Inspection report on compliance with HTA licensing standards
Inspection date: **27/06/2024**

St Peters Hospital
HTA licensing number 12542

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 **St Peters Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*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 St Peters Hospital ('the establishment') had met the majority of the HTA's standards, four major and four minor shortfalls were found against standards for Governance and quality systems, Traceability and remises, facilities and equipment.

Whilst a significant amount of work has be undertaken to implement corrective and preventative actions to address the findings from the HTA Inspection in September 2023, one of the major cumulative shortfalls relates to findings from that inspection. The HTA is concerned that adequate steps have not been taken to address these findings in the intervening period and to embed suitable practices at the establishment. Shortfall findings relating to standard PFE3(e) identified during the previous inspection were also found during this inspection.

Concerns were discussed with the establishment as part of this inspection. The current DI has provided assurance that key personnel have been appointed to manage the activities under the licence and that the establishment is committed to meeting the regulatory requirements. Based on this assurance, 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. However, in light of the establishment's lack of progress in addressing shortfalls from previous inspections, the HTA will consider the need for regulatory action if appropriate action is not taken to meet the regulatory requirements in accordance with the timeframes detailed in Appendix 2.

Compliance with HTA standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
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).	There is a process in place for whole organs and histological samples taken for analysis to be booked out, however the establishment does not obtain confirmation that the tissue has been received by the third party who carries out testing. Furthermore, whilst there is a system in place for slides to be booked out for offsite analysis by pathologists, there is no documented process in place to oversee and escalate the return of slides in a timely manner. This poses the risk of both a loss of tissue and slides, and the retention of tissue against the wishes of the family.	**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	Security audits are undertaken on a regular basis, however there is no audit of swipe card access against CCTV and access logs. There is contradictory information in the security audit of Funeral Director activity undertaken for February 2024, which identified that only mortuary staff and porters had accessed the mortuary out of hours. Furthermore, the inspection team were not assured that security audits contained a sufficient sample size for the establishment to assure themselves that any access for an unauthorised purpose would be identified and follow up action taken in a timely manner. This poses a risk to the safety and dignity of the deceased. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**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	Some of the hydraulic trolleys are not compatible for use with the fridges in use. Some trolleys do not reach the top or bottom fridge tray. This means staff transfer trolleys from dirty to transitional areas to facilitate the removal of bodies from storage. This poses the risk of accidental damage to a body and musculoskeletal injury to staff.	**Major**
e) Where chemicals are used for preservation of tissue samples, there is adequate ventilation	There are plans in place to upgrade the ventilation in the room used for the preparation of placentas for analysis in maternity. However, funding has not been approved and there is no proposed start date for the work to be undertaken.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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.	The establishment is undertaking a significant review of SOPs and the quality of these is much improved. Some SOPs still lack detail and others are awaiting final approval before publication. These include, but are not limited to, SOPs detailing the process for: - Out of hours and lone working - Staff Induction - Oversight and governance of histological slides taken offsite for analysis - Post Mortem Examination Additionally, whilst there is a security policy in place, there is no dedicated SOP reflecting the activities carried out by staff to maintain security within the mortuary. Guidance for staff is provided across several SOPs. This is not an exhaustive list of the SOPs requiring amendment. To fully address this shortfall, the establishment should review all SOPs relating to mortuary activities to ensure they are accurate and contain sufficient detail to reflect current practice.	**Minor**
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	Staff have received an assessment of competency, however it is not always clear what was assessed in order to provide assurance that staff were working in accordance with SOPs.	**Minor**
f) There is a documented induction and training programme for new mortuary staff	Staff have received corporate and local inductions. The local induction document takes the form of a checklist and lacks detail regarding the information provided. Furthermore, there is no list of SOPs and Policies to be read by staff in this document.	**Minor**

g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	The Inspection team are not assured visiting pathologists are required to read and acknowledge updated SOPs and Policies relevant to their practice.	**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.	CQ1(c)	The DI is advised to review and strengthen the process in place for bodies at an increased risk of deterioration who require their condition to be checked more frequently. Additionally, consideration should be given to the amendment of the release form to add a section for Funeral Directors to confirm a condition check has been undertaken immediately before release into their care.
2.	GQ2(c)	The DI is advised to continue with existing plans for an audit of all tissue stored by the third party licensed establishment to be undertaken. This will provide additional assurance tissue transferred offsite is fully traceable.
3.	GQ4(a)	The DI is advised to consider the implementation of an electronic mortuary database. This will reduce the risk of a transcription error due to the use of more than one paper based system.
4.	T1(c)	The DI is advised to ensure that release always takes place using the paperwork brought by the

		Funeral Director against the information on the body, and to make sure any additional tags on the body are checked to ensure all details are correct.
5.	T1(d)	The DI is advised to review and strengthen the process relating to same or similar names. Consideration should be given to the use of an additional alert on the body.
6.	PFE1(a)	The DI should consider the removal of the desk from the storage room accessed via the PM suite. Whilst the door is kept closed, there is a risk of cross contamination from dirty to transitional areas. Additionally, the desk is constructed from porous material which is difficult to clean effectively.
7.	PFE1(d)	The DI is advised to consider the installation of an additional CCTV camera to provide oversight of the entrance door to the fridge unit used for the storage of bariatric bodies.

Background

St Peters Hospital has been licensed by the HTA since April 2009. This was the sixth inspection of the establishment; the most recent previous inspection took place in September 2023.

Since the previous inspection, there have been no significant changes to the licensed activity within the establishment. However, there has been a change to the licensed personnel with a change to the DI in December 2023 and Corporate Licence holder Contact (CLhC) in January 2024.

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
69 of the 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017), standards T2(a)(c) and (d) are not applicable as the establishment does not store or dispose of tissue.

Review of governance documentation
The inspection included a review of the establishment's governance documentation relating to licensed activities. This included documents submitted as evidence in support of the corrective and preventative actions undertaken by the establishment in response to the most recent previous inspection. 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, porters, maternity staff and contracted funeral directors.

Visual inspection
The inspection included a visual assessment of the mortuary body storage areas including the external storage unit, PM room, viewing room and maternity unit. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records
Audits were conducted for two bodies from long term (frozen) storage and four bodies from refrigerated storage. Identification details on bodies were crosschecked against the information recorded in the mortuary electronic register and associated paperwork. No discrepancies were identified. Audits of tissue traceability were limited to transfer paperwork and confirmation of receipt from third party establishments who undertake the analysis of tissue. The establishment does not routinely obtain confirmation of receipt for delivery of histology samples and whole organs. Refer to shortfall T1(g) above.

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, mortuary manager, trainee APT, quality lead, tissue lead, and bereavement midwife.

Report sent to DI for factual accuracy: 05 July 2024

Report returned from DI: 18 July 2024

Final report issued: 22 July 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: 7 January 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.