Inspection report on compliance with HTA licensing standards
Inspection date: **18-19 January 2022**

University Hospital Coventry and Warwickshire NHS Trust

HTA licensing number 30018

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 **University Hospital Coventry and Warwickshire**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab			*Carried out*
Maternity		*Carried out*	*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 University Hospital Coventry and Warwickshire NHS Trust ('the establishment') had met the majority of the HTA's standards, 11 major and five 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**
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	Not all staff involved in the consent seeking process for perinatal/paediatric post mortem (PM) examination have received training which addresses the requirements of the HT Act and the HTA's codes of practice. *(as a result, standards C2 (b), (c) and (d) cannot be met)*	**Major**
GQ2 There is a documented system of audit		

a) There is a documented schedule of audits	Mortuary The current audit schedule covers most licensable activities, however, audits for consented PM examinations are currently not conducted. Arden Tissue Bank Although *ad hoc* audits are conducted when sending tissue away there is no formal documented schedule of audits in place. The inspection team found that no *ad hoc* audits had taken place between October 2020 and October 2021. *See advice item 2*	**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	Arden Tissue Bank Audits are not carried out of stored tissue or consent documentation. *Refer to shortfall against standard T2(a) for further detail.*	**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	Mortuary There is a risk assessment (RA) for HTA reportable incidents (HTARI) in place (MORA 33 HTARI risk assessment). This RA has not been reviewed since 2015 and does not assess all HTARI categories. Arden Tissue Bank There is no risk assessment in place to cover the risk to staff of lone working in the building housing the tissue bank's freezers.	**Major**
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	<u>Arden Tissue Bank</u> During the tissue traceability audit the inspection team found a discrepancy on a consent form that had been ticked for both retain for research and quality and assurance and for disposal. No follow up with the consent seeker had taken place to clarify the wishes of the family.	**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	Surgical skills training courses take place next to the mortuary out of hours including weekends. Access to the body store is directly from the training room into the body store which surgical skills staff use to retrieve body parts from the freezer situated in the body store. There is a risk that the door to the body store could be left open and unauthorised access gained by surgical skills students. There is an added risk as currently the temporary storage units have no external alarm and the contingency for the temperatures of these units to be recorded over the weekend means the PM room is left unlocked. *See advice item 6*	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The establishment use the base of the freezer unit to increase capacity for body storage. The body trolley does not lower to the level of the storage trays used: this means that bodies stored in this location are subject to additional manual handling when being placed into and removed from the body storage units. This practice poses an increased risk of accidental damage to the deceased. Body condition checks are being carried out on a weekly basis; however, the inspection team noted several bodies that were leaking or in soiled sheets when completing the body audit. Body condition checks should be conducted more frequently to ensure the dignity of the deceased is preserved.	**Major**

b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	The establishment is currently operating at near capacity for the storing of bodies. At the time of the inspection all the refrigerated storage at another hospital under the Trust was full as well as three of the five temporary storage units in the establishments body store. *See advice item 7*	**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 and bariatric bodies. At the time of the inspection, mortuary staff had identified several bodies being held in refrigerated storage for longer that the HTA's recommended 30 days. 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	The toxicology fridge and baby fridge in the body store and the fridge unit on the maternity department only has a local alarm which is not tested to ensure that the alarm triggers when temperatures go out of upper or lower set range.	**Major**
i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods	A documented contingency plan stating refrigerated bodies could be stored with funeral directors or the alternative hospital site as set out in the SOP and SLA is in place, however there are insufficient contingency arrangements in place for the continued storage of frozen bodies.	**Major**

Minor 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		
b) There is a documented standard operating procedure (SOP) detailing the consent process	The Adult consent procedure for seeking consent for post-mortem (PM) examination does not include the process of obtaining the use of a translator if needed in the consent process. The procedure should be reviewed to ensure that all external website links work.	**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.	<u>Mortuary</u> SOPs lack sufficient detail. Key steps are included but these do not specify the individual actions that need to be undertaken to accomplish each step. These include, but are not limited to, SOPs detailing the process for: • admission of bodies; • post-mortem examination; • out of hours release; and • retaining, disposal and transfer of PM samples. 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. <u>Arden Tissue Bank</u> SOPs currently refer to outdated HTA codes of practice.	**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 PM room floor is cracked and damaged in several places. • Cabinets and racks in the PM room have large areas of rust. • Tissue and hair were found in the drains of the PM and high-risk PM examination rooms. • Door frames in the body store and PM room are made of wood. The frames are not sealed and show signs of damage.	**Minor**
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	Due to the temporary Nutwells in place in the PM room, the pass-through fridges are not in use. Bodies have to be transferred from the PM room to the body store on trolleys to place them back into refrigerated storage. No cleaning or decontamination of the trolleys takes place between the movement of the bodies from the PM room following or during PM examinations. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
f) Temperatures of fridges and freezers are monitored on a regular basis	The inspection team noted that the temperature of the fridge on maternity was not being recorded daily as per written procedure.	**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 (g)	The DI is advised to liaise with referral centre providing the consent forms for perinatal/paediatric 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 repatriation. The consent form also refers to outdated HTA Codes of Practice.
2.	GQ2 (a)	The DI is advised to develop an audit schedule for the Arden tissue bank to include horizontal and vertical audits for example, consent forms, receipt of tissue and release of tissue. The DI is advised to use these procedural audits as an opportunity to review SOPs to see if practice reflects what is written in the SOP for each activity.
3.	GQ5 (a)	The DI is advised to develop a flowchart for reporting HTARIs on the maternity wards and to ensure that all staff are aware of the incident reporting process.
4.	T1 (g)	The DI is advised to ensure that the number of tissue taken at PM examination is recorded on the tissue form. During the tissue traceability audit the inspection team found that the pathologist had not stated the amount of tissue taken. This may mean that any discrepancies of number of tissue in the pot and on the documentation would not be raised by laboratory staff to mortuary staff.
5.	T2 (d)	The establishment are storing a small amount of PM examination tissue. The DI is advised to add the method of disposal of tissue blocks and slides to the electronic spreadsheet.
6.	PFE1 (e)	The DI is advised to move the freezer storing body parts for surgical skills training from the mortuary to reduce the risk of unauthorised access.
7.	PFE (b)	The DI is advised to progress the current talks to introduce a fee to funeral directors for storage of bodies after an agreed amount of time, when the Coroner’s release authorisation form has been emailed to both the establishment and the families appointed funeral directors. This may allow a steady movement of bodies from the mortuary to ensure sufficient capacity for storage of bodies, which takes into account predicated peaks of activity.

Background

University Hospital Coventry and Warwickshire NHS Trust (UHCW) 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.

UHCW has been licensed by the HTA since 2009. This was the third inspection of the establishment; the most recent previous inspection took place in August 2016.

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, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents and staff training records for both the mortuary and Arden Tissue Bank.

Visual inspection

The inspection included a visual inspection of the mortuary body store, PM room, viewing room and maternity fridge. The inspection included a visual inspection of the receipt area for tissue and the tissue bank freezer store.

Audit of records

Mortuary

Audits were conducted for six bodies in refrigerated storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and electronic database.

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. No discrepancies found.

Arden Tissue Bank

Audits of traceability were conducted for three samples; two blocks and slides stored at room temperature and one tissue sample stored at -80^{o}C. Consent documentation for the use and retention of these tissues was checked; one consent form had both retain for research and disposal ticked.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, mortuary manager, Anatomical Pathology Technologists, portering staff, maternity staff, and adult consent seeker.

Materials held for the police

Under section 39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. Any information provided by the establishment in relation to police holdings have been shared with the Home Office, but do not appear in the report as they are outside the scope of the HT Act.

Report sent to DI for factual accuracy: 15 February 2022

Report returned from DI: 1 March 2022

Final report issued: 21 March 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: 28 June 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.