Inspection report on compliance with HTA licensing standards
Inspection date: **15 April 2025**

Salford Royal Hospital
HTA licensing number 12541

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
Salford Royal Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Cellular Pathology	-	-	*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 Salford Royal Hospital (the establishment) had met the majority of the HTA's standards, five major and two minor shortfalls were found against standards for Governance and quality systems and Traceability. Six of the shortfalls

related to the management of the material taken at post mortem examination (PM) within Cellular Pathology.

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 does not conduct audits of PM tissue being stored in the block and slide archive. During the HTA audit of retained tissue many of the records were incomplete. The inspection team is not assured that the Trust is aware of what relevant material is being held under the licence, and that its retention and disposal is in accordance with both the Human Tissue Act 2004 (HT Act) and the families' wishes.	**Major**
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)	Systems in place do not robustly ensure the traceability of tissue taken at PM. During the HTA audit of retained tissue staff were unclear of where the material is stored. Once located, some of the blocks and slides were not traceable.	**Major**

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete	There is no active management of the retained tissue taken at PM which means that tissue is not disposed of as soon as reasonably possible.	**Major**
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	There is no effective system for communicating with the Coroner's Office. Some records for retained PM tissue do not have documentation relating to families wishes. There is no follow-up process to identify and escalate these missing records.	**Major**
c) Disposal is in line with the wishes of the deceased's family	The establishment are continuing to store some PM tissue where the families have requested disposal.	**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	Although HTA matters are discussed at governance meetings, issues identified at the meetings are not actioned and/or escalated. For example, since 2022 issues relating to the management of retained PM tissues has been discussed however there has been no definitive plans and actions to address them.	**Minor**
GQ6: Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register.	There are insufficient numbers of permanent staff available to manage the volume and complexity of mortuary activity. Although there are two full-time members of staff, there has been a significant period of time where there has only been one full-time member of staff carrying out all mortuary duties, both practical and administrative tasks. The current situation poses a risk to the continued provision of the mortuary service.	**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.	C1(b)	The SOP relating to hospital PMs (CP-Mort.010) refers to the HTA's old Codes of Practice. The DI is advised to update the references to the new Codes which were published in 2017.

2.	C1(b)	The SOP relating to hospital PMs (CP-Mort.010) makes it clear that the named next-of-kin may not be the person in the highest-ranking qualifying relationship to provide consent, however the document then refers to the next-of-kin within section 4.8. The DI is advised to remove this reference.
3.	C2(a)	The DI is advised to include the training and competency requirements for consent seekers within the hospital PM SOP (CP-Mort.010) to ensure that consent is not taken by an untrained member of staff.

Background

Salford Royal Hospital has been licensed by the HTA since March 2009. 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 significant change in licensable activities. The establishment no longer carry out routine Coronial PMs. They only carry out PMs that require a neuropathology specialism.

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 policies and procedural documents relating to licensed activities. This included standard operating procedures, risk assessments, audits, incidents, meeting minutes, equipment servicing reports, and training and competency assessment documents. Consent seeking procedures and information for families giving consent for adult PM examinations were also reviewed.

Visual inspection
The inspection team undertook an unannounced site visit inspection which included the mortuary body storage area, PM room and the cellular pathology storage area.

Audit of records
The inspection team undertook traceability audits for four bodies in storage including one body in long-term storage. Traceability details were crosschecked between the identification bands on the body, internal paperwork and information on the electronic register. No discrepancies were identified.

Audits were conducted of stored tissue taken at PM examination for 12 cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, the mortuary electronic database, and tissue being stored. Five of the cases chosen has outstanding families wishes forms and the missing documentation has not been followed up. The tissue retention spreadsheet showed that in 2023 only three out of 69 cases had the associated families wishes paperwork. In 2022, only 16 cases out of 74 had the paperwork (*see Shortfall under standard T1(a) and T1(b)*).

Five of the cases audited that did have family wishes paperwork should have been disposed of but were still in storage (*see Shortfall under standard T2(c)*).

Two cases audited could not be found (*see Shortfall under standard T1(g)*).

Meetings with establishment staff
The inspection team met with staff carrying out activities under the licence, including the Mortuary Manager, porter, Cellular Pathology manager, and a Consultant Histopathologist who is the establishment's DI.

Report sent to DI for factual accuracy: 9 June 2025

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

Final report issued: 24 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.