Inspection report on compliance with HTA licensing standards
Inspection date: **28 March 2022 and 7 April 2022**

East Kent Hospitals University NHS Foundation Trust

HTA licensing number 30011

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 **William Harvey Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab			*Carried out*
Satellite site **Queen Elizabeth Queen Mother Hospital**	Licensed	Licensed	Licensed
Mortuary (satellite site)	*Carried out*	*Carried out*	*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 Kent Hospitals University NHS Foundation Trust ('the establishment') had met the majority of the HTA's standards, five major and seven 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		
a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice	There is no training in place for the consent seeking process for Adult PM examination which addresses the requirements of the HT Act and the HTA's codes of practice. *(as a result, standards C2 (b), (c) and (d) cannot be met).*	**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	The inspection team identified a number of incidents since the previous inspection which have not been reported to the HTA. *Following the inspection, these incidents have been reported to the HTA for assessment and will be managed accordingly.*	**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 standard GQ1) are risk assessed on a regular basis	Risk assessments of procedures related to licensable activities do not identify all the associated risks; examples include, but are not limited to: • loss of tissue; and • lone working while conducting a viewing. *WHH* The route used by mortuary staff to transfer bodies to and from the body store to the standalone freezer in the undercroft is via an external covered area which is frequented by members of the estates team and could be viewed by members of the public through the secure gate to the under-croft area; this does not ensure the dignity of the deceased. This task is usually undertaken by a single member of staff; there is an increased risk to accidental damage to the body due to an uneven surface for the trolley and the difficulty of removing a body in a scoop from the freezer. This is not addressed in the existing risk assessments.	**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	While completing the body audit the inspection team found a number of discrepancies. <u>*QEQMH*</u> • One body only had two identifiers on the ankle band and when the inspection team reviewed the paperwork the unique reference number (URN) and hospital number did not match the written and electronic records; • One body had only two identifiers on the wristband of which the date of birth was incorrect when the inspection team reviewed the paperwork; and • The fridge position for one body audited had not been updated in the electronic spreadsheet. <u>*WHH*</u> • The position of one body in the fridge was found not to match the location recorded on the mortuary whiteboard and mortuary register. The use of less than three separate identifiers when identifying bodies, presents a risk of releasing or viewing the wrong body. The establishment currently uses a Brain and Tissue Bank consent form supplied from another establishment. This consent form only asks for two identifiers to be recorded on the form. This presents a risk of retrieving or releasing the wrong organ or tissue. *See advice item 5.*	**Major**
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	The mortuary staff at either site do not manually challenge the body store alarms on a regular basis. This does not provide assurance that the alarms will trigger when temperatures deviate from the expected range and that the call-out procedure is effective.	**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.	Some Standard Operating Procedures (SOPs) relating to mortuary activities are not reflective of current practice. These include, but are not limited to, SOPs detailing the process for: • admission of unidentified bodies; • movement of bariatric bodies to the mortuary; and • release of bodies and corresponding paperwork received from the funeral directors.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
f) There are procedures for releasing a body that has been in long term storage and is therefore not in the current register	The establishment uses a URN which is added to each body on admission to the mortuary; for example, 001/22. QEQMH is not writing the year of the URN on the body tag. This poses a risk of release of a wrong body that has been in long term storage.	**Minor**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The establishment do not receive confirmation that PM specimens are received at the relevant histopathology or toxicology laboratories. The DI cannot be fully assured of PM specimen traceability.	**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 establishment is not recording the method of disposal of tissue.	**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	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: *WHH* • Areas of exposed wood on doorframe; • Damage to walls exposing plaster; and • Seal on the floor of the PM room and body store has deteriorated. *QEQMH* • Area of exposed wood on the step over barrier to the PM room; • Seal under the bariatric fridge pulling away from the wall; and • Floor seal in the body store pulling away from the wall.	**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	There are areas of rust on the base of the fridges at WHH.	**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 at both sites are suffering from obvious signs of wear and tear for example: • the trolleys have areas of rust and peeling paint from the equipment; and • a bench in the PM room at WHH has large 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 DI is advised on the next review of the Consent Policy to remove references to next of kin and refer to the person highest in the hierarchy of qualifying relationships. The policy should also include the timeframe when refresher training for those trained and competency assessed should be completed.
2.	C1(b)	The DI is advised on the next review of the adult and perinatal Consent SOP to remove references to next of kin and refer to the person highest in the hierarchy of qualifying relationships. Although the consent seeker notes in the consent form gives a minimum timeframe for family to change their minds the SOP does not. The DI is also advised to include the contact details for the Trust interpreter service.
3.	C1(c)	The DI is advised to download the updated Stillbirth and Neonatal Death Society (SANDs) family leaflet/booklet on the post mortem examination procedure.
4.	GQ4(b)	The DI is advised to add into the records management SOP how errors should be corrected in written records.
5.	T1(c)	The establishment are currently not undertaking viewings. The DI is advised to review the viewing procedure prior to viewings taking place again to ensure that three identifiers are received from the coroner's officer or Bereavement team at the time of booking a viewing, and to receive three identifiers from the family prior to them viewing the deceased.
6.	PFE1(c)	The DI is advised to record the cleaning procedure for the PM room at QEQMH.
7.	PFE1(d)	The DI is advised to lock the funeral director entrance doors to the body store when maintenance work is being carried out in the under croft area.
8.	PFE2(g)	The DI is advised to ensure that all bodies are fully shrouded when stored in the fridges.

Background

William Harvey Hospital (WHH) (hub) and Queen Elizabeth Queen Mother Hospital (QEQMH) (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.

WHH has been licensed by the HTA since 2007. This was the third inspection of the establishment; the most recent previous inspection took place in December 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 WHH and QEQMH. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register, whiteboard and electronic database. Discrepancies were found at both sites.

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, portering staff, pathologist, maternity staff and adult consent seeker.

Materials held for the police

Under section 39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. Any information provided by the establishment in relation to police holdings have been shared with the Home Office, but do not appear in the report as they are outside the scope of the HT Act.

Report sent to DI for factual accuracy: 5 May 2022

Report returned from DI: 13 May 2022

Final report issued: 16 May 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.