Inspection report on compliance with HTA licensing standards
Inspection dates: **4th and 10th of February 2022**

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, four major and five minor shortfalls were found against standards for 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 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.	Standard Operating Procedures (SOPs) lack sufficient detail. Key steps are included however there are instances where SOPs do not fully reflect the individual actions being carried out. These include, but are not limited to: • release of bodies to funeral directors; • identification of deceased for viewing of adult, paediatric and perinatal bodies; and • transfer of tissue taken at post mortem for analysis. In addition, there is no SOP to cover the transfer of super bariatric patients to an alternative establishment in the event that it is not possible to perform a post mortem. This is not an exhaustive list of the SOPs that need to be created or amended. To fully address this shortfall the establishment should review all SOPs relating to mortuary activities to ensure that they reflect current practice.	**Major**

GQ2 There is a documented system of audit		
(a) There is a documented schedule of audit.	The scope of the audit schedule does not include sufficient horizontal audits to cover all licensed activities. No audits of consent forms are carried out or horizontal audits of bodies in storage. During the inspection the team identified a discrepancy with an identifier on the paper register for perinatal bodies, which had not been identified by the establishment.	**Major**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
(a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised.	Clinical site managers are responsible for the viewing of bodies out-of-hours. Although some of the site management team have received training, the establishment could not provide records to demonstrate that training or that (re)competency had been conducted.	**Major**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
(a) All procedures related to the licensed activities (as outlined in GQ1) are risk assessed on a regular basis.	The contingency route for funeral directors to access the mortuary (used when their primary route is blocked due to ongoing building work) passes through the hospital building via a busy service entrance which includes a staff rest area. When using this access point, funeral directors are unable to reverse their vehicles into the area and accordingly there is a heightened risk that passers-by at ground level and those in the adjacent Trust office building could have a clear view of the transfer of bodies in and out of the vehicles. The risk to the dignity of the deceased from using this route for the transfer of bodies is not covered by a risk assessment of the type described in GQ6 (b).	**Major (cumulative)**
(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.	The contingency route for funeral directors to access the mortuary (used when their primary route is blocked due to ongoing building work) includes the use of a steep ramp creating an increased risk of accidental damage to a body. While a risk assessment has been carried out for the use of this ramp, it does not meet the requirements in GQ6(b). For example, the mitigating steps are advisory/optional in nature and do not place an obligation on staff or funeral directors to take the necessary steps to mitigate the risk.	

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ4 There is a systematic and planned approach to the management of records		
b) There are documented SOPs for record management which include how errors in written records should be corrected.	Although there is a record management SOP, it does not detail how errors in written records should be corrected.	**Minor**
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). The traceability system ensures the following details are recorded: i. material sent for analysis on or off site, including confirmation of arrival.	The establishment does not receive confirmation that specimens sent for cytogenetic testing are received at the off-site laboratory.	**Minor**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's Codes of practice		
(d) The method and date of disposal are recorded.	Although the establishment records the date of disposal, the method of disposal is not recorded.	**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.	There are areas where the sealant between the wall and floor have separated in the post mortem room, making the surface difficult to clean and disinfect.	**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.	Some items of equipment are suffering from obvious signs of wear and tear and are not fit for purpose, for example: • the utensil trolleys and hydraulic trolleys have areas of rust; • some implements used in the post mortem room are rusty and in need of replacement; • some equipment is made from wood and should be replaced with equipment of non-porous construction.	**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.	PFE 1a	There is CCTV covering the door to the mortuary, which sits within an internal hospital corridor. However, there is no CCTV coverage at either of the two outside access points where funeral directors transfer the deceased to and from their vehicles. The DI is strongly advised to consider installing CCTV at these two points to enhance security and oversight of these areas which, due to the site layout, are physically distanced from the mortuary itself. On the day of the site visit inspection, it was noted that, despite controlled access having recently been fitted, the exterior door at the usual access point for funeral directors had broken and could not be securely closed, it also showed significant wear and tear. The DI is advised to closely monitor the closing mechanism and general condition of this door and may wish to consider a replacement to further strengthen security in this area.
2.	C1a	The DI is advised to review the PowerPoint presentation used for consent training to remove outdated references to old HTA codes of practice and replace with correct references.
3.	GQ5a	The DI is advised to display an aide memoire covering the HTA reportable incident categories within the body store area.
4.	T1g	The DI may wish to consider adding the completed MORT-FORM20 PM Histology list to the mortuary database system to help facilitate traceability of the tissue taken at PM examination.

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 2006. This was the fourth inspection of the establishment; the most recent previous inspection took place in January 2017.

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 four bodies in refrigerated storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and relevant documentation. One discrepancy was found.

Audits of traceability were conducted for tissue blocks and slides from four PM cases, including audits of the consent documentation for the retention 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 Technologists, a pathologist, portering staff and maternity staff.

Report sent to DI for factual accuracy: 1 April 2022

Report returned from DI: 2 April 2022

Final report issued: 21 April 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: 22 July 2022

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.