Inspection report on compliance with HTA licensing standards
Inspection date: **02 July 2024**

West Suffolk Hospital

HTA licensing number 12242

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
West Suffolk Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab			*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 West Suffolk Hospital ('the establishment') had met the majority of the HTA's standards, three major, two cumulative major and one minor shortfall were found against standards for Consent, Governance and quality systems 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 shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
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	Out of hours viewings are undertaken infrequently and staff are able to describe the process followed including obtaining three identifiers. However, the SOP does not reflect staff practice and lacks detail. This poses the risk of a viewing of the wrong body. *The establishment addressed this shortfall prior to the publication of the final report.*	**Major**

	See advice, item 1.	

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, some areas require maintenance: • The doors and step over barrier into the post-mortem (PM) room are made of wood which makes it difficult to clean and disinfect properly • The PM room has pooling of water which is causing the floor surface to raise • The floor in the body store has some small cracks.	**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 viewing room door has a bolt lock at the top of the door and if unlocked the door opens into the body store. Although the door is not visible when a viewing is being conducted, there is a risk of the public gaining access to the body store.	**Major**

	The establishment addressed this shortfall prior to the publication of the final report. *See advice, item 3.*	

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 the upper temperature trigger point for the fridges is tested regularly to ensure call out procedures are working, tests do not include the lower temperature trigger point.	**Major (Cumulative)**
f) Temperatures of fridges and freezers are monitored on a regular basis.	The lower temperature trigger point is set to alarm at 0°C and staff manually check temperatures during working hours only. This poses a risk to accidental damage to bodies should there be a deviation in temperatures.	

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	The oscillating saws have areas of rust which make them difficult to clean and disinfect.	**Major (Cumulative)**

c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The ventilation check for the PM room is not up to date and was last checked in September 2022.	

Minor shortfalls

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	Whilst staff have been trained in seeking consent for PM examination, the inspection team were informed that refresher training is not up to date. The establishment have not sought consent for a PM examination for a number of years and their policy is to provide refresher training just prior to the need to seek consent for PM examination.	**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 ensure that once the viewing SOP is updated (to include more detail of how staff confirm three identifiers with the family), this is communicated to staff who have been trained to conduct out of hours viewings.
2.	GQ6 (a)	The DI is advised to risk assess the area that has been identified for contingency storage. The DI is also advised to carry out a gap analysis against HTA standards prior to use.
3.	PFE1 (e)	The DI is advised to continue with plans to install swipe card access to the relatives room. The DI may also wish to consider installing swipe card access at the door in the viewing room that leads into the body store area.

Background

West Suffolk Hospital is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

West Suffolk Hospital has been licensed by the HTA since July 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in February 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, records of equipment servicing, audits, risk assessments and reported incidents.

Visual inspection

The inspection included a visual inspection of the mortuary body store, PM room and viewing room.

Audit of records
Audits were conducted for three bodies in refrigerated storage and one body in freezer storage. Body location and identification details on bodies were crosschecked against the information recorded in the electronic system and relevant documentation. No discrepancies were found.

Audits of traceability were conducted for tissue blocks and slides from four PM cases, including storage location and audits of the consent documentation for the retention and disposal of these tissues. No discrepancies were found.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, Anatomical Pathology Technologist, a pathologist, portering staff and consent seekers for PM examinations.

Report sent to DI for factual accuracy: 25 July 2024

Report returned from DI: 06 August 2024

Final report issued: 07 August 2024

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.