Inspection report on compliance with HTA licensing standards
Inspection date: **16 April 2025**

Warrington Hospital

HTA licensing number 12024

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 **Warrington Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Satellite site **Dataspace**	Not licensed	Not licensed	Licensed
Tissue Store	-	-	-

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 Warrington Hospital ('the establishment') had met the majority of the HTA's standards, two minor shortfalls were found against standards relating to consent documentation.

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

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue, and which reflects the requirements of the HT Act and the HTA's Codes of Practice	There is a documented policy which governs consent for a post mortem examination, however this does not accurately reflect the service offered or the requirements of the HT Act and the HTA's Codes of Practice. This includes: • Incorrectly stating that adult post mortems are offered by the establishment; • Reference to unavailable documents and out of date external links; and • Incorrectly using the term 'next of kin' rather than 'a person of qualifying relationship'.	**Minor**
b) There is a documented standard operating procedure (SOP) detailing the consent process	Whilst a consent SOP has been published, this has not been distributed to, or acknowledged by, staff responsible for taking post mortem consent. *This combined with an inaccurate policy increases the risk of invalid consent being taken.*	**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 practices:

Number	Standard	Advice
1.	GQ2(a)	The DI and Mortuary Manager are advised to incorporate the use of the porter's mortuary key into the access audits to strengthen oversight.
2.	GQ2(a)	The DI and Mortuary Manager are advised to review randomly selected times of CCTV footage in order to strengthen security audits.
3.	GQ6(a)	All HTA reportable incidents have documented risk assessments. In the next review, the DI and Mortuary Manager are advised that they include details of all risk mitigations, as some which are already in place are missing. For example, security measures regarding mortuary access.
4.	PFE1(a)	The floor in the post mortem room is showing minor signs of cracking. The DI is advised to monitor the flooring as any further deterioration may compromise the ability to fully clean and decontaminate the area which would result in standard PFE1(a) not being met.

Background

Warrington Hospital has been licensed by the HTA since May 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in May 2022.

Since the previous inspection there has been a change to both the DI and Corporate Licence Holder contact in 2024. Dataspace remains a satellite site on the licence; however, Warrington Hospital is currently not utilising it to store post mortem tissue for a scheduled purpose.

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 hub site including the mortuary access points, mortuary fridge rooms, post mortem room, 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. The satellite site did not form part of this visual inspection, as the establishment provided evidence that it was no longer storing post mortem tissue.

Audit of records

Audits were conducted for six 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 four coronial cases. These included audits of the consent documentation for the retention of these tissues. No discrepancies were identified.

Meetings with establishment staff

Staff conducting processes under the licence were interviewed including the DI, Mortuary Manager, Quality Lead, Mortuary Porter, and Bereavement Midwife.

Feedback was provided on 02 May 2025 to the DI, Mortuary Manager, Quality Lead, Bereavement Midwife, Divisional Services Manager, and Corporate Licence Holder contact.

Report sent to DI for factual accuracy: 06 May 2025

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

Final report issued: 16 May 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.