Inspection report on compliance with HTA licensing standards
Inspection date: **26 April 2023**

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*

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, four minor shortfalls were found against standards for Governance and quality systems 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

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 for example: • Admission of bodies to the mortuary. Not all SOPs include all practices that are undertaken by staff. These include, but are not limited to, SOPs detailing the process for: • Body condition checks of deceased. • Lone working arrangements for out of hours work.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Although the establishment have a schedule of audits, the schedule does not include audits of all mortuary activities for example, security audit. Mortuary staff are informally undertaking horizontal audits, however, these have not been included in the audit schedule for example, admittance of bodies.	**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	The fridge and freezer doors are damaged and the seals are deteriorating.	**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 have multiple areas of rust. This means that it is difficult for staff to adequately clean and disinfect this equipment.	**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(g)	Currently only verbal consent is sought for the removal of relevant material for cytogenetics testing. The DI is advised to document the seeking of consent for cytogenetic testing on the existing in use consent form.
2.	C1(g)	The DI is advised to include the repatriation of tissue on the consent form.
3.	GQ2(b)	The DI is advised to review the vertical audit template form to remove sections relating to admittance of community deceased as this is no longer provided by the establishment.
4.	GQ2(b)	The DI is advised to amend the audit template standards column from UKAS to HTA standards and to include the premises, facilities and equipment (PFE) standards to the template.
5.	GQ3(c)	The DI is advised to ensure that mortuary staff have signed the competency (re)assessment documents in the training records.
6.	GQ5(a)	The DI is advised to have signage on the maternity wards of applicable HTARI categories and personnel to contact as an aide memoire for staff.
7.	GQ6(a)	The establishment have risk assessments in place related to licensed activities and these include how to mitigate the identified risks, however; the inspection team found that the risk assessments are out of review date. The DI is advised to ensure that the risk assessments are reviewed within the stated review period.
8.	PFE2(e)	The DI is advised to add the temporary body storage unit to the existing alarm testing procedure.
9.	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
King's Mill Hospital (KMH) is licensed for the removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

KMH has been licensed by the HTA since 2010. This was the fourth inspection of the establishment; the most recent previous inspection took place in November 2017.

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

Since the previous inspection, there has been no significant changes to 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

64 out of 72 standards were assessed. Standards GQ1b, GQ2c, T1g, T2a-d 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 policies and procedural documents relating to licensed activities, cleaning records for the mortuary and post-mortem room, records servicing of equipment, 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.

Audit of records

Audits were conducted for three bodies in refrigerated storage and one in long term storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register. No discrepancies found.

Removal of samples for research

The inspection team undertook audits of traceability for two samples in storage.
Traceability details were crosschecked between the identification details on the samples and completed consent forms. No discrepancies were

identified.

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, mortuary assistant, portering staff, tissue repository manager, maternity staff, and adult consent seeker.

Report sent to DI for factual accuracy: 16 May 2023

Report returned from DI: 31 May 2023

Final report issued: 6 June 2023

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: 20 September 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.