Inspection report on compliance with HTA licensing standards
Inspection date: **04 November 2021**

Warwick Hospital
HTA licensing number 12080

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
Warwick Hospital	Not licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	-	*Carried out*
A&E	-	*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 Warwick Hospital (‘the establishment’) had met the majority of the HTA’s standards, three major and nine minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities, and equipment. These related to standard operating procedures (SOPs) and risk assessments, consent policies, staff awareness of incidents reportable to the HTA, fridge alarm testing and maintenance of the mortuary.

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 establishment's bereavement policy which covers seeking consent for post mortem (PM) examination does not fully reflect the requirements of the HT Act 2004 and the HTA's Codes of Practice. This includes, but is not limited to the following: • The policy references to consent sought from the 'next of kin'. • The policy does not provide explanation of options available for the retention or disposal of tissue taken at PM examination. • The policy does not govern consent for perinatal or paediatric PM examination.	**Major (cumulative)**
b) There is a documented standard operating procedure (SOP) detailing the consent process	There are no documented SOPs which detail the process for seeking consent for perinatal, and adult PM examinations.	
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	The establishment are storing a small amount of tissue estimated to be from fewer than 15 cases, for which there is no consent for continued retention following Coroner authority ending. Cases date from 2010 onwards.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
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	The fridge unit on the maternity department and the temporary body storage units within the mortuary have local alarms which are not tested to ensure that they trigger when temperatures go out of upper or lower set range. Furthermore, the units are located in areas which do not provide assurance local alarms would be heard or responded to effectively.	**Major**

Minor Shortfalls

Standard	**Inspection findings**	**Level of shortfall**
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training	The establishment does not have a process to record when individuals completed consent training, and when refresher training is due.	**Minor**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	Standard Operating Procedures (SOPs) do not always include sufficient detail of identification checks performed relating to traceability of bodies. These include but are not limited to: • M-REC-006 Identification and viewing of deceased patients does not sufficiently detail that identification checks are performed using a minimum of three points of identification when preparing a body for viewing or prior to entry of visitors to the viewing room. • M-REC-005 Deceased patient release - the inspection team noted that the staff carried out sufficiently detailed crosschecks to identify the deceased against information provided by the funeral director at the point of release, however this is not reflected fully in the SOP. 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.	**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	Review of the incident log discovered that whilst staff know how to identify and report incidents, some incidents falling within the HTA reportable incident (HTARI) categories had not been reported to the HTA as the establishment had determined them to be a near miss. *The establishment reported the incidents to the HTA following the inspection for review.*	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded, and monitored		

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	Risk assessments do not sufficiently detail how identified risks are mitigated.	**Minor**
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 procedure for viewing of the deceased does not include a final check using a minimum of three points of identification of the deceased prior to visitors entering the viewing room.	**Minor**

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The establishment are storing a relatively small amount of retained tissue from PM examination within the laboratory, however, the following issues relating to traceability were identified: • One case was identified where tissue blocks and slides had consent for retention information attached from a different case. • The inspection team were unable to complete the tissue traceability audit of the material held in the laboratory due to temporary unavailability of hospital technical staff to explain the recording system and temporary IT issues with the system itself on the day of the inspection. Therefore, no assurance was provided that blocks and slides held by the establishment are fully traceable.	**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	Some areas of the mortuary premises are showing signs of wear and require maintenance to ensure decontamination procedures are effective: • The body store floor is cracked and damaged in several places. • Radiators in the body store have areas of rust and damage. • Ceiling tiles in the viewing room waiting area are heavily stained and damaged in some areas. • Door frames between the body store and PM room are made of wood. The frames are not sealed and show signs of damage.	**Minor**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The establishment do not have a system in place to review records of swipe card access to the mortuary to ensure that it is limited to those with legitimate right of access.	**Minor**
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 establishment no longer undertake PM examinations however, the PM room may still be used for tissue retrieval in cases where consent has been given for tissue donation. During the inspection the establishment were unable to provide maintenance records which demonstrate the ventilation system provides the necessary ten air changes per hour.	**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(c)	The DI is advised to review the information booklets provided to those giving consent for adult examination to ensure they are fully reflective of the HT Act and in line with HTA guidance: *'Information should include who can give consent for post-mortem examination, removal of relevant material from the deceased and the retention of tissue. References to the 'Next of Kin' should be avoided.'*

2.	C1(d)	The DI is advised to review the information booklet provided to those giving consent for perinatal PM examination. Whilst the booklet adequately informs of the option to retain tissue following PM examination, there is no detail of options to dispose of the material or for families to have material returned at a later date.
3.	C1(g)	The DI is advised to liaise with referral centre providing the consent forms for perinatal PM examination as the forms do not adequately reflect the requirements of the HT Act. The form only gives the option for tissue taken at PM to be retained and relies on consent seekers to provide other options such as disposal of the material or return at a later date. Furthermore, the information on the form regarding who to contact to change or withdraw consent and by when is not clear. The consent form also refers to outdated HTA Codes of Practice.
4.	GQ1(g)	The DI is advised to nominate the HTA representatives in the maternity and Accident & Emergency departments as Persons Designated (PD) on the licence. Furthermore, the DI is advised to extend the invitation to the HTA governance meetings to the bereavement lead responsible for the adult consent seeking process.
5.	GQ4(b)	The DI is advised to review how errors in written records are managed within the mortuary to ensure correction is in line with the record management SOP.
6.	PFE1(d)	The DI is advised to consider the use of CCTV to monitor access to the mortuary. Furthermore, the DI is advised to consider additional screening of the window between the viewing room and body storage area to prevent the risk of oversight to the body store by visitors.

Background

Warwick Hospital has been licensed by the HTA since April 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in June 2016

Since the previous inspection, PM examinations are no longer undertaken at this establishment. The licence for this activity was revoked in October 2020. Bodies requiring PM examination are now moved to another HTA licensed premises.

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
Two standards (GQ1(b) and PFE3(e)) out of the total 72 were not covered during the inspection. These standards were not applicable. The establishment does not undertake PM examination.

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 for the mortuary were reviewed. Traceability audits, risk assessments, meeting minutes, incidents, consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the premises which included the mortuary body storage area, PM room (currently housing temporary body storage units) and viewing room. The area within the maternity department for the storage of bodies was inspected as well as the storage arrangements for relevant material held within the pathology department.

Audit of records
The inspection team undertook audits of traceability for four bodies in storage. This included bodies with same / similar names and a body in long term storage. Traceability details were crosschecked between the identification band on the body, information on the door of the storage unit, the mortuary register and paperwork. One minor discrepancy was identified to the spelling of a surname between the identification band on the body and that recorded on the door of the refrigerated unit.

The inspection team also witnessed a release of a body from the mortuary. Records produced and used to identify the body prior to the activity being undertaken were reviewed. The activity conducted used three-points of identification of the deceased crosschecked between paperwork produced and the identification bands on the body. No discrepancies were identified.

Audits were conducted of tissue taken at PM examination for four cases. Information was crosschecked between the mortuary documentation, family wishes forms, and tissue blocks and slides being stored. Two cases reviewed demonstrated disposal of tissue had been completed in line with the wishes of the family. The audit of the further two cases could not be completed as the inspection team were unable to review the computer records whilst on site and instructions on the wishes of the family had not been received. During the audit the inspection team identified that whilst the establishment are storing minimal amounts of relevant material retained from PM examination, blocks and slides dating from 2010 onwards are being stored where there is no consent in place for continued retention. One further case was identified where tissue blocks and slides had consent for retention information attached from a different case.

Meetings with establishment staff
The assessment team met with staff carrying out processes under the licence, including mortuary staff, a portering staff member, staff involved in the consent seeking process for adult and perinatal PM examination, staff responsible for the removal of relevant material in the Emergency Department and the DI.

Report sent to DI for factual accuracy: 20 December 2021

Report returned from DI: 07 January 2022

Final report issued: 07 January 2022

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: 20 July 2022

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.