

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 District General Hospital	Licensed	Licensed	Licensed
Mortuary	<i>Carried out</i>	<i>Carried out</i>	<i>Carried out</i>
Pathology lab			<i>Carried out</i>
Satellite site Conquest Hospital	Licensed	Licensed	Licensed
Mortuary (satellite site)	<i>Carried out</i>	<i>Carried out</i>	<i>Carried out</i>
Pathology lab (satellite site)			<i>Carried out</i>

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 NHS Trust ('the establishment') had met the majority of the HTA's standards, six major and five 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 shortfalls

Standard	Inspection findings	Level of shortfall
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	The establishment could not provide assurance that records of training for bereavement midwives and clinicians seeking consent for perinatal post mortem (PM) examinations are in place.	Major
d) Competency is assessed and maintained	The establishment could not provide assurance that competency assessments are in place for clinicians seeking consent for perinatal PM examinations.	Major
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		

<p>a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis</p>	<p>The risk assessment relating to licensed activities in the mortuary has not been reviewed regularly. The risk assessment was last reviewed in August 2020. It is not clear in the risk assessments if all risks relating to licensed activities have been assessed.</p> <p><u>EDGH</u></p> <p>The movement of bodies in and out of the overflow fridge/freezer unit at the funeral director's entrance is overlooked by Trust office workers; this does not ensure dignity of the deceased.</p> <p><u>Conquest Hospital</u></p> <p>The alternative route used by portering staff to transfer bodies to the body store when the mortuary lift is out of service is via a road which is frequently used by members of the public and Trust staff. This does not ensure the dignity of the deceased and there is an increased risk to accidental damage to the body due to the uneven road surface.</p> <p>The road passing the funeral director's entrance to the mortuary is also used as a public thoroughfare for the nearby school pupils and constructions workers currently on site working opposite the mortuary; this does not ensure the dignity of the deceased.</p>	<p>Major</p>
<p>c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register</p>	<p>The number of staff employed at the establishment is not currently sufficient. This poses a risk that could lead to the unplanned closure of the establishment and impact its ability to deliver services.</p>	<p>Major</p>
<p>PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.</p>		

<p>a) The premises are clean and well maintained</p>	<p>Issues were identified with the maintenance of the establishment, making it difficult to adequately clean or decontaminate this area, posing a potential health and safety risk to mortuary staff and visitors. Issues include but are not limited to:</p> <p><u>EDGH</u></p> <ul style="list-style-type: none"> • Area of exposed plaster in a wall in the body store; and • Areas of rust at the base of the shutters at the funeral director entrance. <p><u>Conquest Hospital</u></p> <ul style="list-style-type: none"> • The outside wall of the mortuary at the funeral director entrance is in a state of disrepair. Due to the large section of exposed plaster this poses a risk of failure to the fridge bank directly next to this wall inside the body store from water damage; • There are areas of rust at the base of the fridges; and • Areas of rust on and around the drains on the floor of the body store. 	<p>Major</p>
<p>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)</p>	<p><u>EDGH</u></p> <p>The overflow fridge/freezer unit outside the funeral director's entrance is in an unsecured area which is regularly used by Trust staff.</p> <p><u>Conquest Hospital</u></p> <p>The door to the overflow freezer unit area is accessed by a magnetic release door button and not swipe card access. There is an unsecure door opposite this area leading from the outside of the building which is regularly used by Trust staff and construction workers. This poses a risk of Trust staff and members of the public being able to access bodies stored in the overflow units.</p>	<p>Major</p>

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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	The inspection team identified an incident since the previous inspection which has not been reported to the HTA. <i>Following the inspection, this incident has been reported to the HTA for assessment and will be managed accordingly.</i>	Minor
d) Information about incidents is shared with all staff to avoid repeat errors	There is no mechanism or practice of sharing information about incidents with the maternity team.	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	The method of disposal of blocks and slides is not recorded.	Minor
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
d) Fridge and freezer units are in good working condition and well maintained	<u>Conquest Hospital</u> The seal on one fridge door has deteriorated. This poses a risk of the fridge bank not running at optimal temperature which may result in deterioration of the condition of the bodies stored.	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 trolleys at both sites are suffering from signs of wear and tear and have areas of rust.	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 Trust consent policy refers to the Care Quality Commission (CQC) standard for the need for consent. The DI is advised on the next review of the Trust consent policy to also refer to the HTA standards for obtaining consent in accordance with the requirements of the Human Tissue Act (HT Act) 2004. The DI is also advised to review the hyperlinks in the policy to ensure all are present and working.
2.	C1(g)	The DI is advised to review the adult hospital consent form to remove the references to the old HTA codes of practice and ensure that links to the HTA website are accurate.
3.	GQ1(a)	The DI is advised on the next review of standard operating procedures (SOPs) to ensure that the procedures accurately reflect all steps and details of licensed activities.
4.	GQ3(g)	The DI is advised to ensure that the coroner's pathologist have signed that they have read and understood the latest versions of relevant SOPs.
5.	T1(c)	The DI is advised to communicate with the coroner's office to reintroduce the inclusion of the establishment's unique reference number to the coroner's release form to increase the robustness of the release procedure.

Background

Eastbourne District General Hospital (EDGH) (hub) and Conquest Hospital (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.

EDGH has been licensed by the HTA since 2010. This was the third inspection of the establishment; the most recent previous inspection took place in March 2016.

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 and post-mortem room, records servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents and staff training records.

Visual inspection

The inspection included a visual inspection of the mortuary body store, PM room and viewing room for both the hub and satellite site.

Audit of records

Audits were conducted for four bodies in refrigerated storage at EDGH and Conquest Hospital. Body location and identification details on bodies were crosschecked against the information recorded in the electronic database.

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

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, Anatomical Pathology Technologists (APT), trainee APT, portering staff, pathologist, maternity staff and adult consent seeker.

Report sent to DI for factual accuracy: 16 May 2022

Report returned from DI: 14 June 2022

Final report issued: 15 June 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: 14 April 2023

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.