Inspection report on compliance with HTA licensing standards
Inspection date: **23 July 2025**

Royal Liverpool University Hospital

HTA licensing number 30002

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
Royal Liverpool University Hospital	Licensed	Licensed/Not licensed	Licensed/Not 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 Royal Liverpool University Hospital (‘the establishment’) had met the majority of the HTA’s standards, three major and two minor shortfalls were found against standards for Governance & Quality, Traceability and Premises, Facilities & 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		
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	Audits on tissue retained prior to 2022 are not completed. Staff are therefore not fully aware of what is being held and why. This poses a risk that tissue is being stored without consent for its continued retention. The inspection team identified shortfalls for tissue traceability, which may have been identified if regular tissue audits had taken place. *See shortfall T1(g)*	**Major**
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).	Tissue taken at post mortem is not fully traceable. Laboratory staff were unaware of the location of traceability records for tissue predating 2022. The inspection team was subsequently informed that traceability paper records for tissue between 2016 and 2022 had been sent off site for storage, and families wishes were not always documented prior to 2016. The inspection team completed a tissue traceability audit for those cases where family wishes were available and identified the following discrepancies: • for one case the incorrect number of slides was recorded on the laboratory electronic system. • for two cases the establishment had consent to retain the tissue. At the time of the inspection the slides could not be located and subsequently remain mislaid.	**Major**
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	A system for communicating with the coroner's office has been in place since 2022. This has resulted in tissue being disposed of in a timely manner. However, the establishment has not retrospectively followed up with the coroner or police to receive confirmation of the end of authorisation for tissue held preceding 2022. This poses a risk that tissue has not been disposed of or retained in line with the family's wishes.	**Major (cumulative)**
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary		

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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	Wooden doors at either side of the fridge room have damaged door frames. The splinted wood poses a risk to ineffective cleaning and decontamination.	**Minor**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The inspection team noted that the fridge room doors and external shutters were not always closed during funeral service collections. Whilst the area would always be staffed, it poses a risk of unauthorised access during this time, as the door in between these areas has no restricted access mechanism.	**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.	PFE1(b)	The mortuary currently has a large amount of stored items within an annex of the post mortem room. The mortuary manager is advised to remove open plug extension leads, cardboard boxes, and stored tissue samples from this area to further mitigate against risk to staff safety.
2.	PFE1(d)	The designated individual is advised to change the mortuary intruder alarm codes at regular intervals, to further strengthen security arrangements.

3.	PFE1(d)	The mortuary manager is advised to select random times, and not just known admissions, when auditing CCTV footage to further strengthen security arrangements. The ability to have direct access to CCTV playback would increase the efficiency of the audit process.
4.	PFE2(b)	The designated individual and mortuary manager are advised to monitor the condition of the mortuary fridge doors and seek assurance that the minor areas of perished door seals are not affecting the efficient running of the equipment. Further deterioration to this equipment may result in a shortfall to standard PFE2(b).

Background

Royal Liverpool University Hospital has been licensed by the HTA since 10 August 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in November 2022.

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

Visual inspection
The inspection included an unannounced visual assessment of the establishment including the mortuary access points, mortuary fridge rooms, postmortem rooms, contingency storage areas, viewing facilities and tissue storage areas. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records
Audits were conducted for three bodies from refrigerated storage and one from frozen storage. Identification details on bodies were crosschecked against the information recorded in the mortuary register and associated paperwork. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides from six coronial cases. These included audits of the consent documentation for the retention of these tissues. A discrepancy was identified where additional slides were made but not recorded on the electronic system, for two further cases the electronic system stated that the slides had been retained but could not be located. The tissue audit also identified that traceability records prior to 2022 were unavailable. See shortfall T1(g).

Meetings with establishment staff
Staff conducting processes under the licence were interviewed including the DI, Pathologist, Mortuary Manager, Histopathology lead, and Mortuary Porter.

Feedback was provided on 27 August 2025 to the Chief Medical Officer (CLHc), Pathologist (DI), Mortuary Manager, Senior APT, Manager of Cellular Pathology, and the Director of Operations.

Report sent to DI for factual accuracy: 18 September 2025

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 09 October 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.