Inspection report on compliance with HTA licensing standards
Inspection date: **22 August 2024**

Southampton General Hospital
HTA licensing number 12214

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 **Southampton General Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	*Carried out*	-
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 Southampton General Hospital ('the establishment') had met the majority of the HTA's standards, ten major and six minor shortfalls were found against standards for Consent, 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.

Compliance with HTA standards
Major shortfall

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
d) Competency is assessed and maintained.	The establishment does not have a system in place for assessing the competency of the bereavement care team against the HTA requirements when seeking consent for Post mortems. (See *Shortfall* against standard GQ3(c)).	**Major**

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) relating to mortuary activities are not reflective of current practice or do not contain sufficient details of procedures. For example: There are inconsistencies with what is covered in SOPs. These include but are not limited to: • Post mortem Consent and Human Tissue Disposal Policy. • HTA Training Reference Guide. • Protocol required to document and record a mortuary post mortem • Procedure for viewing the deceased by authorised persons. This is not an exhaustive list of the amendments required to all the SOPs and, to fully address this shortfall, the establishment should review all SOPs relating to all mortuary activities to ensure that they are accurate, reflect current practice and contain sufficient detail of procedures. (See *Advice* item 2).	**Major**

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 inspection team were not assured tissue audits contain a sufficient sample size for the establishment to assure themselves non-conformances are identified and that any follow up action is taken in a timely manner.	**Major**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks

c) Staff are assessed as competent for the tasks they perform.	Not all staff are assessed as competent for the tasks they perform. • No evidence was present to confirm the bereavement care team are assessed as competent for Post mortem consent seeking. • No evidence was present to confirm staff carrying out viewings are assessed as competent. • No evidence was present to confirm the lead porter, who is responsible for carrying out training for all new porters, is accessed as competent.	**Major**

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, the inspection team identified three incidents which met the threshold for reporting to the HTA which had not been reported. (See *Advice* item 3).	**Major**

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.	Procedures for identification of bodies and tissue do not always use a minimum of three identifiers of the deceased. • Viewings of the deceased are arranged and accompanied by the bereavement care team. For these viewings, no evidence was present to confirm they ask for a minimum of three identifiers of the deceased from relatives on arrival, or check a minimum of three identifiers of the deceased provided by relatives against the identification on the body before a viewing takes place. This poses the risk of the viewing of the wrong body. • The inspection team identified one case during the onsite body audit where three identifiers were not present on the body. This error was immediately rectified following the finding. • The inspection team identified five cases during the onsite tissue audit where a minimum of three identifies of the deceased where not present on tissue records.	**Major**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	Organs or tissue taken during post-mortem examination, including blocks and slides, are not fully traceable. • The inspection team identified three non-conformities during the onsite tissue audit. The DI does not have full oversight of what tissue is retained and the relevant consent to allow the retention or disposal of that tissue. • The establishment does not receive confirmation that organs/tissue sent off site for analysis are received, or check that it has arrived at the receiving establishment. This poses a risk of loss of traceability. • The type and quantity of tissue is not recorded on the establishment's spreadsheet. This poses a risk of loss of traceability. (See *Shortfall* against standard T2(a)).	**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.	The inspection team identified three non-conformities during the onsite tissue audit. The inspection team also found inconsistencies in the establishments record keeping. This poses the risk of tissue blocks and slides being retained without appropriate consent. (See *Shortfall* against standard T1(g)).	**Major (cumulative)**
c) Disposal is in line with the wishes of the deceased's family.	The inspection team were unable to confirm disposal of tissue is in line with the wishes of the deceased's family.	
d) The method and date of disposal are recorded.	Whilst there is a system in place to record the date of disposal, the method of disposal is not recorded. (See *Advice* item 4).	

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access).	• Although CCTV is in place outside the funeral directors entrance, it is currently obstructed by scaffolding. • Although the entrance for the viewing suite has an audio visual entry system in place, the corridor leading to the viewing suit is not covered by CCTV. Furthermore, there is also an insecure door on this corridor which leads directly into a secure external compound area of the mortuary.	**Major (cumulative)**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	• Refrigeration and ventilation plant equipment is located in an insecure outside area. Power switches for the plant equipment are not fitted with tamperproof mechanisms. • The inspection team located an insecure external door to the side of the mortuary. This door provided potential access to the roof space above the mortuary fridges. This poses a risk to the security of the mortuary. (See *Advice* item 5).	

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	Whilst fridge and freezer alarms are regularly tested, a test of the lower set range is not undertaken.	**Major**

Minor Shortfalls

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		
g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided.	The inspection team were not assured the establishment use one ratified version of the consent for Post-Mortem examination of an adult form. It is unclear which form should be used during this process. This poses a risk that the incorrect version could be used to obtain consent.	**Minor**

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	Whilst scheduled Pathology Governance Group meetings do take place, there are currently no documented meetings relating to HTA activity involving the designated individual, mortuary staff and staff working outside the mortuary who undertake activities under the licence.	**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	Although risk assessments identify who is responsible for each mitigating action, deadlines for completing actions and confirmation that actions have been completed are not covered. (See *Advice* item 6).	**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	Whilst the premises are clean and well maintained, the floor in the body store has a small area where the floor covering has cracked and lifted, this poses the risk of ineffective cleaning and decontamination.	**Minor**
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	Although the premises have a transitional clean to dirty area, there is currently no signage to state when you are entering a dirty or clean area.	**Minor**

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	Although items of equipment in the mortuary are in good condition and appropriate for use, the inspection team found the following: • The oscillating saw in the paediatric Post mortem room presents early signs of rusting. This poses the risk of ineffective cleaning and decontamination. • The bin holder in the Post mortem room is heavily rusted. This presents the risk of ineffective cleaning and decontamination. (See *Advice* item 7).	**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(f)	Whilst a timeframe for family members to change their minds is provided by consent seekers, the timeframe is not detailed in any policy or SOP. This poses a risk of inconsistences in this process. The DI should review the documents governing consent to ensure information is consistent and reflective of staff practice.
2.	GQ1(a)	The DI is advised to remove references to ‘next of kin’ when documents are next reviewed.

3.	GQ5(a)	The DI is advised to place signage in the mortuary to raise awareness for staff of the importance of reporting any incidents or near misses, including a list of all the appropriate HTA Reportable Incident (HTARI) categories.
4.	T2(d)	The DI is advised to place markers in the block and slide archives to confirm tissue has been disposed of.
5.	PFE1(e)	• Although the mortuary office window is fitted with a reflective film, the inspection team were able to see into the body store though this window. This poses a risk of oversight of the transfer of the deceased. The DI is advised to review current arrangements. • The DI is advised to continue with current plans to install an intruder alarm in the mortuary. • The exterior door leading to the internal entrance to the mortuary is currently broken and permanently propped open. This door should be repaired and secured to ensure only appropriate staff have access to this corridor.
6.	GQ6(b)	Staff training and competency assessments are not listed in your risk assessments as existing controls. Where appropriate this should be included.
7.	PFE3(a)	The DI is advised not to place cardboard boxes directly on the floor in the Post mortem room.

Background

Southampton General Hospital has been licensed by the HTA since 2007. This was the sixth inspection of the establishment; the most recent previous inspection took place in April 2022. 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 included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records for the mortuary, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and training records for mortuary staff and the bereavement care team.

Visual inspection
The inspection included a visual assessment of the mortuary body storage areas including the Post mortem rooms and viewing suite. The inspection teams observed the processes for release within the mortuary.

Audit of records
Audits were conducted for five bodies from refrigerated storage. Identification details on bodies were crosschecked against the information recorded in the mortuary electronic register and associated paperwork. One discrepancy was identified. Audits of tissue traceability were undertaken for five histology cases, discrepancies between written records and physical holdings were identified for three cases.

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, Mortuary Manager, Governance and Quality Lead for Pathology, Pathologist, Qualified APT, Trainee APT, Tissue Lead, Consent Seekers and a Porter.

Report sent to DI for factual accuracy: 11 September 2024

Report returned from DI: 23 September 2024

Final report issued: 16 October 2024

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: 22 April 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.