Inspection report on compliance with HTA licensing standards
Inspection dates: **9th, 11th and 12th January 2023.**

Royal Shrewsbury Hospital
HTA licensing number 12184

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 Shrewsbury Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
A&E	-	*Carried out*	-
Satellite site **Princess Royal Hospital Telford**	Not licensed	License Applied for	Licensed
Mortuary	-	-	*Carried out*

Maternity	-	-	*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 Shrewsbury Hospital ('the establishment') had met the majority of the HTA's standards, eight major and six 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

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 HTA's Codes of Practice.	Whilst there is an adult post-mortem (PM) consent policy in place, it was due for review in April 2021, and has not been updated to reflect the names and contact details of key personnel involved in the consent taking process. *The inspection team has since received assurance from the establishment that hospital consented PMs are currently on hold until current systems and processes and associated paperwork have been reviewed and updated.*	**Major (cumulative)**
b) There is a documented standard operating procedure (SOP) detailing the consent process	Whilst there is an SOP in place for the consent seeking process for adult PMs it lacks detail regarding who can give consent for PM examination, removal of relevant material from the deceased and retention of tissue. *The inspection team has since received assurance from the establishment that hospital consented PMs are currently on hold until current systems and processes and associated paperwork have been reviewed and updated.*	
c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice	Whilst there is written information available for those giving consent, it was due for review in April 2021 and has not been updated to reflect the contact details of key personnel involved in the consent process. *The inspection team has since received assurance from the establishment that hospital consented PMs are currently on hold until current systems and processes and associated paperwork have been reviewed and updated.*	

g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided	Whilst the consent form used by the establishment for adult PMs has been agreed and ratified, it was due for review in April 2021. *The inspection team has since received assurance from the establishment that hospital consented PMs are currently on hold until current systems and processes and associated paperwork have been reviewed and updated.*	
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	There is no training available for those responsible for seeking consent for adult PMs. *The inspection team has since received assurance from the establishment that hospital consented PMs are currently on hold until current systems and processes and associated paperwork have been reviewed and updated*	**Major (cumulative)**
b) Records demonstrate up-to-date staff training	Records do not demonstrate up to date training in HTA requirements when seeking consent. There are no records available to review indicating which staff have received training in obtaining consent for adult and perinatal PMs.	
d) Competency is assessed and maintained	The establishment does not have a system in place for assessing staff as competent with the HTA requirements when seeking consent for PMs. This includes those who have received consent training.	
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) lack detail and do not reflect best practice guidance. These include, but are not limited to, SOPs detailing the process for: - Viewing of bodies - Post-Mortem Examinations - Body storage contingency planning - Operation of body storage fridges and freezers This is not an exhaustive list of the SOPs requiring amendment. 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 to reflect current practice.	**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 only requires relatives to provide one identifier for the deceased when they attend the mortuary for a viewing. This practice poses a risk of viewing the wrong body.	**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	Although CCTV cameras cover the entrances of the mortuaries, staff were not aware whether these cameras are functioning and do not have access to the recordings. There are no CCTV cameras inside the mortuaries including the body stores. Staff access the mortuary using swipe cards. However, out of hours porters give access to trained Funeral Directors who facilitate admissions and releases. As there is no CCTV within the mortuary, there is no oversight of these visitors who are left alone within the body stores. There is an internal door between the viewing room and body store area at Princess Royal Hospital that cannot be effectively secured during viewings which poses a risk of unauthorised access.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The fridge within the maternity department is housed within an alcove in a corridor on the ward. This area is subject to a high footfall of staff and patients. Although secured by a padlock with the key stored in a secure area, these arrangements do not constitute a dignified environment for the storage of the deceased.	**Major**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	There is insufficient freezer storage capacity to meet establishment needs. During the body audit, there were three bodies that had been in refrigerated storage for over 30 days and were awaiting transfer to the freezer. There are nine freezer spaces across both sites, and none of these are suitable for the storage of bariatric bodies.	**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	Some of the temporary storage fridges (that are in continual use) across both sites and the freezer used to store human material within the mortuary at Princess Royal Hospital do not have remote monitoring and alarm systems. This is not sufficient to alert staff in the event the storage temperature deviates from an acceptable range. The temporary storage fridge located in the mortuary at Royal Shrewsbury Hospital is not included as part of the regular schedule of temperature excursion testing.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Whilst there is a schedule of audits checking compliance with documented procedures, security audits have not been listed in the schedule and there is no formal audit documentation in place.	**Minor**
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 were not assured that all porters involved in undertaking licensed activity had received training on the use of the overhead hoist. This poses the risk of accidental damage to a body.	**Minor**
c) Staff are assessed as competent for the tasks they perform	The inspection team were not assured that all porters carrying out licensed activity had been assessed as competent.	**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	There is only one hydraulic trolley at Princess Royal Hospital and it is not fully functioning, this poses a risk of accidental damage to a body due to poor handling and transfer. Additionally, this puts staff at risk of musculoskeletal damage due to poor handling techniques. The PM room at Royal Shrewsbury Hospital had areas of exposed wood. This presents the risk of ineffective cleaning and decontamination. *The inspection team has since received assurance from the establishment that there are plans in place to refurbish the PM room in 2023.*	**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(b)	The DI is advised to prioritise the ratification of the adult PM consent seeking SOP which is currently in draft form. Additionally, consideration should be given to the consent for removal of tissue for the testing of DNA.
2.	C1(e)	The establishment gives the option to families for retention of PM material for research. Currently the establishment does not conduct research. The DI is advised to consider providing this information to families to set expectations and ensure that informed consent is obtained.

3.	GQ1(g)	Whilst there is HTA representation in the Emergency Department, the DI is advised to nominate a Persons Designate.
4.	GQ3(a)(c)	The DI is advised to keep copies of training and competency records for non-mortuary staff undertaking licensed activity out of hours (porters and site managers) in the mortuary.
5.	PFE3(a)	The isolator switches for the refrigerated units are on a wall outside the mortuary and in an area open to the public. The DI is advised to cover and secure the switches so that they are not inadvertently turned off.
6.	PFE3(f)	The systems and equipment within the mortuary are subject to regular testing and servicing however records are not kept within the mortuary and only available upon request. The DI is advised to request copies of all maintenance, servicing and repair reports so that they are easily accessible to the Mortuary Supervisor for review and monitoring purposes.

Background

Royal Shrewsbury Hospital has been licensed by the HTA since 29th May 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in March 2018.

Since the previous inspection, the satellite site has made licensing changes as it no longer carries out PM examinations and the activity of 'making of a PM examination' was removed from the licence in January 2022 Although the activity of 'removal of relevant material from the deceased' was also removed from the licence in January 2022, it has recently been reapplied for to cover removal that takes place in the A&E department as part of the Sudden Unexplained Death in Childhood (SUDIC) protocol. There has also been changes to the named personnel on the licence with a change of DI in March 2019 and CLHc in July 2021.

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 applicable 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, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and training records for both the mortuary staff and porters.

Visual inspection
The inspection included a visual assessment of both establishments including, body storage areas in the mortuaries and in the maternity department, PM room, viewing rooms and tissue storage areas. The inspection teams observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records
Hub Site
Audits were conducted onsite of four bodies from refrigerated storage. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides from five coronial consented cases and one case undertaken by an independent pathologist. These included audits of the consent documentation for the retention of these tissues. No discrepancies were identified.

Satellite Site
Audits were conducted onsite of five bodies from refrigerated and frozen storage. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork. No discrepancies were identified.

Meetings with establishment staff
Staff carrying out processes under the license were interviewed including the DI and Clinical Director for Pathology, mortuary manager, APT, pathologist, mortuary porter, and bereavement midwives.

Report sent to DI for factual accuracy: 30/01/2023

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 15/02/2023

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: 1 December 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.