been held no record or minutes have been recorded. A plan to reintroduce formal governance meetings relating to HTA activities is underway. *This issue was identified in advice and guidance at the previous inspection in 2022.*	**Major**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The scope of the audit schedule for licensed activities conducted under the licence is limited. The audit schedule does not include sufficient audits to check compliance with documented procedures, the completion of records or traceability of bodies.	**Major**

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	Although tissue disposal audits are undertaken, the audits do not include tissue blocks and slides where consent has been given for retention. During the traceability audit of post mortem (PM) tissue one discrepancy was found with a case dating back to 2022 of an additional slide being stored that was not recorded on the laboratory information management system (LIMS). There is risk of loss of tissue blocks and slides if regular audits are not undertaken to ensure that records are accurate.	**Major**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
c) Staff are assessed as competent for the tasks they perform	Porters do not have competency assessments.	**Major**
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	Portering staff are not aware of the HTA reportable incidents (HTARI) reporting requirements that must be reported to the HTA. During the inspection one incident was identified that may be a near-miss HTARI and has not been reported. *See advice item 1* *This shortfall was identified as a minor shortfall at the previous inspection in 2022.*	**Major**
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	Not all procedures relating to licensed activities have been risk assessed. These include but are not limited to: • major equipment failure. • incidents leading to unplanned closure of mortuary/inability to deliver services. The majority of the risk assessments are out of review date and do not have consistent review periods. This is not an exhaustive list of the risks not assessed and, to fully address this shortfall, the establishment should review all risk assessments relating to all licensed activities to ensure that all risks have been identified. *This shortfall was identified as a minor shortfall at the previous inspection in 2022.*	**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	Procedures for identification of bodies do not always use a minimum of three identifiers of the deceased. • Staff conducting viewings do not ask for a minimum of three identifiers of the deceased from relatives on arrival or check a minimum of three identifiers of the deceased provided by relatives against the identification on the body before a viewing takes place. • Unidentified bodies admitted to the mortuary are only labelled with two identifiers.	**Major**
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>Royal Lancaster Infirmary</u> A CCTV camera is situated at the door to the entrance of the body store allowing staff to see the entrance and down the side of the building during working hours. This camera feed is an internal feed and is seen only by mortuary staff. Out of hours (OOH) a shutter is closed and locked with a key which prevents the CCTV camera from viewing the entrance to the body store. There is a Trust CCTV camera which overlooks the gate entrance to the mortuary courtyard. However, this camera does not cover all of the courtyard and the entrance to the body store. In addition, there is no intruder alarm fitted in the mortuary. There is a risk of unauthorised access to the mortuary which would not be seen by security staff. *See advice item 4*	
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	<u>Royal Lancaster Infirmary</u> There is a risk that the transfer of deceased to the external contingency unit can be seen by the public from the house overlooking the mortuary courtyard. OOH a key is used to open the shutter by the porters or contracted ambulance staff to gain access to the door to the body store. There is also a key which is kept in the porters office. The establishment are not aware of where this key is kept and if it is used by the porters. There is a risk that there are a number of keys in circulation as the key is not a restricted key. <u>Furness General Hospital</u> The transfer of deceased for release or to the external contingency unit can be overseen by members of the public, Trust staff and contractors. This poses a risk to the dignity of the deceased. The external contingency unit control panel is not secure. There is risk of the unit being switched off.	**Cumulative Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

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	Manual alarm testing of the fridge and freezer units OOH are not undertaken at both sites to ensure that alarms trigger and that the call-out procedures are effective. The toxicology fridge and freezer are not alarmed.	**Major**

Minor 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	Although there is a consent policy in place, the consent policy does not include that competency assessments must be completed and the re-training and competency reassessment review period.	**Minor**
e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained	Information for the future use of retained tissue is not discussed with families.	**Minor**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity	Deviations from documented SOPs are not recorded and monitored via a scheduled audit activity.	**Minor**
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 establishment's risk assessments do not reflect all existing mitigating controls that are in place.	**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).	The procedures for traceability of post mortem samples do not provide a full audit trail of transfer of the samples off-site. The establishment does not receive confirmation that organs sent off site for analysis are received at the receiving establishment.	**Minor**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	At Furness General Hospital (FGH) there is no demarcation of a transitional area between the post mortem (PM) room and the body store, making it difficult for staff and visitors to determine clean areas from dirty areas of the mortuary. There is no procedure in place for the cleaning or decontamination of the trolleys when transfer of the deceased takes place from the PM room following or during post mortem (PM) examinations.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
f) Temperatures of fridges and freezers are monitored on a regular basis	Temperature monitoring of the external contingency units and toxicology fridge and freezer are not checked and recorded on weekends including bank holidays. The establishment do not undertake trend analysis of the temperatures to identify trends and the extent of any variations in storage temperatures.	**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	At both Lancaster Royal 26 Infirmary (LRI) and FGH the trolleys have multiple areas of rust and both body stores have wooden body measuring rods. This means it is difficult for staff to adequately clean and disinfect this equipment.	**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.	GQ5(a)	The DI is advised to place signage in the mortuary to raise awareness amongst porters working there of the importance of reporting any incidents, including a list of all the appropriate HTARI categories.
2.	T1(d)	The DI is advised to add the same colour coding system to the deceased paperwork as a visual aid for staff when transferring or releasing deceased.
3.	T1(f)	The DI is advised to add the year to the unique reference number (URN) that is added to the wristband on admittance in the event that a body is released that has the same URN but was admitted in the previous year.
4.	PFE1(d)	At FGH the room where foetal tissue is stored is on a busy public thoroughfare corridor through the maternity department. There is no security to the room where the fridge and freezer is situated. The DI is advised to secure the room by either swipe card or key to prevent the risk of unauthorised access. The mortuary courtyard is secured by a wooden gate with a key code lock. The inspectors demonstrated that the gate could be opened from the outside from the base of the gate. The key code lock is not suitable as an external lock.
5.	PFE1(e)	Any failed attempts to enter the mortuary are forwarded to the security team to investigate. An incident is raised on the Trust incident system, however, the mortuary are not made aware of the results of the investigation. The DI is advised that they have access to the investigation report to assure themselves that any action taken has been completed and is appropriate.

6.	PFE2(e)	At both RLI and FGH the fridges and freezers on the gynaecology wards are not alarmed and therefore no alarm testing takes place. The DI is advised to have alarms fitted and a schedule put in place to test the alarms to ensure that in the event the fridge or freezer breaks then the contents can be transferred.
7.	PFE2(f)	At both RLI and FGH the temperatures of the fridges and freezers on the gynaecology wards are not monitored.
8.	PFE3(c)	The DI is advised to ensure that the issues identified in the most recent ventilation report for FGH are addressed in order to ensure the system works to standard.

Background

University Hospitals of Morecambe Bay NHS FT are 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.

University Hospitals of Morecambe Bay NHS FT has been licensed by the HTA since 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in March 2022.

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, records servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and staff training records.

Visual inspection

The inspection included a visual inspection of the mortuary body store, PM room, maternity fridges and viewing room.

Audit of records

Audits were conducted for eight bodies in refrigerated storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and electronic system. No discrepancies found.

Audits of traceability were conducted for tissue blocks and slides from six PM cases, including audits of the consent documentation for the retention of these tissues. One discrepancy found (see shortfall against GQ2(c)).

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, Anatomical Pathology Technologists (APT), quality lead, portering staff, pathologist, consent seekers for perinatal and adult PM examination and mortuary manager.

Report sent to DI for factual accuracy: 23 August 2024

Report returned from DI: 17 September 2024

Final report issued: 26 September 2024

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: 28 May 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.