Inspection report on compliance with HTA licensing standards
Inspection date: **2 December and 8-9 December 2021**

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*
Delivery suite	-	*Carried out*	*Carried out*
Neonatal suite	-	*Carried out*	*Carried out*
A&E	-	*Carried out*	
Satellite site	Not licensed	Licensed	Licensed

Friarage Hospital			
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, one major shortfall was found against standards for Governance and Quality Systems and one minor shortfall was found against Traceability.

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 shortfall

Standards	**Inspection findings**	**Level of shortfall**
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 or supervised	*Viewings conducted out of hours* There is no formal training in place for nurses and porters who conduct out of hours viewings at James Cook University Hospital. *As a result standard GQ3(c) cannot be met. Refer to advice item 3.*	**Major**

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).	During the traceability audit the inspection team identified one case where tissue blocks and slides had a spelling error for the surname of the deceased; however, other identifiers on the blocks and slides were correct. In addition, the consent form for this case indicated the tissue could be retained for a scheduled purpose or disposed of if not used. It was identified by the inspection team that the tissue was still in storage although electronic records indicated the tissue had been disposed of.	**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(d)	The DI is advised to liaise with the referral centre providing the consent forms for perinatal PM examination as the forms do not adequately reflect the requirements of the HT Act. The form only gives the options for tissue taken at PM to be retained or returned at a later date and relies on consent seekers to provide other options such as disposal of the material. The consent form also refers to outdated HTA Codes of Practice.
2.	GQ1 (a)	The DI is advised to review the SUDIC protocol to ensure that it accurately reflects the procedure which details at what stage the coroner should be contacted and if there is blanket approval for removal of samples from the coroner.
3.	GQ2 (c)	The DI is advised to include the following additional audits of licensable activities:

		• tissue taken from PM examination to ensure tissue is disposed of in accordance with the wishes of the family • the procedure for nursing staff and porters conducting viewings out of hours to ensure that the minimum three identifiers of the deceased are checked with the family prior to entry to the viewing room and the identification is cross matched to the identification details on the body tags
4.	PFE2 (e)	The DI is advised to consider connecting the delivery suite and the neonatal fridges to the pathology temperature monitoring system. This will provide a more robust challenge of procedures currently in place (e.g. testing of the alarms) to ensure procedures work as expected in the event of a fridge failure.

Background

The establishment has been licensed by the HTA since June 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in November 2017.

Since the previous inspection, there has been significant changes to the licence. Since July 2018, James Cook University Hospital and University Hospital of North Tees (UNHT) mortuary services have been working collaboratively. This change was led by HM Coroner and is part of a wider pathology collaboration. Adult PM examinations are performed at James Cook University Hospital, with UNHT PM suite designated for contingency purposes. A joint mortuary manager is in post and employed across both sites.

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 assessment 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 mortuary were reviewed. Traceability audits, risk assessments, meeting minutes, incidents, consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection
The inspection included a visual inspection of the mortuary body store and viewing room at the hub and satellite site as well as the PM room at the hub site.

Audit of records
Audits were conducted for four bodies in refrigerated storage and one body in freezer storage at the hub site and three bodies in refrigerated storage and one body in freezer storage at the satellite site. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and relevant documentation.

Audits of traceability were conducted for tissue blocks and slides from four PM cases, including audits of the consent documentation for the retention and repatriation of these tissues. A discrepancy was found in one case where there was a spelling and recording error.

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, Anatomical Pathology Technologists, portering staff, and consent seekers for PM examinations.

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: 10 January 2022

Report returned from DI: 11 January 2022

Final report issued: 21 January 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: 24 March 2022

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.