Inspection report on compliance with HTA licensing standards
Inspection date: **08 April 2025**

James Paget University Hospital
HTA licensing number 12127

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
James Paget University Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*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 James Paget University Hospital ('the establishment') had met the majority of the HTA's standards, six major and seven minor shortfalls were found against standards for Governance and quality systems, Traceability and Premises, facilities and equipment.

One of the identified shortfalls (T1g) pertains to findings from the previous inspection conducted in May 2022. During the inspection feedback meeting, the HTA raised concerns that sufficient action had not been taken to adequately address this finding and that effective, fully embedded procedures, had not been implemented during the intervening period. This was acknowledged by the establishments and progress will be monitored through an agreed corrective action plan.

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
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) describing the procedures for identification of the deceased do not always make it clear that a minimum of three identifiers should be checked, what the identifiers could be and what they should be checked against. This includes the SOPs for: • SOP Instruction 056 - Moving deceased from the JPUH mortuary to the temporary fridges in estates. • SOP 014 - High risk PMs. This is not an exhaustive list. To fully address this shortfall, the establishment should review all SOPs relating to mortuary activities where there is a requirement for checking the identity of bodies to ensure they are accurate and contain sufficient detail to reflect current practice.	**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 the identification of bodies do not always use a minimum of three identifiers for the deceased. While viewings are arranged and attended by mortuary staff, there was no evidence to demonstrate that staff routinely request 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. This poses the risk of viewing of the wrong body.	**Major**

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	Whilst there are systems and processes in place to maintain the traceability of organs and tissue removed during post mortem examination, the establishment does not obtain confirmation of receipt for tissue transferred to their third-party storage provider. This shortfall was previously identified during the last HTA inspection in 2022. *See advice item 1.*	**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)	The inspection team found the following in relation to standard PFE1d: • There is insufficient CCTV coverage to monitor access, both in and out of hours, at the main internal viewing suite entrance door and the external door leading from the viewing waiting room to the memorial garden. • There is also inadequate CCTV coverage out of hours that can directly monitor the main internal mortuary doors and the external mortuary bank of fridges in the Estates Department. • Although an audio intercom is installed on the main internal mortuary doors, there is no visual camera, which prevents staff from visually verifying individuals before granting access to the mortuary.	**Major**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The inspection team found the following in relation to standard PFE1e:
	
	• Visitors and non-mortuary staff are not required to sign in and out of the mortuary, therefore there is currently no system for recording who has been in the mortuary, the nature of their business and when they arrived and left.
	
	The establishment submitted sufficient evidence to address this shortfall before the report was finalised.
	
	• The security arrangements in the viewing suite do not prevent unauthorised access to the body store:
	
	  • A door situated in the viewing suite is secured using a bolt lock mechanism, if unlocked inside the viewing suite, the door opens directly into the body store. This poses a risk that the relatives could gain access to the body store.
	
	  The establishment submitted sufficient evidence to address this shortfall before the report was finalised.
	
	  • This same door situated in the viewing suite also has a two-way window viewing mechanism, which presents a risk that relatives could observe mortuary activities in the body store from the viewing suite.
	
	  The establishment submitted sufficient evidence to address this shortfall before the report was finalised.
	
	  • The thumb lock between the viewing waiting room and the viewing room has been fitted on the wrong side of the door.
		Major cumulative

	• Panic alarm tests for lone working are not currently documented. A test conducted during the on-site inspection highlighted that the call-out procedure did not function as intended, raising concerns about the effectiveness of the current process.
	
	See advice item 2.
	
	• Although monthly security audits are undertaken, the process around these audits do not appear to be well defined. The following concerns were found:
	
	  • It is not clear if the external bank of fridges, located in the Estates Department, are included as part of the scheduled monthly security audit.
	
	  • The inspection team were not assured that security audits contained a sufficient sample size for the activity at the establishment, to assure themselves that any access for an unauthorised purpose would be identified.
	
	  • The security SOP lacks sufficient detail regarding the process and requirements for conducting the security audit.
	
	See advice item 2.	

GQ2 There is a documented system of audit.		

a) There is a documented schedule of audits.	A documented audit schedule is in place; however, it does not currently incorporate the establishment's monthly security audits. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	With regard to the external bank of fridges, located in the Estates Department, the inspection team was not assured that the location and access arrangements sufficiently safeguard the dignity of the deceased. As such, under the current set up, the use of this area for body storage is deemed unsuitable. *See advice item 3.*	**Major**

Minor Shortfalls

Standard	**Inspection findings**	**Level of shortfall**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
e) There is a system for recording that staff have read and understood the latest versions of these documents	Pathologists have not routinely read and acknowledged documents relevant to the activities they undertake in the mortuary. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.* *See advice item 4.*	**Minor**

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	The inspection team are not assured all staff who carry out licensed activities receive regular competency assessments. This includes but is not limited to the viewing process. *See advice item 5.*	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
d) There is system for flagging up same or similar names of the deceased	During the body traceability audit undertaken during the inspection, the inspection team identified a minor discrepancy to one deceased patient who was identified with a same or similar name. The deceased patient did not have the corresponding band, or laminated card, in accordance with the written same and similar name procedure. *See advice item 6.*	**Minor**

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 multiple breaches to the floor edging in the mortuary, this presents a potential route for water ingress and thereby increasing the risk of ineffective decontamination.	**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	Whilst fridge and freezer units are alarmed, the alarms are not tested regularly to ensure that they trigger when temperatures go out of upper and lower set ranges.	**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	Several items of equipment in the mortuary are in an unsuitable condition: • The hydraulic trolleys used in the mortuary show signs of significant rust. • A set of steps in the post-mortem room show signs of significant rust. *The establishment have provided sufficient evidence to address this before the report was finalised.* • The bin frames in the post-mortem room show signs of significant rust. • A large area of exposed wood is visible near the Funeral Director's entrance door. • One autopsy saw is showing signs of rust. • Areas of exposed wood are visible on the shelves in the post-mortem room. • The fridge door seals are heavily soiled and require a thorough deep clean. *The establishment have provided sufficient evidence to address this before the report was finalised.* These conditions present a risk of ineffective cleaning and decontamination. *See advice item 7*	**Minor**

f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	There was no evidence to confirm mortuary autopsy saws are included as part of the maintenance testing schedule.	**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.	T1g	It is advised that the DI incorporates confirmation of receipt, for tissue transferred to their third-party storage provider, into their existing tissue audit. This will help ensure that this aspect of the process is fully adopted and effectively embedded.
2.	PFE1e	• The DI is advised to replace the thumb lock on the door from the viewing waiting room to the viewing room with a key lock mechanism. This means the door can be locked out of hours for security purposes but open during viewings. • The DI is advised to review the current security audit template to make it clear how many activities should be reviewed and what areas must be reviewed (including external units) during the audit. • The DI is advised to review the capability of panic alarms currently in use for lone working.
3.	PFE2a	The DI is advised to expedite the plans to explore a more suitable and appropriate location for the external fridge bank.

4.	GQ1e	While Q-Pulse is currently in use by mortuary staff, its full range of features (including document distribution and acknowledgement) is not yet being fully utilised. It is recommended that the DI considers arranging training for mortuary staff to enable them to make full use of Q-Pulse's capabilities.
5.	GQ3c	The DI is advised to ensure competency records detail both the date and method of assessment. This will support the maintenance of complete and accurate documentation following the completion of any competency assessments.
6.	T1d	The DI is advised to review the current process for managing bodies with same and similar names. The HTA advises the DI to simplify the process, transitioning and adopting only the use of coloured wristbands attached to the body, as opposed to the current multi-method system. This change will move away from either using colour wristbands or laminated cards placed on top of bodies, with the latter being found to be ineffective during the body audit.
7.	PFE3a	A cleaning record is in place; however, the DI is advised that additional detail be incorporated. For instance, the current record does not include specific tasks such as the cleaning of fridge door seals.
8.	C2b	The DI is advised to reconsider the way the establishment record training and competency assessments to ensure it is always clear when the assessment was undertaken.
9.	GQ1c	• While condition checks are conducted regularly, the records documenting these checks lack the necessary level of detail. It is advised that the DI collaborates with relevant staff to develop a standardised set of approved wording and guidelines for staff to use when recording the results of these checks. This will ensure consistency, accuracy, and completeness in the documentation process. • The DI is advised to include a final condition check at release. This will ensure there is a documented condition record at the point the body is released from the mortuary.
10.	C2b	Although competency assessments are undertaken each year, consent training was last completed in March 2022. The DI is advised to ensure training for all consent seekers is undertaken in 2025.
11.	T1c	The DI is advised to implement a final check during the viewing procedure to ensure that the identification of the deceased is cross-checked against the information provided by the relatives before they are brought into the viewing room. This additional final check will help to safeguard against any incidents pertaining to the viewing of the wrong body.

Background

James Paget University Hospital has been licensed by the HTA since 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in May 2022. Since the previous inspection, there have been changes to both the Designated Individual and the Corporate Licence Holder contact.

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:

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 team undertook an unannounced visual inspection of the mortuary body storage areas, the post mortem room and the viewing suite. The inspection team also observed the process for release within the mortuary.

Audit of records

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. The inspection team identified a minor discrepancy to one deceased patient who was identified with a same or similar name (see shortfall against standard T1(d)).

Meetings with establishment staff

The inspection team met with staff carrying out activities under the licence, including the Mortuary Manager, a Senior APT, a Porter and Security Supervisor, a Pathologist and the Designated Individual.

Report sent to DI for factual accuracy: 20th May 2025

Report returned from DI: 3rd June 2025

Final report issued: 3rd June 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.