Inspection report on compliance with HTA licensing standards
Inspection date: **02 & 09 May 2025**

Whittington Hospital NHS Trust
HTA licensing number 12099

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 Whittington Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Maternity	-	*Carried out*	*Carried out*
A&E	-	*Carried out*	-
NICU	-	*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 Whittington Hospital NHS Trust ('the establishment') had met the majority of the HTA's standards three major and three minor shortfalls were found against standards for Governance and quality systems 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
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	The establishment has not undertaken an audit of spleen samples stored to ensure staff are aware of what is held and why.	**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	All procedures relating to licensed activities have not been risk assessed. These include but are not limited to: • Disposal or retention of an organ or tissue against the express wishes of the family; • Loss, disposal or retention of a whole fetus or fetal tissue (gestational age less or greater than 24 weeks) against the express wishes of the family; • incident leading to unplanned closure of mortuary/inability to deliver services; • Loss of an organ or tissue; • Major equipment failure; • Post-mortem cross-sectional imaging of the body of a deceased person included an invasive procedure for which consent had not been given; • Post-mortem examination conducted was not in line with the consent given or the PM examination proceeded with inadequate consent; and • Removal of tissue from a body without authorisation or consent.	**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	The -80^{o}C freezer storing spleen samples is not alarmed. The establishment do not test the lower fridge alarms in both the mortuary and maternity. The establishment do not manually challenge the body store alarms or the maternity alarms OOH. This does not provide assurance that the alarms will trigger when temperatures deviate from the expected range and that the call out procedure works.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	There are no governance meetings in place with persons designated (PD's) in other areas where licensed activity takes place.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	There is no documented training in place for Coroners contracted funeral directors (FDs) who undertake activities out of hours (OOH). Although the maternity department can release babies and conduct viewings, these practices are rarely undertaken. However, there is no documented training in place for maternity staff. These practices pose a risk of viewing or releasing a wrong body.	**Minor**
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	The establishment are not currently conducting viewings. The inspectors found at the time of the inspection in the relatives viewing room that the door to the garage area has a thumb-lock. There is a risk that families would exit the viewing area into the garage area at a time when deceased were being admitted into the mortuary. Although the door leading from the relatives viewing room to the outside could be locked by a key the inspectors found that not all of the mag lock had been installed.	**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.	C1(a)	The DI is advised on the next review of the Consent to Post Mortem Examination and the Retention of Tissue Policy to include what training is in place and that competency assessments are to be undertaken, and the timeframe when competency reassessment is to be undertaken. The DI is advised to remove any references to conducting adult post mortem examinations as this service has not been offered at the establishment since 2018. The DI is advised to ensure that all references to documents are up to date.
2.	GQ1(a)	The establishment has recently undergone a full refurbishment and some Standard Operating Procedures (SOPs) relating to mortuary activities are not reflective of recent change in current practice for example: • viewing of bodies; and

		• Retention, disposal, donation and repatriation of organs. Not all SOPs include all practices that are undertaken by staff. These include, but are not limited to, SOPs detailing the process for: • Body condition checks of deceased. The DI is advised to review the SOPs as part of the horizontal audits undertaken.
3.	GQ2(a)	The DI is advised to include vertical audits in the audit schedule. The DI is advised to use horizontal procedural audits as an opportunity to review SOPs to ensure practice reflects what is written in the SOP for each activity.
4.	GQ2(b)	At the time of the inspection there were two audit templates in use. One of the audit templates does not include who is responsible for the follow-up actions, what findings there are and the timeframe for completing these actions. The DI is advised is remove this audit template and move forward with audit template which includes the follow up actions.
5.	GQ5(a)	The DI is advised to include which HTA reportable incident (HTARI) categories are applicable to porters and consent seekers in their respective training packages. The DI is advised to have signage in the mortuary and maternity wards of applicable HTARI categories and personnel to contact as an aide memoire for staff.
6.	PFE1(d)	The DI is advised to change the keycode on the gate to the entrance of the garage area and the intruder alarm on a regular basis.
7.	PFE2(f)	The DI is advised to complete a trend analysis of fridge and freezer temperatures in both the mortuary and maternity.

Background

Whittington Hospital NHS Trust 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.

Whittington 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 June 2022.

Since the previous inspection, the establishment has had a full refurbishment of the mortuary.

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.

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, reported incidents and staff training records.

Visual inspection

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

Audit of records

Audits were conducted for four 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 seven PM cases, including audits of the consent documentation for the retention of these tissues.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the portering staff, pathologist and perinatal consent seeker.

Report sent to DI for factual accuracy: 6 June 2025

Report returned from DI: 17 June 2025

Final report issued: 1 July 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.