Inspection report on compliance with HTA licensing standards
Inspection date: **01 August 2025 (Unannounced)**

The County Hospital

HTA licensing number 12409

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 **The County Hospital**	Licensed/Not licensed	Licensed/Not licensed	Licensed/Not licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*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 The County Hospital ('the establishment') had met the majority of the HTA's standards, three major and three 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

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.	Three identifiers are not directly cross-referenced with information on identification bands of the deceased for release of bodies to funeral directors or with families prior to a viewing. Although the address is cross-referenced against documentation, this is not detailed on identification bands on the body.	**Major**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue		
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.	Security audits do not include swipe card access lists against CCTV footage; CCTV footage is only reviewed if an incident is discovered. In addition, the staff access list contains over 100 staff members. This increases the risk of staff who have authorised access entering the mortuary for an unauthorised purpose. Furthermore, the double doors between the body store and viewing room do not meet when closed leaving a slight gap between them. As there is no means to cover the door when a viewing is in progress, family	**Major**

	members could have oversight of activity being undertaken in the body store.	

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
d) Staff have access to necessary PPE.	Although staff have access to FFP3 masks, they are not face-fitted.	**Major**

Minor shortfalls

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.	Refresher training for staff seeking consent for paediatric and perinatal post-mortem examination was not up to date in line with hospital policy which states that refresher training takes place every two years.	**Minor**

GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use.	Some of the mortuary SOPs are authored and authorised by the same person. Examples include, but are not limited to the following: • SOP 50 Retention of Records • SOP 45 Transfer to Off-site Storage • SOP 51 Consent Non-Coroner Post-Mortems	**Minor**

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.	Although the upper temperature trigger point for the fridges is tested regularly to ensure call out procedures are working, tests do not include the lower temperature trigger point.	**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.	GQ6 (a)	The establishment is advised to consider an overarching risk assessment for the HTARI categories or a title which clearly indicates the HTARI category for each risk to allow for easy reference. The DI is also advised to risk assess the storage location of the temporary mortuary unit in the PM room in terms of effective disinfection and cleaning.
2.	T1 (b)	The establishment is advised to consider the use of a colour coded system for organ traceability during PM examination.
3.	PFE1 (e)	The DI is advised to review the list of staff who have access to the mortuary to determine the reason for the access and if it is essential.

Background

The County Hospital, ‘the establishment’ is 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.

The establishment has been licensed by the HTA since 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 relating to licensed activities, cleaning records for the mortuary and post-mortem room, records servicing of equipment, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents and staff training records.

Visual inspection

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

Audit of records
Audits were conducted for two bodies in refrigerated storage and two bodies in long term storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and electronic database. (See shortfall against T1c).

Audits of traceability were conducted for tissue blocks and slides from three PM cases, including audits of the consent documentation for the retention of these tissues. No discrepancies were found.

Meetings with establishment staff
Discussions with staff including the DI, Mortuary Manager, Bereavement Officer, General Manger, Pathologist, Quality Lead, a porter, staff in the histology department and consent seeker for PM examinations.

Report sent to DI for factual accuracy: 01 September 2025

Report returned from DI: 01 September 2025

Final report issued: 02 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.