Inspection report on compliance with HTA licensing standards
Inspection date: **26 & 27 June 2024**

James Cook University Hospital

HTA licensing number 12089

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 **James Cook University Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	*Carried out*	*Carried out*
A&E	-	*Carried out*	-
Satellite site **Friarage Hospital**	Not licensed	Licensed	Licensed
Mortuary (satellite site)	-	*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 James Cook University Hospital ('the establishment') had met the majority of the HTA's standards, five major and six 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

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	Some Standard Operating Procedures (SOPs) require review to ensure they contain up to date external document references, sufficient detail and reflect practice. For example: CP-H08-SOP0368 Sensitive disposal of PM tissue, blocks and slides includes the options relatives may consent to for the storage and use of tissue. However, the SOP also states 'organs or wet tissue are stored at the discretion of the pathologist' implying the relatives' wishes for tissue may not be followed and could be stored and/or used for purposes for which consent is not in place. CP-MBS-SOP0001 Receipt of deceased patients: • states the address of patients who die in the hospital is on identification bands. In practice, this is not the case; • refers to the use of a red pen to highlight new admissions to the mortuary which is not reflective of current practice; • does not state what three identifiers are checked against paperwork when bodies are transferred for PM examination from another establishment; and • omits the use of fridge door magnets to highlight when a body has an implantable device. CP-MBS-SOP0018 Transfer of deceased patients between sites is not clear how many staff are involved in the transfer of bodies from the satellite site. CP-MBS-SOP0012 Release of patients refers to placing tissue blocks and slides in bodies when relatives request repatriation of tissues. Tissue blocks and slides should be placed with the body ready for collection by funeral directors. CP_MPM_SOP0033 Handling and storing of tissue retained at PM and transfer to the lab for testing does not state that specimen containers are labelled with three identifiers of the deceased. In practice, three identifiers are used. In addition, the timescale and who is responsible for following up unreturned receipts for tissues and organs sent off site is not included.	**Major**
GQ2 There is a documented system of audit		

a) There is a documented schedule of audits	The establishment informed the inspection team that audits have not always been completed as scheduled and have not included relevant activities at the satellite site. In addition, the number of cases included in audits that have been completed do not reflect representative numbers to provide sufficient assurance of an activity. For example, quarterly tissue traceability audits only include one case.	**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	There are multiple areas within the mortuary that require attention to help ensure they can be cleaned and disinfected effectively. For example: • the surfaces of the body store and PM room floors are eroded in areas exposing the underlying concrete. Previous remedial repairs have not lasted and there is exposed concrete at the base of one PM table; • some of the plastic protective casings on the corners of walls and door frames are damaged; • there are areas of rust associated with the screws securing the metal plates at the base of the fridges; • the fridge door label holders are rusty; and • the isolation PM room does not have a drain or barrier in front of the fire exit door to prevent the egress of water and other contaminants onto the porous concrete floor beyond.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	The establishment use their refrigerated contingency storage routinely to manage mortuary capacity at the hub site. Therefore, temporary storage units are being used on a permanent basis.	**Major (Cumulative)**

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The establishment rely on an external freezer storage unit to store long-term bodies as there is insufficient permanent freezer capacity at the hub and satellite sites.	
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 size of the standard and bariatric refrigerated body storage spaces at the hub site no longer meet the minimum requirements set out in the NHS England Health Building Note 16-01: Facilities for mortuaries, including body stores and post-mortem services. The size of the spaces is not sufficient to accommodate the size of bodies stored at the establishment. There is a risk of unnecessary accidental damage to bodies when moving bodies and out of storage. The PM tables do not have a functioning water supply as the parts to repair them are no longer available. Staff have to rely on a hose at one end of the PM room for cleaning the room and washing bodies which is impractical and poses a health and safety risk to staff. The body store doors at both the hub and satellite site are damaged and require attention. Body trolleys at both sites have damaged surfaces and require attention.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
e) There is a system for recording that staff have read and understood the latest versions of these documents	Whilst there is a system for recording that staff and pathologists have read and acknowledged SOPs relevant to their role, a review by the inspection team identified some staff and pathologists have not acknowledged all SOPs.	**Minor**

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Although staff discussed HTA-licensed activities, there are no formalised regular mortuary staff meetings.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The tissue audit conducted during the inspection identified one case which had two additional tissue slides in storage not recorded on the laboratory system at the processing establishment.	**Minor**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The mortuary security audits do not include review of mortuary visitor logs.	**Minor**
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	Although the upper temperature trigger point for the fridges are tested regularly to ensure call out procedures are working, tests do not include the lower temperature trigger point.	**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 fridge in the maternity unit at the hub site is not regularly serviced.	**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)	Before the updated PM consent and retention and disposal of tissues and organs thereafter policy is finalised, the DI is advised to: • remove section 5.8 as this refers to tissue for donation, not PM examination and the reference to the HT Act states 2006 not 2004; • include the option for return to body before funeral (section 5.9); and • remove references to 'next of kin' (section 5.17).
2.	C1(b)	Although the PM consent and retention and disposal of tissues and organs thereafter policy refers to the requirements to seek consent for PM examination on a fetus, infant and children, the DI is advised to liaise with the Persons Designated in the maternity ward to develop a ward level SOP with further detail of the process.
3.	GQ1(a)	As part of the ongoing review of SOPs, the DI is advised to ensure that references to external documents are up to date.
4.	GQ2(c)	The DI is advised to conduct regular tissue audits of the PM tissue blocks and slides now being stored at the satellite site and include these in the audit schedule.
5.	T1(h)	The DI is advised to ensure that when PM tissue slides are received at the hub site and subsequently returned to the processing establishment, the spreadsheet records are completed in a timely manner.
6.	PFE1(d)	The DI is advised to:

		• ensure that the additional CCTV and updated swipe card system is installed at the hub site as planned in July 2024; • regularly change the mortuary alarm codes and newly installed key safe codes to help maintain mortuary security; and • lock the old PM room door at the satellite site to maintain the security of the PM tissue blocks and slides now stored there.
7.	PFE	The DI is advised to continue with the plans to refurbish the mortuary at the hub site as this will help to address the premises, facilities and equipment shortfalls identified during the inspection. The DI is advised to ensure that the entrance used to admit bodies to the mortuary at the satellite site is free of equipment and other items currently stored there.

Background

James Cook University Hospital has been licensed by the HTA since June 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in December 2021.

Since the previous inspection, the DI has changed and the list of Persons Designated under the licence has been updated to reflect changes in staff working under the licence. The histology laboratory on the hub site is currently being transferred to another licensed establishment.

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 team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities for the mortuaries were reviewed. This included standard operating procedures, risk

assessments, audits, incidents, meeting minutes, training and competency assessment documents. Consent seeking procedures and information for families giving consent for adult and perinatal PM examinations were also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the hub and satellite premises which included the mortuary body storage areas (including the external fridge and freezer units at the hub site), viewing rooms and PM rooms (the old PM room at the satellite site is used to store archive PM tissue blocks and slides). The process for receiving and returning PM tissue slides from another licensed establishment to the hub site for pathologists to analyse was also reviewed.

Audit of records

The inspection team undertook audits of traceability for four bodies in storage. This included a perinatal case and a body from long-term storage. Traceability details were crosschecked between the identification bands on the bodies, information in the mortuary register, paperwork and mortuary electronic record. No discrepancies were identified.

Audits were conducted of stored tissue taken at PM examination for three cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms and tissue being stored. One discrepancy was identified (see shortfall against T1(g)).

Meetings with establishment staff

The assessment team met with staff carrying out processes under the licence, including mortuary staff, quality manager, portering staff, a pathologist, staff involved in the consent seeking process for adult and perinatal PM examination, staff responsible for the removal of relevant material in the Emergency Department and the DI.

Report sent to DI for factual accuracy: 18 July 2024

Report returned from DI: 31 July 2024

Final report issued: 06 August 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.