Inspection report on compliance with HTA licensing standards
Inspection date: **4-5 March 2024**

Royal Victoria Infirmary

HTA licensing number 12341

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 Victoria Infirmary**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Maternity			*Carried out*
A&E		*Carried out*	*Carried out*
Satellite site **Freeman Hospital**	Licensed	Licensed	Licensed
Mortuary (satellite site)	*Carried out*	*Carried out*	*Carried out*
Satellite site	Not Licensed	Not Licensed	Licensed

Balliol Storage Unit			
Tissue Archive			*Carried out*
Satellite site **Wolfson Building**	Not Licensed	Not Licensed	Licensed
Pathology lab			*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 Victoria Infirmary ('the establishment') had met the majority of the HTA's standards, one cumulative critical, two cumulative major, 12 major and seven minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability 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

Critical Shortfalls

Standard	**Inspection findings**	**Level of shortfall**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		

d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	The body stores at both Royal Victoria Infirmary (RVI) and Freeman Hospital (FH) have closed circuit CCTV cameras that can only be accessed by mortuary staff. Alongside this are Trust CCTV cameras also in the body store. At RVI the Trust CCTV is positioned to look directly at the whiteboard containing deceased identifiers. There is no assurance in place that footage from the Trust CCTV is not controlled to prevent inappropriate access or use of images. *Freeman Hospital* • There are no CCTV cameras facing the Funeral Director's (FDs) entrance. • A key is required along with swipe card access to enter the mortuary from the porters entrance out of hours. There is no procedure in place for porters or security staff to sign the key in and out of the security office. • The mortuary staff have no list or knowledge of the number of keys in circulation to the mortuary door. *Balliol Storage Unit* This storage unit has no reception and is unmanned. The unit is used by three different Trusts to store a variety of items, paperwork and relevant material. Staff have a sign in and out sheet to complete when on site. • The gate to the premises uses a small locking latch padlock to prevent access. At the time of the inspection the padlock was unsecured. • A key is required to enter the building. At the time of the inspection the door was unlocked. The establishment have no list or knowledge of the number of keys in circulation. • There is no swipe card access or CCTV in place internally or externally. A security audit of the premises does not take place.	**Cumulative Critical**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The mortuary has audio/camera equipment in place at the entrances to the mortuary. The inspection team observed FDs attending the mortuary at RVI by pressing the audio ringer but not being visual to staff in the mortuary via the camera. The door was released without verifying who was requesting entrance. This poses a risk to staff and of staff allowing unauthorised access to the mortuary.	

Major shortfalls

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training	At the time of the inspection, consultant obstetricians and trainee doctors were seeking consent for perinatal hospital consented post mortem (PM) examinations without completing the training which addresses the requirements of the Human Tissue (HT) Act. The establishment have since instructed that only those staff that have completed the appropriate training and been competency assessed can seek consent for PM examination.	**Cumulative major**
d) Competency is assessed and maintained	The competency of staff seeking consent for perinatal PM examinations is not assessed and maintained.	
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 of the standard operating procedures (SOPs) do not accurately reflect current practice and some do not contain sufficient detail for staff regarding the procedures that must be followed. Particular examples include but are not limited to: • Receipt and release; • Return of pre-24 week foetuses; • Storage of deceased; and • Transfer of deceased. To fully address this shortfall, the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate and contain sufficient detail of the procedures. In addition, many SOPs are extremely long and challenging to follow. If procedures are not clear this could lead to issues with staff not following correct practice.	**Major**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Although a schedule of audits is in place, the scope for licensed activities conducted under the licence is limited. The audit schedule does not include sufficient vertical or horizontal audits to check compliance with documented procedures, the completion of records and traceability of bodies or tissues.	**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	The establishment cannot provide assurance that tissue is being disposed of as soon as reasonably possible. The establishment is currently storing tissue in various locations at the satellite sites, and there are no regular audits conducted of all tissue stored to ensure staff are aware of what is held and why. *Refer to shortfall against standards T2 (a) for further detail*.	
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		

a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete	During the inspection, cases were identified where tissue taken at PM examination had been retained: • A case from 2014 were tissue blocks were found, but no tissue slides. The histology form indicated that no tissue was taken at PM examination. • A hospital consented case from 2022 was not found on the laboratory information management system (LIMS). • Two cases from 2013 and 2015 were tissue blocks and slides stored, but no histology forms found. • One case from 2020 were potentially the person highest in the hierarchy of qualifying relationship did not give consent for the retention of tissue which was not followed up. The satellite storage facility is storing the majority of the tissue archive for both diagnostic and post mortem material. There is no placement map in place to easily identify the location of forensic and post mortem tissue blocks and slides. The hospital consent forms, mortuary histology forms and coroners families wishes forms are scanned into several databases which make it difficult to conduct tissue audits. *See advice item 9.*	**Cumulative 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 establishment could not provide evidence that portering staff, FDs and chaplains are trained or competency assessed for the activities they undertake. *Standard GQ3(c) could not be assessed for these staffing groups.* *See advice item 4.*	**Major**
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	The inspection team identified a number of incidents and near-misses since the previous inspection which have not been reported to the HTA. *See advice item 5.*	**Major**
d) Information about incidents is shared with all staff to avoid repeat errors	Relevant information about incidents is not shared with portering staff, bereavement midwife or sudden infant death in children (SUDIC) representative who undertake activities under the licence.	**Major**
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 of procedures related to licensable activities do not identify all the associated risks; examples include, but are not limited to: • Serious security breach; • Any other incident; • PM cross-sectional imaging of a body; and • Major equipment failure. *Royal Victoria Infirmary* Staff transfer deceased to the external body store in hours only. The route used by mortuary staff to transfer deceased to the external body store is via a road which is frequently used by members of the Trust. External controls on the unit are not secured; there is a risk that the unit could be switched off. At the time of the inspection the lighting on the road was out of order making it difficult to navigate. Due to previous incidents, the ramp up to the external body store door has had railings fitted. However, the ramp to the door is extremely steep and difficult to maneuver a trolley up and the railings have impeded the opening of the door fully. The front of the unit is facing the road with no screening in place. This does not ensure the dignity of the deceased and there is an increased risk to accidental damage to the body due to the uneven road surface, lack of lighting and impeded body store door.	**Major**

b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed	Where risk assessments have been documented, many of the assessments of risks and current control measures do not accurately reflect procedures and practices. The residual risk ratings do not therefore provide an accurate representation of the risks involved with undertaking licensed activities.	**Major**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	The establishment's procedures for identification of bodies do not always use a minimum of three identifiers of the deceased. • The inspection team observed a transfer release from Freeman Hospital (FH) to Royal Victoria Infirmary (RVI). The Trust contracted FD did not bring any written documentation to verify the collection of the correct deceased. The FD verbally gave the mortuary staff the name only. • For release of bodies from the mortuary, the notice of death form only contain two identifiers of the deceased that can be checked against the wristband for hospital deceased. Identification of bodies for release from the mortuary to funeral directors may be performed using only two identifiers. • Chaplains are not checking three identifiers of the deceased on the body against paperwork prior to the family viewing the deceased. The use of less than three separate identifiers when identifying bodies, presents a risk of releasing or viewing the wrong body.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

a) Storage arrangements ensure the dignity of the deceased	*Royal Victoria Infirmary* The porter entrance to the mortuary is from a hospital corridor which is constantly used by both the public and Trust staff. The mortuary reception area currently has a temporary storage unit erected and a temporary fixed refrigeration unit. The doors to the reception area of the mortuary are open for an extended period of time of which there is a risk that the public and Trust staff may see movement of the deceased in and out of the temporary units. The bay area used by FDs is uncovered. There is a risk that Trust staff could view movement of bodies in and out of the mortuary. A shutter is in place to block off the bay area, however at the time of the inspection this was not used. This does not ensure the dignity of the deceased.	**Major**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	A Trust policy has been approved to facilitate the release of a number of deceased in long term storage and finance has been approved to increase the number of permanent fridges and freezers including for bariatric bodies. However, currently the establishment does not have any freezer storage for bariatric bodies. At the time of the inspection, mortuary staff had identified a bariatric body being held in refrigerated storage for longer that the HTA's recommended 30 days. The establishment is currently operating at near capacity for the storing of long term deceased. This poses a risk to the dignity of the deceased.	**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	Mortuary staff stated that Trust estate staff carry out testing of the fridge and freezer temperature alarms but could not provide evidence of assurance of this or that call-out procedures were tested and are effective. The temperature alarm trigger points for the fridges are not set at appropriate temperatures to ensure that there will be no accidental damage to the deceased. Although the fridge on the maternity unit is monitored once a day, it does not have an external alarm, meaning staff will not be alerted if temperatures deviate from the expected range.	**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	The ventilation system for RVI was inspected in May 2023. The report concludes that the systems performance is not adequate to meet the required standards: some areas do not achieve desired air changes and that this is an urgent action to be undertaken. The inspection team were not assured that this action had been escalated to mortuary and senior staff. *See advice item 12.*	**Major**

Minor 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	A procedure is in place to document the condition of the deceased on arrival and throughout the length of stay in the mortuary. The procedure does not include the recording of any actions undertaken before the deceased is released.	**Minor**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Not all staff involved in HTA licensed activities attend governance meetings.	**Minor**
GQ4 There is a systematic and planned approach to the management of records		
b) There are documented SOPs for record management which include how errors in written records should be corrected	When conducting body audits the inspection team observed that corrections in the mortuary register were illegible. This does not allow for full auditability of any changes to a record. There is no SOP in place which includes how errors in written records should be corrected.	**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 this area, posing a potential health and safety risk to mortuary staff and visitors. Issues include but are not limited to: *Freeman Hospital* • Wooden window frames on door to PM examination room; • Deteriorating seals around PM examination tables; • Rust on base of trolley legs in PM examination room. *Royal Victoria Infirmary* • Wooden doors to PM examination rooms; • Small areas of exposed plaster in body store; • Floor in PM room deteriorating around drains.	**Minor**
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	There is no demarcation of a transitional area between the PM room and the body store for both FH and RVI. Bodies are 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 FDs 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**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
d) Fridge and freezer units are in good working condition and well maintained	Some seals on fridge doors are deteriorating at both FH and RVI. Mould was also observed on some seals of fridge doors at FH. This poses a risk of the fridge banks not running at optimal temperature or contamination of the fridge unit which may result in deterioration of the condition of the bodies stored. Small areas of rust were observed at the base of the fridge racking.	**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 trolley hoists are suffering from signs of wear and tear; small areas of rust and peeling paint were seen making it difficult to clean and decontaminate sufficiently.	**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 Trust consent policy refers to next of kin, which could imply that a person not ranked highest in the hierarchy of qualifying relationships could give consent to a PM examination or retention and future use of tissue. The policy is inconsistent on when refresher training should be undertaken by those seeking consent for PM examination.
2.	C1(b)	The SOP for obtaining consent refers to next of kin throughout the document and references code of practice 1.
3.	C1(e)	The DI is advised to align the adult consent seeking form with the perinatal consent seeking form to separate the retaining of tissue for medical record from research, training and clinical audit.
4.	GQ3(c)	Mortuary staff are currently undergoing competency reassessment. The DI is advised to ensure that the competency documents are fully completed.
5.	GQ5(a)	The DI is advised to place signage in the mortuary, maternity unit and emergency department to raise awareness amongst all staff working there of the importance of reporting any incidents, including a list of all the appropriate HTA Reportable Incident (HTARI) categories.
6.	T1(a)	During the body audit the inspection team found that the wrist band on a deceased that was in long term storage

		was illegible. The DI is advised that when placing deceased into long term storage that the wristbands are legible to reduce the risk of releasing the wrong body.
7.	T1(d)	The DI may wish to consider using magnets to flag up same/similar names as the current system has a risk of the labels falling from the fridges.
8.	T1(g)	The DI is advised to receive confirmation of receipt of tissue transferred between FH and RVI.
9.	T2(a)	A business case was submitted to look at employing the services of an external tissue storage company instead of the Trust continuing to manage the tissue archive. The DI is advised to continue exploring this avenue to facilitate the traceability of tissue blocks and slides.
10.	PFE1(a)	The tissue archive at Balliol satellite site is situated on the mezzanine level. The DI is advised to ask for the structural engineer to check that the mezzanine level has the structural capacity to hold the weight of the large number of tissue cabinets.
11.	PFE2(f)	The DI is advised to look at introducing the same temperature monitoring system on the maternity unit as is used in the mortuary to reduce the risk of manual temperature monitoring being forgotten. The DI is advised to undertake trend analysis of the temperatures to identify trends and the extent of any variations in storage temperatures.
12.	PFE3(f)	While the majority of equipment does undergo regular maintenance, this is overseen by estates and mortuary staff had difficulty accessing the maintenance reports for the fridges, trolleys and ventilation during the inspection. The mortuary should have copies to provide assurances the equipment is functioning to the required standard. This would allow mortuary staff to identify when servicing, maintenance and equipment issues need to be escalated to senior staff.

Background

Royal Victoria Infirmary (RVI) (hub) and Freeman Hospital (satellite site) are both 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. Balliol storage unit and Wolfson building (satellite sites) are licensed for the storage of bodies of the deceased and relevant material for use for scheduled purposes.

RVI has been licensed by the HTA since 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in May 2019.

Since the previous inspection, the establishment has introduced a CT scanning service and has taken on the post mortem examinations for surrounding coroner services.

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.

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, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and staff training records.

Visual inspection

The inspection included a visual inspection of the mortuary body store, PM room and viewing room for both RVI and FH and the tissue archive area at Balliol storage unit and Wolfson building.

Audit of records

Audits were conducted for six bodies in refrigerated storage at RVI and three bodies at FH. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and paper documents. No discrepancies found.

Audits of traceability were conducted for tissue blocks and slides from seven PM cases at Balliol storage unit, including audits of the consent documentation for the retention of these tissues. Two discrepancies found (see shortfall against T2(a)).

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, Anatomical Pathology Technologists (APT), quality lead, laboratory personnel, portering staff, pathologist, maternity staff and adult consent seeker.

Report sent to DI for factual accuracy: 26 March 2024

Report returned from DI: 27 March 2024

Final report issued: 17 April 2024

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.