Inspection report on compliance with HTA licensing standards
Inspection date: **16, 21, 22 February 2023**

Royal Glamorgan Hospital
HTA licensing number 12338

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 **Royal Glamorgan Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Satellite site **Prince Charles Hospital**	Licensed	Licensed	Licensed
Mortuary (satellite site)	*Carried out*	*Carried out*	*Carried out*

Satellite site **Princess of Wales 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 Royal Glamorgan Hospital ('the establishment') had met the majority of the HTA's standards, two minor shortfalls were found against standards for Consent and Governance and quality systems. These related to the consent policy, recording of competency assessment for consent seekers and mortuary standard operating procedures.

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
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		

d) Competency is assessed and maintained	Whilst regular training and refresher training is provided to those seeking consent for adult post mortem (PM) examination and consent seekers are assessed as competent through a verbal assessment, there is no system in place to formally record this assessment process. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
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.	Whilst condition checking of the deceased is completed regularly and actions are taken to expedite the release of bodies from the mortuary, these practices are not recorded in an SOP as a formalised process. Furthermore, whilst there is a notice in use for funeral directors informing of the three identifiers that could be written on to the identification bands for unidentified bodies, this detail is not reflected in the admission of the deceased SOP. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**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)	Whilst the overarching Health Board consent policy refers readers directly to the HTA Codes of Practice to fully understand the requirements of the HT Act and HTA Codes of Practice, the link to HTA information in the policy is broken. The DI is advised to ensure the policy is fully reflective of requirements of the HT Act and the HTA Codes of Practice to ensure information continues to be available in the event links to supporting information do not function.
2.	C1(b)	Whilst there is a process in place to manage a change of consent or a withdrawal of consent for adult PM examination, the DI is advised to review the SOP for adult consent seekers for assurance it is fully reflective of the procedure that consent seekers should follow.
3.	C1(c) C1(g)	The DI is advised to liaise with the group responsible for the production of the 'All Wales' consent package and seek to have the information leaflet for relatives and the consent form in use updated with a recently reviewed date. The documents currently state '2010' which suggests this was the last review date.
4.	GQ5(a)	Whilst the HTARI SOP details the types of incidents that require reporting to the HTA, the DI is advised to update the associated guidance in the SOP to align with the relevant guidance from the HTA: Post Mortem HTA Reportable Incidents (HTARIs)
5.	GQ6(b)	Whilst all licensable activities are risk assessed, the DI is advised to consider separating health and safety risks from risks that may result in a HTARI. This may assist staff to be fully aware of all the control measures in place to mitigate the different HTARI risks as relevant detail would be in one associated document rather than across several.
6.	T1(b)	At the time of the inspection, it was noted there were a couple of occasions where staff had not signed the mortuary register following a release of a body. The inspection team were assured this was an

		oversight rather than a trend in practice following review of all registers in use. Regular audits of mortuary records are also in place which would have identified and rectified such discrepancies; however, the DI may wish to consider placing a visual reminder for staff in the area of the register to ensure they fully complete the record at the time of a release of a body.
7.	T1(g)	The DI is advised to consider training additional staff in the management of the tissue traceability system in the laboratory. Currently the establishment only have one trained member of staff completing this function.
8.	T1(h)	The establishment have recently started working with an external agency through a Service Level Agreement for the completion of PM examinations. This is to assist with reducing the number of deceased awaiting PM examination during a period of high demand on the service. Whilst the establishment have implemented a tissue traceability system for tissue transferred off site to the agencies laboratory for processing, the DI is advised to audit receipt of the tissue to ensure it has arrived as expected.
9.	PFE1(a)	The DI is advised to declutter and reorganise the consumables store in the PM room at the hub site to ensure the room can be effectively decontaminated.
10.	PFE1(d)	Whilst the external fridge condenser units at the Princess of Wales Hospital are secured in a locked and high gated area, the DI is advised to consider fully enclosing this area to reduce the risk of tampering with the units to a minimum. The door between the viewing room and body store at Prince Charles Hospital is reliant on the use of a manual lock. The DI is advised to consider alternative arrangements to reduce any risk of access to the body store should the manual lock not be deployed. Whilst an external fire door to the side of the building at the Princess of Wales Hospital was locked and is alarmed out of hours, the DI is advised to consider adding additional security measures to this door as it is situated near the bereavement offices. This would alert staff the door is open in the event hospital staff visitors to this area inadvertently use the fire door as an exit during working hours.
11.	PFE1(e)	The DI is advised to review the completion of visitor logs as part of the security audits in place.

12.	PFE2(b)	Whilst the establishment have sufficient capacity for the level of activity undertaken across all three sites, the hub site currently is the main site for the activity of post mortem examination. The hub site has less body storage capacity than the satellite sites which means that bodies are frequently transferred out to the satellite sites for storage. This is to ensure there is sufficient capacity for bodies requiring PM examination at the hub site. The DI is advised to review the current arrangements and consider whether there is an alternative arrangement that may reduce the necessity for frequent transfers from the hub site, which would then see capacity managed more effectively at this site.
13.	PFE2(c)	Whilst it appeared there was sufficient freezer storage at the time of the inspection, the DI is advised to continue monitoring freezer capacity closely based on the increasing level of demand discussed with the inspection team. In the event that capacity is deemed as insufficient, actions should be taken to address any risks of potential deterioration to the deceased from lack of freezer storage. This should also form part of the Health Board risk register to ensure oversight of actions to address any significant risks identified.
14.	PFE2(h)	The hub site very rarely receives perinatal bodies; however, this site has four adult size refrigerated storage spaces allocated for this purpose. The DI may wish to consider an alternative storage arrangement, such as acquiring an additional pregnancy remains unit, this would then free up the refrigerated spaces to assist with the management of capacity at this site.
15.	N/A	The DI is advised to consider methods to reduce the external sound level in the viewing room at the hub site. Whilst the inspection team were undertaking the visual inspection of this area, activity from other areas of the mortuary could be heard clearly which has potential to cause distress to visitors.

Background

Royal Glamorgan Hospital has been licensed by the HTA since November 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in March 2018. However, following this inspection, two CAPA follow up site visit inspections were completed in August 2018 and March 2019 for assurance the findings of this inspection were fully addressed due to the severity.

Since the previous inspection, the following changes have been made to the licensing arrangements: changes to the list of Persons Designated in 2018, 2019, 2020, 2021, and 2022. There have been changes to the CLHc in July 2019, October 2020 and the current CLHc has been in place since June 2021. The current DI has been in place since October 2020.

The name of the organization changed in May 2019 to Cwm Taf Morgannwg University Health Board. In March 2020, the Princess of Wales Hospital was added to the licence as a satellite site. There was a temporary extension to premises at the Prince Charles Hospital satellite site with the procurement of additional body storage units to manage capacity in November 2020. A further permanent extension to premises at this site occurred in January 2023 with the procurement of a designated body storage unit for 85 deceased.

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 were reviewed. This included cleaning records for the mortuary and PM room, records of servicing of equipment, fridge and freezer alarm testing records, ventilation reports, body and tissue traceability audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training and competency records, including induction records of visiting staff. Consent seeking policies and procedures, information for relatives giving consent and current consent forms in use for both adult and perinatal PM examination were also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the premises at the hub site and both satellite sites which included the mortuary body storage areas, PM rooms (Princess of Wales satellite site is not licensed for PM activity but has retained the PM suite), viewing rooms, the laboratory where tissue retained at PM is stored and the maternity department at Princess of Wales Hospital satellite site.

Audit of records
The inspection team undertook audits of traceability for four bodies in storage at the hub site, four bodies in storage at Princess of Wales hospital satellite site and five bodies in storage at the Prince Charles Hospital satellite site. This included bodies with same / similar names, a body stored longer term and a perinatal body. Traceability details were crosschecked between the identification bands on the body, information on the door of the storage unit, the mortuary register, associated paperwork, and the electronic mortuary database. The inspection team audited more bodies at the Prince Charles hospital satellite site as a discrepancy was noted with the storage location of two bodies with the recording of the fridge location on the doors of the storage unit. This was rectified at the time of the inspection.

The inspection team observed release of bodies from all three sites, and it was noted that funeral directors arrive with an establishment release form which contains three identifiers of the deceased. This form is physically crosschecked against the information on the identification bands of the deceased. The mortuary staff and funeral director staff both confirm the identity and sign the release form as evidence the identification procedure has been completed as expected.

Audits were conducted of tissue taken at PM examination for seven cases. Information was crosschecked between the mortuary traceability documentation, Coroner's paperwork, family wishes forms, and the tissue blocks and slides being stored. Four cases were identified as being stored for a scheduled purpose with appropriate consent, one case had been returned at a later date, one case was awaiting repatriation at a later date and one case had been disposed of in line with the wishes of the family. No discrepancies were identified.

Meetings with establishment staff
The inspection team met with staff conducting processes under the licence, including the mortuary manager, mortuary staff, laboratory staff, facilities managers and portering staff, staff involved in the consent seeking process for both adult and perinatal PM examination, a pathologist undertaking PM examinations and the DI.

Report sent to DI for factual accuracy: 09 March 2023

Report returned from DI: 23 March 2023

Final report issued: 03 April 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: 3 April 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.