Inspection report on compliance with HTA licensing standards
Inspection date: **07, 09 & 10 November 2022**

Grange University Hospital
HTA licensing number 12036

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 **Grange University Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Satellite site **Royal Gwent Hospital**	Not licensed	Licensed	Licensed
Mortuary (satellite site)	-	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*

Satellite site **Nevill Hall Hospital**	Not licensed	Licensed	Licensed/Not 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 Grange University Hospital (the establishment) had met the majority of the HTA's standards, eight major and five minor shortfalls were found against standards for Consent, Governance and Quality Systems and Premises, Facilities and Equipment. These related to the consent seeking policy, standard operating procedures (SOPs), audits and risk assessments, consent seeking training and competency assessment, the governance framework across the hub and satellite sites, mortuary security arrangements, freezer storage, and bariatric transfer arrangements to the mortuary.

One of the shortfalls, PFE1(e), relates to findings from the last inspection. The HTA is concerned that adequate steps were not taken to address these findings in the intervening period and to embed suitable practices at the establishment.

Concerns were discussed with the establishment as part of this inspection and the current DI has provided assurance that the establishment is committed to meeting the regulatory requirements. Based on this assurance, 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
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice	The overarching consent policy is not fully reflective of the requirements of the HT Act or the HTA Codes of practice: • Whilst the policy details that consent for post mortem (PM) examination should be obtained from an appropriate person, there is no subsequent detail of who would qualify as the most appropriate person to also include the person in life or a nominated representative of the deceased. • The policy does not detail that those seeking consent should be trained and assessed as competent in the consent seeking procedure. • The policy does not cover the retention of tissue or the scheduled purposes for which consent may be obtained to retain tissue from the deceased.	**Major (cumulative)**
b) There is a documented standard operating procedure (SOP) detailing the consent process	The consent SOP in place for the seeking of adult PM examination is not fully reflective of the consent seeking process and does not detail how a change or withdrawal of consent would be communicated to the mortuary. An SOP detailing the process for the seeking of consent for perinatal PM examination was not provided as part of the inspection.	
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		

a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice	The mortuary manager, alongside Consultant Pathologists, provides 'just in time' training to clinicians seeking consent for adult PM examination as requests are infrequent. Whilst the mortuary manager has a good understanding of the consent seeking process, he has not undertaken any formal consent training in the last 10 years.	**Major (cumulative)**
b) Records demonstrate up-to-date staff training	The establishment were unable to provide assurance that all staff involved in the adult consent seeking process have up-to-date training as there is no consistent record of training.	
d) Competency is assessed and maintained	Competency for those seeking consent for adult PM examination has not been assessed or maintained.	
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	The establishment has three separate sites. The hub site is managed and governed by the pathology department, whilst the two satellite sites are managed and governed by the Care After Death team. Whilst the teams have close links and communication to one another, the sites have separate procedural documents, risk assessments, staff training documents, competency assessments and audits for similar activities conducted under the licence as well as different governance frameworks for the management of mortuary documents and records. As the governance frameworks are not aligned, this poses a risk to the DIs ability to oversee licensed activity methodically and ensure consistency in standards across the sites.	**Major**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		

c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	During the external premises inspection of the hub site, it was noted that the doors to the body store open out directly opposite to a turning circle used by hospital vehicles and cars of members of the public. The inspection team observed several instances where those in vehicles were able to see directly into the body store when the doors were open. This means there can be oversight of activity in the body store which could compromise the dignity of the deceased leading to a risk of reputational damage to the establishment. This risk has not been assessed or actions identified to ensure oversight of activity is minimised.	**Major**
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 inspection team identified the following risks to the security arrangements of the mortuaries: • The decommissioned PM room at the Nevill Hall Hospital satellite site has manual locks to the old changing room area. The changing room has been repurposed to a patient specimen collection area which is now part of pathology. There is a risk should the manual locks not be deployed, of access directly into the mortuary from patients attending this area. • The viewing rooms at the satellite sites do not have systems in place for staff to be able to raise an alarm should this be required. This may pose a risk of visitors accessing the rest of the mortuary if staff security is compromised. Furthermore, the viewing room at the Royal Gwent Hospital satellite site has a door in the waiting area which leads directly to the rest of the mortuary which was not locked at the time of the inspection and is reliant on the deployment of manual locks.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The establishment have identified that freezer capacity is frequently not sufficient to meet the demand to move bodies into long term storage. Lack of freezer storage poses significant risk of deterioration to bodies that could otherwise be preventable.	**Major**
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	Following the previous inspection in 2019, manual systems were put in place to regularly monitor local audible fridge and freezer alarms out-of-hours in the body stores at the satellite sites, however, the system adopted has not been effective at the Royal Gwent Hospital site as this monitoring activity ceased in November 2020. This means there is no assurance at this site that an alarm would be responded to within a reasonable timeframe to ensure bodies continue to be stored at an optimal temperature. Whilst the fridges at the Nevill Hall Hospital satellite site are regularly monitored, including out-of-hours, there was no assurance provided that alarms have been tested to ensure they would trigger if temperatures deviated from the acceptable range.	**Major**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
b) Equipment is appropriate for the management of bariatric bodies	The establishment do not have appropriately sized concealment trolleys or other suitable alternative arrangements in place for the transfer of bariatric bodies from the wards to the mortuary at the hub site and the satellite site, Nevill Hall Hospital. Currently bariatric bodies are transferred on beds and in a manner which does not provide assurance that the dignity of the deceased is being fully preserved.	**Major**

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.	Standard Operating Procedures (SOPs) do not always include sufficient detail of the identification checks performed relating to traceability of bodies or describe current practice. These include but are not limited to: • Whilst bodies are regularly checked to ensure condition of the body is being maintained, these checks are not recorded or detailed within an SOP. • SOP MO0007 - Procedure for the release of patients from the Mortuary. Whilst this SOP details that three points of identification on the body are checked on release of the deceased against information brought by funeral directors there is no detail of what actions are taken in the event there are discrepancies in the information. • SOP MO0009 - Procedure for the identification and viewing of the deceased. This SOP is not clear how the identifiers received from visitors at the time of a viewing are checked against the body to confirm the correct visitors have arrived to view the correct body. Furthermore, standard operating procedures are not aligned across the sites for similar procedures (see shortfall against standard GQ1(g)). To fully address this shortfall the establishment should review all SOPs relating to traceability of bodies to ensure they contain sufficient details of identification checks performed and are reflective of current practice across the sites.	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Whilst the establishment are conducting regular audits, the schedule of audits conducted across all sites is limited. Traceability of bodies in storage audits are only completed yearly and do not cover accuracy of mortuary records relating to the deceased audited. Security audits at the hub site have been completed but do not form part of the audit schedule. The audits have included a review of swipe card access; however, the audit did not include a review of the CCTV in operation. Furthermore, process audits conducted are not aligned across the sites (see shortfall against standard GQ1(g)).	**Minor**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents	The SOP for the management of HTA reportable incidents (HTARIs) does not clearly outline responsibilities for investigating incidents or the process for management of HTARIs and follow up to the HTA.	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	Risk assessments do not sufficiently detail how identified risks are mitigated. Not all risk assessments have been reviewed against the HTARI categories to ensure appropriate mitigation for identified risks. Furthermore, risk assessments are not aligned across the sites for similar procedures. (see shortfall against standard GQ1(g))	**Minor**
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	The inspection team identified the following areas that require maintenance at the satellite sites: • There are areas of damage to walls in the body store and mortuary corridors at Royal Gwent Hospital satellite site exposing porous plaster. Furthermore, there are areas of damage to doors, doorframes, and some wooden fittings. This means these areas would be difficult to effectively clean and decontaminate. • Some ceiling tiles in the decommissioned PM room and the viewing room at Nevill Hall Hospital are damaged or not present and require replacement.	**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.	GQ1(d)	The DI is advised to ensure that procedural documents in place in the mortuaries are detailed with the author and authoriser of the document in the relevant section as currently this is only recorded on QPulse which is not in operation at all sites.
2.	GQ3(c)	The DI is advised to adopt the staff competency framework in use at the hub site at the satellite sites.

3.	GQ5(a)	The DI is advised to place visual Human Tissue Authority reportable incident (HTARI) guidance in the mortuary body stores to assist portering staff to understand the types of incidents which require reporting to the HTA. Details of who should be informed of an incident within the establishment both in and out-of-hours, so timely HTARI reporting can be completed, should also be included.
4.	T1(c)	The DI is advised to ensure that perinatal bodies received are labelled consistently with three points of identification on a label that is attached to the body. The perinatal body audited had three points of identification present and secured with the body but only two identifiers on the band physically attached to the body.
5.	T1(d)	Whilst the systems in place to flag up bodies with a same or similar name appeared effective, the DI is advised to devise a common system for this procedure across all three sites.
6.	T1(g)	The mortuary manager is advised to ensure that the date is clearly recorded of when organs and / or tissue is repatriated to the body prior to release for funeral.
7.	T1(g)	The mortuary manager is responsible for the management of traceability of organs and tissues taken at PM examination and the subsequent compliance with family wishes for retention or disposal. The DI is advised to consider training other mortuary staff members to undertake these procedures to ensure there is resilience in this area.
8.	T2(c)	The DI is advised to liaise with the Coroner's service in regard to the family wishes forms in use. The form has grouped together all the scheduled purposes for which consent can be obtained to retain material. This means those giving consent must consent to retention for all scheduled purposes or to none. Families may not wish to consent to some of the scheduled purposes listed and should be given the option of which scheduled purposes they would like to give consent for.
9.	PFE1(e)	Whilst regular security audits are conducted at the satellite sites which include review of swipe card access and CCTV, the DI is advised to introduce visitor logs at these sites so audits can be reviewed against a documented record of visitors.

10.	PFE2(e)	The DI is advised to review the upper alarm trigger points for the refrigerated units which is currently set at 10 degrees Celsius. This may pose a risk to bodies being stored at suboptimal temperatures for prolonged periods of time prior to the alarm sounding.
11.	PFE2(f)	The mortuary manager is advised to regularly audit the temperature recordings taken by the digital fridge and freezer system in place. This may assist to identify concerning temperature deviations from the optimal range quickly so actions can be taken to prevent a fridge unit failure.
12.	PFE3(a)	The DI is advised to declutter and remove items of equipment no longer in use at both satellite sites. This relates to items being stored in the post mortem rooms which are no longer in use as the activity has ceased and to remove items in storage in the area adjacent to the viewing room at Royal Gwent Hospital.
13.	N/A	The DI is advised to consider if current arrangements are sufficiently sensitive to the needs of patients visiting the specimen collection area directly adjacent to the decommissioned PM room at the Nevill Hall Hospital satellite site.

Background

Grange University Hospital has been licensed by the HTA since May 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in February 2019.

Since the previous inspection, the following changes have been made to the licensing arrangements: a change to the list of Persons Designated under the licence was completed in September 2019. In September 2020, the post mortem licence was revoked at the Nevill Hall Hospital satellite site as this activity had ceased. In November 2020, the hub licence was transferred to the newly opened Grange University Hospital, with Royal Gwent Hospital becoming a satellite site of the hub. The post mortem licence was revoked at Royal Gwent Hospital at the same time as all PM activity transferred to the new hub site. There was a change of CLHc in February 2022 and the current CLHc has been in place since September 2022.

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 post-mortem room, records of servicing of equipment, fridge and freezer alarm testing records, ventilation reports, body and tissue traceability audits, security audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training and competency records. 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 (satellite sites are not licenced for PM activity but have retained the PM suite areas), viewing rooms, the laboratory where tissue retained at PM is processed and the storage area in the gynaecology department for pregnancy remains.

Audit of records
The inspection team undertook audits of traceability for five bodies in storage at the hub site and four bodies in storage at each of the satellite sites. This included bodies with same / similar names, a body stored longer term and a perinatal body. Traceability details were crosschecked between the identification band or toe tag on the body, information on the door of the storage unit, the mortuary register, associated paperwork, and the electronic mortuary database. Whilst no discrepancies with traceability were identified, the inspection team noted that the identification band attached to the perinatal body only contained two points of identification, however, information directly secured with the body contained sufficient identifiers.

Audits were conducted of tissue taken at PM examination for five cases. Information was crosschecked between the mortuary traceability documentation, Coroner's paperwork, family wishes forms, and the tissue blocks and slides being stored. Whilst no

discrepancies were identified with the traceability of tissue in storage, the inspection team noted that for one case, the date of repatriation of tissue with the body had not been clearly documented.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence, including the mortuary manager, mortuary staff and laboratory staff during the onsite visual inspection, staff of the Care After Death team, portering staff, staff involved in the consent seeking process for both adult and perinatal PM examination and the DI.

Report sent to DI for factual accuracy: 09 December 2022

Report returned from DI: 23 December 2022

Final report issued: 03 January 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: 12 July 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.