Inspection report on compliance with HTA licensing standards
Inspection date: **19-20 May 2022**

Salford Royal

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
Hub site **Salford Royal**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*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 ('the establishment') had met the majority of the HTA's standards, nine major and seven minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment. These related to training and competency assessment of consent seekers, standard operating procedures, risk assessments and significant risk on the Trust risk register, security arrangements for the mortuary, completion of audits and storage capacity.

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
All applicable HTA standards have been assessed as fully met.

Major shortfalls

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training	The DI provides consent training to those seeking consent and supports the consent seeking process directly, however the method of recording when training has been provided is not formalised. Furthermore, the bereavement nurses who also support the consent seeking process are overdue refresher training.	**Major (Cumulative)**
d) Competency is assessed and maintained	Competency of those seeking consent is not assessed or maintained.	
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) do not always include sufficient detail of procedures or reflect current practice. These include but are not limited to: • Condition checking of bodies – whilst a system is in place for this to occur regularly it is not documented in a SOP. • CP-Mort.015 Security of Mortuary SOP - refers to keycode locks in use, however all doors are now swipe card access. The SOP makes no reference to who has been authorised to have swipe card access, how swipe card access is to be monitored or how oversight of visitors to the department is maintained. • CP-MORT.016 Viewing of bodies in the mortuary – whilst the establishment have temporarily stopped undertaking viewings, the SOP is blank and does not detail this procedure to reflect the requirements of HTA standard T1(c) should the service resume at short notice. • CP-Mort.004 Mortuary body storage SOP –has a title which refers to the management of long stay bodies over 30 days in storage, but no details of the procedure is included. There are several headers in this document with no detail of the procedure in place. • CP-Mort.012 Post Mortem SOP - does not include sufficient detail of identification checks of the deceased performed prior to PM using three points of identification. Neither does it list the types of identifiers that can be robustly used in the identification procedure. There is no detail as to what identifiers of the deceased should be used when labelling specimens. To fully address this shortfall the establishment should review all SOPs to ensure they contain sufficient detail, are reflective of current practice and cover all mortuary and laboratory procedures relevant to licensed activity.	**Major**

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	The establishment does not currently have sufficient staff to provide the range of complex services provided. This has been identified as a significant risk to the delivery of mortuary services and is on the Trust risk register. Whilst the establishment have identified actions to address this risk, including the use of locum staff, and advertising vacant posts several times, recruitment to vacancies for additional staff has so far been unsuccessful.	**Major**
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 have a generic mortuary swipe access card held in the pathology department. Whilst those using this card are required to sign in and out of the mortuary, there is not always oversight of the use of the card by mortuary staff. Furthermore, the establishment were unable to provide sufficient assurance to the inspection team that swipe card access to the mortuary has been restricted to those with a legitimate right of access and that there is oversight of visitors and contractors to the mortuary. Whilst the viewing rooms are currently not in use for the purpose of viewing of bodies, the door between the viewing room and body store has a gap which may allow oversight of activities in the body store by visitors if viewings resumed.	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	A temporary body storage unit is located in one of the viewing rooms which is described as having been in permanent use for several years. Furthermore, at the time of the inspection, a second unit was being sought to be located in the remaining viewing room which would impact on the establishment's ability to provide a viewing service. Lack of permanent capacity for storage of bodies is currently on the Trust risk register and the establishment have identified actions to address this risk.	**Major**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The establishment does not have freezer storage for bariatric bodies. Arrangements were in place to move bodies requiring freezer storage to other local HTA licensed establishments, however, due to the increase in demand for bariatric freezer storage in the local area, storage may not always be available for use when required. During review of the incident log, two incidents had been raised in the previous year where bariatric bodies had exceeded the recommended 30 days in refrigerated storage whilst alternative arrangements for freezer storage were sought. Lack of onsite freezer storage for bariatric bodies is currently on the Trust risk register and the establishment have identified actions to address this risk.	**Major**
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 fridge and freezer units used for the storage of tissue samples in the mortuary are not alarmed. Furthermore, the temporary body storage unit currently located in one of the viewing rooms is not connected to the remote alarm system.	**Major**

f) Temperatures of fridges and freezers are monitored on a regular basis	Temperatures of the fridge and freezer units used for the storage of tissue samples in the mortuary are not monitored.	**Major**
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	Whilst hydraulic body trolleys used in the mortuary reach the upper trays of the body storage units, the trays are at a height which make it difficult for staff to manage the admission and removal of bodies safely. This poses a risk of accidental damage to bodies and a risk to the safety of staff. Furthermore, some trolleys have been recently condemned for use which is limiting the number of trolleys available.	**Major**

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		
b) There is a documented standard operating procedure (SOP) detailing the consent process	Whilst the consent process is detailed within the consent policy as a joint document, the policy has not been updated to reflect the recent changes to how training is provided to consent seekers by the DI.	**Minor**
GQ2 There is a documented system of audit		

a) There is a documented schedule of audits	Whilst the establishment have a documented schedule of audits, which includes auditing of body traceability records, there are no audits undertaken on bodies in storage. Some audits are not up to date on the schedule due to staffing pressures.	**Minor**
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	Regular audits are carried out to ensure tissue has been disposed of in a timely manner and in line with the wishes of the family, however, traceability audits of tissue in storage retained with consent for scheduled purposes are not undertaken.	**Minor**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	Whilst staff know how to identify and report incidents, some incidents falling within the HTA reportable incident (HTARI) categories had not been reported to the HTA as the establishment had determined them to be a near miss.	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
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	Risk assessments do not sufficiently detail how identified risks are mitigated. Furthermore, not all risk assessments consider the risks to the deceased or have been reviewed against the HTARI categories to ensure appropriate mitigation for identified risks.	**Minor**
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	The establishment receive neuropathology specimens for specialist analysis from other HTA licensed establishments. The inspection team identified that containers holding such specimens are not always labelled with three points of identification of the deceased by the establishment referring the specimen. This poses a risk to loss of traceability of specimens if further identifiers of the deceased are not added to the containers at the point of receipt into the mortuary.	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	At the time of the inspection, the establishment were unable to provide evidence that the ventilation system provides the necessary air changes. This was due to the ventilation report being held by the estates department.	**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(a)	The DI is advised to liaise with ward managers to seek improvement to the process for transferring bodies from the ward to the mortuary. Porters reported delays in transfers due to incomplete transfer paperwork or rooms not being ready to receive the concealment trolley.

2.	GQ1(a)	The DI is advised to review the mortuary capacity and surge plan SOP to ensure the content is reflective of current capacity management. Whilst the document has been recently reviewed, it refers to the action to take in response to the Trust incident plan, last updated in 2015.
3.	GQ2(c)	The tissue traceability audit form refers the user to HTA guidance on the management of anatomical specimens / former anatomical specimens which is aimed primarily at the anatomy sector. The DI is advised to review this to ensure users are signposted to the more relevant guidance for the management of PM tissue in Code of Practice B – Post Mortem examination.
4.	GQ3(c)	Whilst the establishment have a process in place to review the qualification status of locum APT staff and an induction is provided, the DI is advised to document the competency assessments undertaken.
5.	GQ3(c)	The DI is advised to include a competency assessment for mortuary staff in HTARI reporting procedures.
6.	GQ5(a)	The DI is advised to review the HTARI reporting SOP and include all incidents which are to be reported to the HTA, including those that should be reported as a near-miss. Currently there is an internal link to the HTA guidance, but this relies on staff accessing the link rather than having the information within the SOP.
7.	T1(b)	The DI is advised to update the paper mortuary register when bodies move location or review the necessity of this register as there are several methods in operation for the tracking of bodies through the mortuary.
8.	T1(c)	The DI is advised to liaise with establishments who refer neuropathology specimens for specialist analysis to ensure specimens arrive with three points of identification of the deceased on the containers.
9.	PFE2(a)	The trigger point for the fridges to alarm is 10°C, which is higher than normal. The DI is advised to lower the trigger point. If the fridges run between 8-9°C for extended periods of time, this could compromise the condition of the deceased in storage.

Background

Salford Royal has been licensed by the HTA since March 2009. This was the third inspection of the establishment; the most recent previous inspection took place in June 2017.

Since the previous inspection, the organisation has merged with another NHS Trust which is also a HTA licensed establishment, however the establishments plan to retain separate HTA licenses.

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

71 of the 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017). HTA standard PFE2(h) is not applicable as the establishment do not receive the bodies of babies or infants.

Review of governance documentation

The inspection team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities for the mortuary were reviewed. Traceability audits, risk assessments, meeting minutes, incidents, 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 area, the temporary body storage area, the PM room and viewing rooms (one currently housing a temporary body storage unit). The area for the storage arrangements for relevant material held within the pathology department was also reviewed.

Audit of records

The inspection team undertook audits of traceability for four bodies in storage. This included bodies with same / similar names and a body in long term storage. Traceability details were crosschecked between the identification band on the body, information on the door of the storage unit, the mortuary register, associated paperwork, and the electronic database. Whilst no discrepancies were identified with the identification of bodies, three bodies were found to be in a different storage location to that detailed in the paper mortuary register. The paper mortuary register is not routinely updated due to the information being captured on the electronic database and in the record files of the bodies in storage. These documents are used to track bodies through the mortuary, not the paper register.

Audits were conducted of tissue taken at PM examination for four cases. Information was crosschecked between the mortuary documentation, family wishes forms, and tissue blocks and slides being stored. Two cases reviewed demonstrated disposal of tissue had been completed in line with the wishes of the family. The further two cases were being stored for a scheduled purpose and consent was in place for this storage. A minor discrepancy was identified with the number of slides documented for one case in storage.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including mortuary staff, a portering staff member, a pathologist, staff involved in the consent seeking process for adult PM examination, and the DI.

Report sent to DI for factual accuracy: 20 June 2022

Report returned from DI: 06 July 2022

Final report issued: 12 July 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: 12 April 2023

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.