Inspection report on compliance with HTA licensing standards
Inspection date: **18 September 2025**

King's Mill Hospital
HTA licensing number 12451

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 **King's Mill Hospital**	Not licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*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 King's Mill Hospital ('the establishment') had met the majority of the HTA's standards six major and seventeen 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
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.	Although the establishment have a good range of Standard Operating Procedures (SOPs), some of these provide inconsistent information, are not always clear, and do not reflect current practice. Examples include but are not limited to: SFHKCP-LP-MOR002 Patient Admission refers to the training of porters being carried out by the porter manager, however this is now carried out by the Lead APT. The section relating to high-risk bodies does not state that identification of these cases is checked. The section relating to Paediatric/Foetus/POC admission does not have information relating to paediatric cases. SFHKCP-LP-MOR003 Release of a deceased patient refers to the transfer of bodies for coroner's PM examination where only two identifiers are provided on the coroner's release form, and mortuary staff use the mortuary register to check three identifiers to release the body. This presents a risk of releasing a wrong body It is not clear what documentation the funeral director brings with them to transfer bodies for hospital PM examinations and storage capacity reasons. This is also the case for SFHKCP-LP-MOR004 Release of a foetus or POCs. SFHKCP-LP-MOR007 Direct release of a patients does not contain sufficient or clear details of the procedure for releasing bodies directly from hospital wards (see shortfall against GQ3(a)). SFHKCP-LP-MOR021 Viewing a deceased in the mortuary does not include a requirement to check a minimum of three identifiers on the deceased immediately prior to relatives viewing. This is also reflective of current practice (see shortfall against T1(c)).	**Major**

	The SOP is not clear what staff should do if a minimum of three identifiers of the deceased cannot be provided prior to a viewing. SFHKCP-LP-MOR031 Long term storage of deceased patients and SFHKCP-LP-MOR036 Body condition checks refer to condition checking of bodies, neither reflect current practice (see shortfall against PFE2(a)). Where SOPs refer to checking identification at relevant stages of a procedure, they do not consistently state a minimum of three points of identification should be checked, what these could be and what they are checked against. References and/or links to external documents in some SOPs are out of date. To fully address this shortfall the establishment is required to review all SOPs.	
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	Mortuary staff do not routinely check a minimum of three identifiers on the deceased with details provided by relatives immediately before a viewing takes place. This poses a risk of 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.		

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)	Although there is CCTV coverage of the access doors for the mortuary staff do not routinely visually verify who is requesting access to the internal mortuary corridor before granting access. This poses a risk to staff and a potential risk to the security of the mortuary. There is also a door from the histopathology laboratory into the internal access controlled mortuary corridor. This door is not access controlled and is routinely used by laboratory staff to exit the building via the external door used by funeral directors to collect bodies. The external door is also used by mortuary staff to transfer bodies to the external body storage units. This poses a risk to security and unauthorised persons observing mortuary activities and compromising the dignity of the deceased. The mortuary corridor is also accessed and used by laboratory staff to temporarily store diagnostic tissue blocks and slides before transfer to the main archive. The tissue is stored next to used laundry and clinical waste bins. In addition, this corridor is not covered by CCTV, including the area where the mortuary external door is located up to the mortuary body store doors.	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Visitors and non-mortuary staff are not required to sign in and out of the mortuary, therefore there is currently no system for recording who has been in the mortuary, the nature of their business and when they arrived and left. The current process for mortuary staff who work alone out of hours is not robust. Staff have no way of raising an alarm should there be any issues or safety concerns, especially during out of hours viewings. *See Advice item 8*	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

a) Storage arrangements ensure the dignity of the deceased	The establishment's current frequency for checking the condition of bodies in refrigerated storage is insufficient. During the body traceability audit the inspection team identified a foetus less than 24 weeks gestation that had been in refrigerated storage for more than 30 days. *See Advice item 11*	**Major**
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 main fridge and freezer body store units in the mortuary are old and are showing age-related damage and wear internally and externally that requires attention. For example, the tray racking is rusty, and the fridge trays are significantly damaged in places. The establishment have already identified this and are looking at options to address this.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
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	The Hospital Post Mortem Policy CPG-TW-HPMP, section 6.1 refers to 'properly interested persons' in relation to opposing consent of someone who consented to a post mortem (PM) examination after their death. This wording is not in-line with the HT Act 2004 of the HTA's Codes of Practice.	**Minor**
b) There is a documented standard operating procedure (SOP) detailing the consent process	The SOP and training document for seeking consent for adult PM examination is out of date.	**Minor**
c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice	The adult consent PM information leaflet has not been reviewed since 2018.	**Minor**
g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided	The adult PM consent form has not been reviewed since 2018.	**Minor**
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	Although staff involved in seeking consent for adult PM examination have undertaken training, this has not been completed in-line with the establishment's own training schedule (annually).	**Minor**
d) Competency is assessed and maintained	Staff involved in seeking consent for adult and perinatal cases are not formally competency assessed.	**Minor**
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	SOPs relating to research activity are authored and authorised by the same people.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Although there is an annual audit schedule in place, some audits for 2025 have not been started when scheduled. The number of cases included in audits do not reflect representative numbers to provide sufficient assurance of an activity. For example, the 'Patient release' audit only includes one case and is only carried out once a year.	**Minor**
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 staff	Staff involved in the direct release of bodies from hospital wards are not trained in release procedures.	**Minor**

c) Staff are assessed as competent for the tasks they perform	Competency of staff involved in the retrieval of tissue for research is not formally recorded. Staff involved in the direct release of bodies from hospital wards are not competency assessed in release procedures.	**Minor**
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	The establishment do not have the following risk assessments relevant to the activities they undertake: • Removal of tissue from a body without authorisation or consent. • Loss of an organ or tissue. There is more than one risk assessment relating to the following activities: • SFHKCP-RA-HTA003 and SFHKCP-RA-MOR028 Mortuary security. • SFHKCP-RA-HTA006 and SFHKCP-RA-MOR023 Temporary unplanned closure of the mortuary. Risk assessment SFHKCP-RA-MOR007 in relation to the use of the rear body store in the PM room does not include risks to the deceased and states porters do not use this body store, however, in practice they do.	**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 disposal of excess tissue taken for research which is no longer needed 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 is minor damage to doors and door frames in the mortuary exposing underlying wood. This makes these areas porous and cannot be adequately cleaned and disinfected.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The establishment do not have freezer storage for bariatric bodies or a confirmed documented agreement with another establishment should freezer storage be required.	**Minor**
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 upper alarm trigger point for the refrigerated body stores are not set at an appropriate temperature to alert staff to any failure in a timely manner, potentially compromising the condition of the deceased. The current fridge alarm testing schedule for the main body store fridges does not include testing the lower alarm trigger point. The external body store units are alarm tested by an external company. The mortuary staff are not aware of how the alarm tests are performed, the outcome of these tests and do not hold documented records of these tests. The fridge and freezer used to store tissue for research prior to transfer is not linked to a remote alarm system to alert staff to any alarm triggers out of hours.	**Minor**

f) Temperatures of fridges and freezers are monitored on a regular basis	The external body store units are temperature monitored by an external company. The mortuary staff are not aware if the operating temperatures for the units are reviewed for trends. The fridge and freezer used to store tissue for research prior to transfer is not monitored. The fridge is also showing a fault meaning the temperature cannot be read.	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	The establishment have not provided the servicing/maintenance records for the older external body storage unit installed in 2020; only the commissioning records.	**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 to remove the links to the PM consent training in the Hospital PM Policy to ensure only those staff with appropriate training and competency seek consent for PM examination.

2.	C1(c)	The DI is advised to include in the information for relatives for adult consented PM cases the deceased is transferred to another establishment for the PM examination.
3.	C1(g)	The DI is advised to contact the establishment where consented paediatric/perinatal PM cases are undertaken to ensure the most up to date version of the PM consent form is being used.
4.	C2(d)	The DI is advised to consider options for assessing competency in seeking consent for paediatric/perinatal and adult PM cases, ensuring competency is appropriately recorded.
5.	GQ1(a)	The DI is advised to: • consider combining SOPs with same/similar information to avoid duplicating or providing conflicting information. • check hyperlinks to external documents to ensure they work. • check references to external documents are up to date.
6.	GQ2(a)	The DI is advised to ensure: • review of mortuary swipe card logs include identification of any potential unusual/unexpected patterns, times of entry and failed access attempts and follow these up. • Monthly security audits include visitor logs when these are implemented.
7.	GQ3(a)	The DI is advised to continue with following up porters who have not completed refresher training for mortuary activities.
8.	GQ6(a)	The establishments recent risk assessment relating to lone working in the mortuary has identified that existing control measures to safeguard staff working alone are not adequate. The DI is advised to address this as soon as possible and re-risk assess lone working when adequate control measures are in place.
9.	PFE1(d)	The DI is advised to:

		• consider additional security measures for the external body storage units as they are currently secured by key only. • ensure the external CCTV camera in the mortuary yard is repositioned to cover the second external body storage unit before the unit is used. • periodically change the mortuary alarm code for the mortuary staff and porters.
10.	PFE2(a)	The DI is advised to implement more robust, frequent and documented condition checks of all bodies stored in the mortuary. For example, recording condition on admission then every seven days up to a maximum of 30 days when a body should be moved into frozen storage if there is no indication they are soon to be released or further examined, or before, depending on the condition of the body. Condition of bodies should also be recorded on release.
11.	PFE2(e)	The DI is advised to include the paediatric and foetal fridges in the existing alarm testing schedule.

Background

King's Mill Hospital (KMH) has been licensed by the HTA since May 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in April 2023.

The establishment continues to be a collecting site for a research tissue repository. With appropriate consent, knee joint tissues are removed from the living and the deceased and spinal tissues from the deceased. Tissues are transferred to another site for NHS research ethics committee (REC) approved research into human disease.

Since the previous inspection, there has been a change of DI and CLHc.

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
65 out of 72 standards were assessed. Standards GQ1b, GQ2c, T1g, T2a-c and PFE3e were not assessed as the standards were not applicable.

Review of governance documentation
The inspection included a review of the establishment's governance documentation relating to licensed activities. This included SOPs, risk assessments, audits, incidents, meeting minutes, training records, competency assessment documents, servicing and maintenance records for mortuary equipment . Consent seeking procedures and information for families giving consent for adult and perinatal PM examinations and tissue for research were also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the premises which included the mortuary access points, body storage areas, including the two external body storage units in the mortuary yard, the viewing room, the PM room including the room where tissues retrieved for research are processed and stored prior to transfer.

Audit of records
The inspection team undertook audits of traceability for five bodies in storage, including a perinatal case and bodies with same/similar names. A body in long term storage was not included as none were being stored at the time of the inspection. Traceability details were crosschecked between the identification bands on the bodies, information in mortuary paperwork and the mortuary register. One minor discrepancy was found in a written record of one case; however, this is not sufficient to amount to a shortfall but oral advice was given to the establishment at the time of the inspection.

The inspection team undertook traceability audits of research material for two cases; one deceased and one living donor. Traceability details were crosschecked between the anonymised identifier on the material, the electronic system and paper records through to consent documentation. No discrepancies were identified.

Meetings with establishment staff

The assessment team met with staff carrying out activities under the licence, including mortuary staff, a portering staff member, staff involved in the consent seeking processes for PM examinations and removal of tissue for research, staff responsible for the removal of tissue in the mortuary for research and removal of tissue in the Emergency Department and the DI.

Report sent to DI for factual accuracy: 4 November 2025

Report returned from DI: 17 November 2025

Final report issued: 5 December 2025

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.