Inspection report on compliance with HTA licensing standards
Inspection date: **06-07 September 2023**

Whiston Hospital

HTA licensing number 12043

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 **Whiston Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab			*Carried out*
Satellite site **Southport and Formby District General Hospital (SFDGH)**	Not licensed	Licensed	Licensed
Mortuary (satellite site)		*Carried out*	*Carried out*
Satellite site **Ormskirk Districk**	Not licensed	Licensed	Licensed

General Hospital (ODGH)			
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 Whiston Hospital ('the establishment') had met the majority of the HTA's standards, eight major and eight minor shortfalls were found against standards for Governance and quality systems 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		

c) Procedures on body storage prevent practices that disregard the dignity of the deceased	The inspection team found two deceased during the body audit that had been in storage for over 30 days and had not been placed into frozen storage despite receiving the release paperwork from the coroner. One deceased showed signs of deterioration. The establishment's current procedure is to request permission from the coroner to place long stay deceased into frozen storage at 30 days. There is no procedure in place for the establishment to follow up with the funeral directors before 30 days if no communication has been made by the funeral directors to the establishment to collect the deceased. The cases described demonstrate that the current practice risks accidental damage to bodies through deterioration. *See shortfall against PFE2(c) for further details.* The establishment do not document the condition of deceased over 24 weeks during the length of stay in the mortuary.	**Major**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The scope of the audit schedule for licensed activities conducted under the licence is limited. The audit schedule does not include sufficient audits to check compliance with documented procedures, the completion of records and traceability of bodies. Security audits are being undertaken at both Southport and Formby District General Hospital (SFDGH) and Ormskirk District General Hospital (ODGH) by security staff however, the audit reports are not shared with mortuary staff to ensure that they have been conducted.	**Major**
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	While an audit schedule is in place for storage of tissue and these audits have been completed with no non conformances raised, one discrepancy was identified by the inspection team when conducting tissue traceability audits. Blocks and slides for one case were not in storage. These had been sent off site for specialist analysis in 2022 and no follow up on return of the relevant material had been conducted.	**Major**

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	The inspection team have no assurance that the bed managers have completed the training package for out of hours viewings. *See advice item 4.*	**Cumulative Major**
c) Staff are assessed as competent for the tasks they perform	The inspection team have no assurance that bed managers responsible for out of hours viewings have been competency assessed.	
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 has used a temporary fridge unit to store bodies that had been in use for over six months which is situated in the PM room. The use of temporary storage units should not be used regularly or for extended periods of time.	**Major**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The mortuary does not have sufficient freezer storage capacity to meet the need for long-term storage of bodies. Two deceased were found by the inspection team that had been in fridge storage for over 30 days. The establishment were unable to transfer the deceased to frozen storage as there were no spaces available across the three sites.	**Major**
d) Fridge and freezer units are in good working condition and well maintained	The fridge units racking and rollers at ODGH are heavily rusted making it difficult to adequately clean or decontaminate this area, posing a potential health and safety risk to mortuary staff and visitors. The fridge seals are deteriorating which poses a risk that temperatures could deviate from the expected ranges.	**Major**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	At the time of the inspection the establishment could not provide a service report that the ventilation system is providing the required air changes per hour for Whiston hospital and SFDGH.	**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.	Some standard operating procedures (SOPs) relating to mortuary activities lack sufficient detail to ensure they are accurate and reflect current practice. • Receipt and release of deceased. • Management of the deceased in the mortuary for an extended period. • Sending tissue away for specialist examination.	**Minor**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	Portering staff are not fully aware of incidents that must be reported to the HTA. *See advice item 6.*	**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	*Southport and Formby District General Hospital* Access to the mortuary by the funeral directors is by either by an audio/visual system which can be seen by the bereavement office staff only, or by ringing a bell which is audible in the body store only. Staff cannot visually identify who is requesting access to the mortuary if the bell only is used. This poses a risk of access being granted to unauthorised people and a risk to lone working staff which has not been risk assessed.	**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	Issues were identified with the maintenance of the establishment, making it difficult to adequately clean or decontaminate the body store areas, posing a potential health and safety risk to mortuary staff and visitors. Issues include but are not limited to: • Minor areas of exposed wood on the doorframes; • Minor areas of exposed plaster; • Debris in the drain in the body store room.	**Minor**
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	At Whiston hospital there is no demarcation of a transitional area between the post mortem (PM) room and the body store, making it difficult for staff and visitors to determine clean areas from dirty areas of the mortuary. Bariatric deceased have to be transferred from the PM room on trolleys into the body store area to place them back into refrigerated storage. This area is in constant use by both mortuary staff and funeral directors when they collect and bring bodies to the mortuary. No cleaning or decontamination of the body store area takes place between the movement of the bodies and staff from the PM room following or during PM examinations.	**Minor**
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	There is no formal schedule of cleaning in place for the post mortem room.	**Minor**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Two porters are responsible for opening the mortuary to allow admittance of the coroner's contracted funeral directors out of hours. The procedure includes signing a form and collecting the keys from the portering manager. This procedure is currently not being followed.	**Minor**
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 trolleys have multiple areas of rust. This means that it is difficult for staff to adequately clean and disinfect this equipment.	**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)	The DI is advised on the next review of the consent policy to remove any references to next of kin. The DI is also advised to include how staff can access the Trust interpreter services if required.
2.	C1(g)	The DI is advised to review the consent form to update the references to codes of practice A and B and to include a section on the form that an interpreter can sign should they be used in the consent seeking process.
3.	C2(d)	Although training for staff seeking consent for perinatal PM examination is in place and up to date, there were no competency assessments in place at the time of the inspection. The lack of competency assessments had been identified prior to the inspection team arriving and an action plan is in place for these to be completed. The DI is advised to ensure that the competency assessments are completed within the timeframe set out in the action plan.
4.	GQ3(a)	The DI is advised to include a section on incident reporting and HTARIs in the porters SOP. The DI is also advised to add questions regarding reporting of incidents to the porters and contracted funeral directors training package.
5.	GQ4(b)	The DI is advised to ensure that staff are correcting errors on the paperwork as per procedure.
6.	GQ5(a)	The DI is advised to have memoire aides in the main body store and satellite body stores showing the applicable HTARI categories and persons to contact if an incident should occur.
7.	GQ6(b)	The DI is advised to include staff training and competency as part of the mitigation of identified risks in the risk assessments.

8.	T2(d)	The DI is advised to include in the tissue disposal SOP the method of disposal.
9.	PFE2(e)	The DI is advised to test and record the lower temperature trigger alarm point.
10.	PFE2(f)	The DI is advised to conduct trend analysis of fridges and freezers as a preventative action to a potential failure of the fridge and freezer units..

Background

Whiston Hospital 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.

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

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 inspection included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records for the mortuary and post-mortem room, records servicing of equipment, audits, risk assessments, meeting minutes, ventilation record, temperature monitoring for the storage units, reported incidents and staff training records.

Visual inspection

The inspection included a visual inspection of the mortuary body store, PM room, viewing room at Whiston Hospital and SFDGH and the body store and viewing room at ODGH.

Audit of records

Audits were conducted for five bodies in refrigerated storage Whiston Hospital, four bodies at SFDGH and one body at ODGH and two in long term storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and electronic database. No discrepancies found.

Audits of traceability were conducted for tissue blocks and slides from four PM cases, including audits of the consent documentation for the retention of these tissues. One discrepancy was found (see shortfall against GQ2(c)).

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, anatomical pathology technician (APT), pathologist, portering staff, adult consent seeking staff and maternity staff.

Report sent to DI for factual accuracy: 21 September 2023

Report returned from DI: 6 October 2023

Final report issued: 27 October 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: 17 September 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.