Inspection report on compliance with HTA licensing standards
Inspection dates: **10th and 12th May 2022**

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*
Pathology lab	-	-	-
Maternity	-	-	-
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, 4 minor shortfalls were found against standards for 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.

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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	Although the vast majority of procedures outlined in GQ1 have been risk assessed, the inspection team has not been provided with a risk assessment which assesses the risk of a security breach relating to the mortuary.	**Minor**
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	A number of the establishment's risk assessments lack sufficient detail in terms of describing the risks covered, and the steps taken to mitigate the identified risks. For example: - the risk assessment for releasing the deceased does not describe the risk of releasing the wrong body (although the mitigating steps indicate this risk was envisaged when writing the risk assessment); and - "training" is given as a mitigating step in several risk assessments without details as to specific training undertaken. This is not an exhaustive list, and the DI should review all risk assessments in line with this standard for clarity and consistency. *Please refer to advice item 5 below.*	**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 establishment does not obtain confirmation of arrival for tissue taken during post mortem, all of which is sent off-site for analysis.	**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	One of the taps within the PM room has areas of rust which prevents decontamination procedures from being effective.	**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)	Due to the size of the mortuary team, all mortuary staff are involved in the review of mortuary documentation and are asked to approve any changes made. The DI should review all documentation to ensure that the reviewers name(s) are noted on the document itself as some are recorded as having the same author and approver.
2.	GQ1(e)	The establishment is currently undergoing a transition period in relation to the IT software package used as the document repository for mortuary procedural documentation such as SOPs. Documents are currently stored and

		managed electronically using a manual filing system located on the hospital network. The DI is advised to carry out a GAP analysis of the former system against the current manual electronic system to identify any additional controls that may be necessary during this period and when a replacement system is identified. The DI should consider documenting any manual processes which are currently required (for example how to ensure version control).
3.	GQ1(g)	The establishment has a clear SUDIC Protocol and those involved in removal of tissue within the Emergency Department have oversight from the DI. The DI is advised to add a representative from the Emergency Department as a Persons Designate to the HTA Licence to further increase the DI's oversight of this activity.
4.	GQ2(a)	The establishment carries out monthly checks of the swipe card access list and the log of those who have accessed the mortuary. The DI is advised to consider formalising this process into a regular standalone audit of mortuary access to include a cross check of legitimate rights of access to the mortuary against frequency, duration and patterns of attendance to ensure access is in line with the purpose for which it was granted.
5.	GQ6(b)	The establishment's risk assessments appear to have been produced using a Health and Safety risk assessment proforma. This proforma assumes the risk is a generic risk to the health and safety of staff/visitors and therefore does not prompt the inclusion of the specific individual risks which apply to licensed activities (which means these risks are often embedded in other fields in the form). The DI is advised to consider using a different format for the risk assessments to more clearly highlight the risks addressed. The DI may also wish to consider including a separate risk assessment for all the categories of HTA Reportable Incidents.
6.	PFE2(c)	Although there is adequate refrigerated storage for bariatric bodies, there are no bariatric freezer spaces within the establishment. The DI is advised to take this into consideration when considering any future developments.
7.	PFE2(i)	The establishment has an SOP which includes the protocol to be followed in the event of a major incident or period of overcapacity/fridge failure. However, the SOP does not reference any formally agreed arrangements for contingency storage with other establishments or funeral directors. Although the hire of temporary storage facilities forms part of the establishments' contingency arrangements, the SOP does not detail the steps to be taken to ensure availability of funds, and of units, for hire.

Background

James Paget University Hospital has been licensed by the HTA since 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in June 2017.

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 team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection as well as additional documentation provided during the inspection. Policies and procedural documents relating to licensed activities were reviewed. This included cleaning records for the mortuary and post-mortem room, records of servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training and competency records. Consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the premises which included the mortuary, body storage areas, post mortem suite and the viewing room.

Audit of records

The inspection team undertook audits of traceability for four bodies in storage. This included a body in long term storage and a paediatric body. Traceability details were crosschecked between the identification band on the body, and information in the electronic mortuary register. Whilst one minor discrepancy was identified within a post mortem reference number, this was not sufficient to amount to a shortfall (three additional identifiers were present on the identification band) but oral advice was given to the establishment at the time. Audits were conducted of consent forms and family wishes forms for post mortem examination where tissue was taken. The establishment does not store and retain tissue on site and samples are sent for analysis and storage at a separate establishment.

Meetings with establishment staff

The inspection team met with staff carrying out activities under the licence, including mortuary staff, a pathologist, a porter manager, consent seekers and the DI.

Report sent to DI for factual accuracy: 31st May 2022

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

Final report issued: 14th June 2022

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: 8 August 2022

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.