Inspection report on compliance with HTA licensing standards
Inspection date: **26 January and 1-2 February 2022**

**Royal Cornwall Hospital**
HTA licensing number 12208

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**<br>**Royal Cornwall Hospital** | Licensed | Licensed | Licensed |
| **Mortuary** | *Carried out* | *Carried out* | *Carried out* |
| **Maternity** | - | - | *Carried out* |
| **A&E** | - | *Carried out* | - |
| **Neonatal Unit** | - | *Carried out* | - |
| **Paediatric Ward** | - | *Carried out* | - |

| | | | |
|---|---|---|---|
| **Theatre (Tower Block)** | - | *Carried out* | - |
| **Critical Care Unit (Trelawny)** | - | *Carried out* | - |
| **Satellite site**<br>**West Cornwall Hospital** | Licensed | Licensed | Licensed |
| **Mortuary** | - | - | *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 Royal Cornwall Hospital ('the establishment') had met the majority of the HTA's standards, one major and two minor shortfalls were found against standards for 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 shortfall***

| **Standards** | **Inspection findings** | **Level of shortfall** |
|---|---|---|
| PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored | | |

| | | |
|---|---|---|
| a) Items of equipment in the mortuary are in a good condition and appropriate for use. | The fridges in the mortuary at the hub site are showing significant signs of wear and tear and are not fit for purpose. The DI has identified this on the Trust's organisational risk register and regular maintenance on the fridges is carried out.<br>Examples include:<br>• Large amounts of corrosion on the inside of the fridges and damaged frames exposing the timber. This makes it difficult to disinfect and clean the fridges properly.<br>• Several hinges are loose, and rollers are out of alignment. This increases the risk of accidental damage to bodies.<br>• Sharp edges on the ends of the body trays. This increases the risk of injury to staff. | **Major** |

***Minor shortfalls***

| **Standards** | **Inspection findings** | **Level of shortfall** |
|---|---|---|
| **PFE2 There are appropriate facilities for the storage of bodies and human tissue** | | |
| c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually | The ventilation system provides the necessary ten air changes per hour and is checked at least annually, however the latest maintenance report showed that the air quality is poor. There are outstanding repairs for the system and the estates department have not actioned these repairs. | **Minor** |

| | | |
|---|---|---|
| f) Temperatures of fridges and freezers are monitored on a regular basis. | Temperatures for the maternity fridges at the hub site are monitored by the estates department. Staff are unclear if there is a process for alerting staff when the fridge alarm triggers if the temperatures deviate from the expected range. | **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. | C2 (b) | Staff training for seeking consent for adult post mortem (PM) examinations is up to date. Although consented PM examinations occur infrequently, staff are encouraged to complete refresher training when courses become available. |
| 2. | GQ1 (a) | Staff understand the requirements for seeking consent under the HT Act and HT codes of practice and there is an overarching consent policy that governs the PM consent procedures. However, some of the documentation uses the term ‘next of kin’ or ‘appropriate person’ when referring to seeking consent for PM examinations.<br>The DI is advised to avoid using the term ‘next of kin’ or ‘appropriate person’ in documentation relating to seeking consent for PM examinations and replace with “qualifying relationship”.<br>Documentation for consent should also be reviewed to include the most recent codes of practice. |
| 3. | GQ1 (a) | To increase the robustness of lone working for out of hours viewings, staff are advised to alert security when they are on site for an out of hours viewing. |

| | | |
|---|---|---|
| 4. | PFE2 (f) | The DI is advised to formalise the process for recording temperature trends for the fridges in maternity and the mortuary at the hub and satellite sites. This may help identify any variations in temperatures that may assist in preventing equipment failures before they occur. |

## Background

The establishment has been licensed by the HTA since 2007. This was the third inspection of the establishment; the most recent previous inspection took place in January 2016.

The establishment is 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.

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 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, PM room and viewing room at the hub and satellite site.

*Audit of records*

Audits were conducted for two bodies in refrigerated storage and one body in freezer storage at the hub site and one body in refrigerated storage at the satellite site. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary electronic system and relevant documentation. No discrepancies were found.

Audits of traceability were conducted for tissue blocks and slides from three PM cases, including audits of the consent documentation for the retention and disposal of these tissues. An audit was also conducted of records where a body was transferred from the satellite site to the hub site for a PM examination. No discrepancies were found.

*Meetings with establishment staff*

Staff carrying out processes under the licence were interviewed and roundtable discussions were conducted with staff including the DI, Anatomical Pathology Technologist, Quality Manager, portering staff, Pathologist and consent seekers for PM examinations.

**Report sent to DI for factual accuracy: 28 February 2022**

**Report returned from DI: 11 March 2022**

**Final report issued: 21 March 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: 26 September 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.