Inspection report on compliance with HTA licensing standards
Inspection date: **20 and 21 August 2024**

East Sussex Healthcare NHS Trust

HTA licensing number 12141

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 **Eastbourne General District Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Satellite site **Conquest Hospital**	Licensed	Licensed	Licensed
Mortuary (satellite site)	*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 East Sussex Healthcare Trust ('the establishment') had met the majority of the HTA's standards, one cumulative critical, eleven major and four 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

Critical Shortfalls

Standard	Inspection findings	Level of shortfall
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)	<u>Eastbourne District General Hospital (EDGH)</u> The mortuary has a wall of sash windows either side of a fire door which overlooks into an inner courtyard. Although the windows are frosted to prevent oversight of movement of bodies, none of the lower vertically sliding panels lock and two of the upper sliding panels do not fully close and are at risk of falling open. The inspectors found debris in the inner courtyard indicating that this area is used and a door that was unlocked leading into another unsecure part of the hospital. The funeral directors entrance into the body store is via a concertina door which is secured only by a metal latch. There is a risk of unauthorised access if the door is not properly latched when closed. The external passenger door next to the concertina door has a large letter box that had been covered by duct tape. The tape is ineffectual as this has now detached. <u>Conquest Hospital (CH)</u> Although the funeral directors entrance door has been upgraded with swipe card access the additional slide lock and dead bolt do not have secure clasps.	**Cumulative Critical**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The current annual review of swipe card access is not sufficient to provide assurance that those who have access to the mortuary continue to be authorised to do so. The establishment are currently behind on completing security audits. <u>EDGH</u> Each internal door in the mortuary is locked using a different key. There is a risk that there are a number of keys in circulation as these keys are not security keys and it is not clear if an audit has been conducted of the number of keys in circulation. *See advice item 10.*	

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) relating to mortuary activities are not reflective of current practice or do not contain sufficient details of procedures. For example: • viewing of deceased. • release of deceased. • admittance of the deceased. 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, cross reference the appropriate SOPs and contain sufficient detail of procedures.	**Major**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The scope of the audit schedule for licensed activities conducted under the licence is limited. The audit schedule does not include sufficient audits to check compliance with documented procedures, the completion of records or traceability of bodies. Although audits have been undertaken the establishment are behind schedule.	**Major**

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	Although tissue audits are undertaken, during the traceability audit of post mortem (PM) tissue three discrepancies were found with cases dating back to 2022. • One case from 2022 had an additional slide in storage that was not recorded on the laboratory information management system (LIMS). • One case from 2023 had six missing slides discovered by staff when disposing of the tissue as per the families wishes. However, the absence of these slides has not been followed up. One case from 2024 had the incorrect unique reference number recorded on the mortuary document. Tissue retention audits are undertaken, however all tissue is not audited to ensure that records are accurate. There is a risk of loss of tissue blocks and slides.	**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	During the inspection one incident and two near-miss HTA reportable incidents (HTARIs) were identified that had not been reported from 2022 to 2024. *See advice item 5.*	**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 has identified a significant risk to the delivery of mortuary services due to the current mortuary staffing levels. This risk was placed on the Trust risk register in 2022. Whilst plans are in place to address this risk, these should be expedited and fully supported to ensure the mortuary service is able to work effectively. *See advice item 7.*	**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	Staff conducting viewings do not check a minimum of three identifiers of the deceased provided by relatives against the identification on the body before a viewing takes place. There is a risk of a viewing of a wrong body	**Major**
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	Issues were identified with the cleanliness and maintenance of the establishment. <u>(EDGH)</u> • hair and tissue was found in the drains and sink holes of the PM suite; • the floor of the PM room is cracked and split around the drain; • there are areas of exposed wood and plaster in the body store; • there are several areas of peeling paint on the walls of the body store; • areas of severe rust were seen on the screen at the funeral directors (FD) entrance and step ladder; • the room storing the temporary units is dirty and the floor has areas of cracked tiles. <u>(CH)</u> • areas of rust seen on the radiator in body store; • exposed plaster on walls of PM suite • the floor of the body store is cracked; • debris was found in the drains and sinks of the PM suite; • debris was found on the handle of the PM table hose; • dried blood spots were seen on the saw in the PM suite; • seals around the base of the PM tables have deteriorated; and • the inspection team identified a leak coming from the base of a PM table.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

a) Storage arrangements ensure the dignity of the deceased	CH The movement of bodies in and out of the funeral director's entrance is overlooked. The road passing the funeral director's entrance to the mortuary is also used as a public thoroughfare for the nearby school pupils, members of the public and Trust staff. This does not ensure the dignity of the deceased and there is a risk of oversight of mortuary activities.	**Major**
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	The establishment are permanently using two temporary fridge storage units to store bodies. The use of temporary storage units should not be used regularly or for extended periods of time.	**Major**
d) Fridge and freezer units are in good working condition and well maintained	Some seals on fridge doors are deteriorating at both EDGH and CH. Mould was also observed on some seals of fridge doors. This poses a risk of the fridge banks not running at optimal temperature or contamination of the fridge units which may result in deterioration of the condition of the bodies stored. Areas of rust were observed on the fridge racking and trays.	**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	Mortuary staff stated that Trust estates staff carry out testing of the fridge and freezer temperature alarms in hours at both sites however; the lower temperature alarm is not challenged. Manual alarm testing of the fridge and freezer units out of hours (OOH) are not undertaken at both sites to ensure that alarms trigger and that the call-out procedures are effective. *See advice item 12.*	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		

d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	A small number of SOPs have the same author and authoriser.	**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	Although staff have been initially competency assessed, competency reassessments for all mortuary and portering staff are not up to date.	**Minor**
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	Although visiting pathologists have an initial induction and training in the mortuaries policies and procedures, reviewed SOPs have not been signed as read and acknowledged.	**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	The trolley hoists are suffering from signs of wear and tear; large areas of rust were seen making them difficult to clean and decontaminate sufficiently.	**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(a)	The DI is advised on the next review of the Consent to Treatment, Examination and Care Policy and Procedure to include the list of those in the hierarchy of qualifying relationships referred to in the Human Tissue (HT) Act 2004.

2.	C2(a)	Although a number of maternity staff are trained and competency assessed to seek consent for PM examination many clinicians have not completed retraining or competency reassessment. The DI is advised to ensure that clinicians complete the consent training package in place to reduce the risk of them seeking consent without a trained individual present.
3.	GQ2(b)	The DI is advised to expand on the evidence recorded on audit templates to ensure that the procedure is effective and robust.
4.	GQ3(a)	The DI should reconsider the use of portering bank staff conducting mortuary activities if training cannot be provided to them.
5.	GQ5(a)	The DI is advised to place signage in the mortuary and maternity units to raise awareness amongst all staff working there of the importance of reporting any incidents, including a list of all the appropriate HTA Reportable Incident (HTARI) categories.
6.	GQ6(a)	Although risk assessments are in place that cover all processes and procedures, the documents are confusing to interpret. The establishment are to commence transitioning the risk assessments to a more appropriate Trust template; the DI is advised to ensure that this work is completed in a suitable time period.
7.	GQ6(c)	The DI is advised to investigate the use of process mapping to visually map out workflows and processes. This may provide insight to how a process or staff may be utilised in a more effective and streamlined way.
8.	T1(b)	During the inspection at CH body audits were conducted on deceased in the mortuary. The inspectors found that a body was transferred from CH to EDGH; however the electronic mortuary register was not updated to reflect the freezer position at EDGH. The DI is advised to ensure that staff update the electronic mortuary register on where bodies are stored.
9.	T2(b)	During the inspection tissue traceability audits were conducted on retained blocks and slides. The inspectors found through the cellular pathology departments retention audits that families wishes forms have not been received for a small number of cases dating back to 2017. Although the establishment are communicating with the coroner regarding outstanding forms on an ad hoc basis, the DI is advised to have a more formal procedure in place to ensure that tissue is not retained for any longer than necessary.
10.	PFE1(e)	The DI is advised to consider using the same key system at EDGH that is used at CH with one security key to lock all internal doors.

11.	PFE2(a)	During the body audits at both EDGH and CH the inspectors found that body condition checks had not been carried out on three bodies as per the SOP. The DI is advised to ensure that regular body audits are conducted to ensure that the risk of any deterioration of bodies that has the potential to cause distress to the family or may lead to damage in public confidence is mitigated.
12.	PFE2(e)	The establishment have two concurrently running alarm systems: the Trust switchboard is alerted when the fridge local alarm alerts and a third party temperature monitoring supplier when the temperature probes alert. The temperature alarm monitoring procedure does not test that the temperature probes will trigger and the call-out procedure works. The DI is advised to look at the alarm monitoring procedure and ensure that either both or one system is tested to alert staff to temperature deviations.
13.	PFE2(f)	The DI is advised to undertake trend analysis of the temperatures to identify trends and the extent of any variations in storage temperatures.
14.	PFE2(h)	The DI is advised to reintroduce a specified fridge bank for use for babies when transferred to the mortuary.
15.	PFE3(c)	The DI is advised to ensure that the issues identified in the most recent ventilation report are addressed in order to ensure the system works to standard.

Background

Eastbourne District General Hospital (EDGH) (hub) and Conquest Hospital (CH) (satellite site) are both 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.

East Sussex Healthcare NHS Trust has been licensed by the HTA since 2010. This was the fourth 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, records servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and staff training records.

Visual inspection

The inspection included a visual inspection of the mortuary body store, temporary store room, PM room and viewing room at EDGH and mortuary body store, PM room and viewing room at Conquest Hospital.

Audit of records

Audits were conducted for eight bodies in refrigerated storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and electronic system. No discrepancies found.

Audits of traceability were conducted for tissue blocks and slides from ten PM cases, including audits of the consent documentation for the retention of these tissues. Three discrepancies found (see shortfall against GQ2(c)).

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, deputy mortuary manager, Anatomical Pathology Technologists (APT), trainee APT, quality lead, portering staff, pathologist, consent seekers for perinatal and adult PM examination.

Report sent to DI for factual accuracy: 11 September 2024

Report returned from DI: 24 September 2024

Final report issued: 26 September 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.