Inspection report on compliance with HTA licensing standards
Inspection date: **04 December 2024**

University Hospital Coventry
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**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Gynaecology Ward	-	-	*Carried out*
A&E	-	*Carried out*	-
Arden Research Tissue Bank and research collections	-	-	*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 ('the establishment') had met the majority of the HTA's standards one cumulative critical, one cumulative major, seven 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

Critical 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 provided the Trust policy/procedure relating to seeking consent for adult post mortem (PM) examination following the inspection. Review of the document demonstrated the establishment have not followed their own procedure for seeking and obtaining consent for PM examination. For example: • Staff have been seeking consent for PM examination who are not trained in this task and trained staff have not had refresher training; • Relatives are not provided with a copy of 'A simple guide to a PM examination', to read and this is not confirmed before consent is sought. The reference to the information leaflet does not match the title of the document provided to the inspection team following the inspection. • Where consent is sought over the telephone, relatives are not sent a copy of the completed consent form (via email) to respond and confirm they agree with the documented consent. Where email is not an option, other methods to confirm consent have not been considered. • The policy refers to mortuary staff being involved in the consent process, which is not the case. The inspection team identified three cases within the research tissue collections where consent forms evidencing donation had not been fully completed.	**Cumulative Critical**

b) There is a documented standard operating procedure (SOP) detailing the consent process	The inspection team identified cases since 2022 where consent for adult PM examination has not been obtained in-line with the HT Act and the HTA's Codes of Practice and not in-line with the establishment's own procedure. The HTA are not assured that in all cases since 2022 consent for PM examination has been sought from the individual ranked highest in the hierarchy of qualifying relationships, or they have been provided with sufficient information to provide appropriate and valid consent for PM examination and retention of tissue.	
c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice	The written information provided for relatives regarding consented adult PM examinations 'Hospital Post Mortem Examination – Information for relatives' is limited. It does not include who can give consent for the PM examination, removal of relevant material and retention of tissue. In addition, it refers to consented PM examinations helping to identify a cause of death, which is misleading as a Medical Certificate of Cause of Death has to be issued before this type of PM examination can take place.	
d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives	Options for tissue following PM examination is not included in the written information for relatives, for example, repatriation to the body or disposal and does not include what will happen to tissue stored for future use should it not be used for that purpose within a certain time frame. *See advice item 2*	

e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained.	There are samples stored on behalf of a third party within the research tissue bank that do not have consent in accordance with the HT Act.	
f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds	The written information provided for relatives does not include: • what relatives should do if they wish to change their minds and/or withdraw consent. • the time relatives have to reflect on their decision and the point up to which they have to change and/or withdraw consent.	
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 or refresher training in place for those staff seeking consent for PM examination. The need to address training for staff to seek consent for PM examination has been identified by the establishment but has not been actioned and consent has continued to be sought by untrained staff or staff who have not undertaken refresher training.	
b) Records demonstrate up-to-date staff training	The bereavement staff member involved in seeking consent for PM examination has not undertaken refresher training in this task. Other staff who have been seeking consent for PM examination have not been trained in this task.	

c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual	The inspection team identified cases since 2022 where consent for adult PM examination has been obtained by staff who are not trained in this task, or were accompanied by a trained individual.	
d) Competency is assessed and maintained	The bereavement staff member involved in seeking consent for PM examination has not been re-competency assessed in this task. Other staff who have been seeking consent for PM examination have not been competency assessed in this task.	

Major shortfalls

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 was tested in May 2024 and indicated that the air changes per hour could not be measured for both PM rooms. Therefore, the establishment have no assurance that the ventilation system is working to the required standard. Documentation provided following the inspection still does not demonstrate the number of air changes per hour in each PM room. *See advice item 14*	**Major (Cumulative)**
d) Staff have access to necessary PPE	Although staff have access to FFP3 masks, those staff that can wear them have not been face-fit tested to ensure they will work. Staff do not have access to alternative respiratory protective equipment (RPE), for example, fully ventilated hoods. In the absence of assurance that the ventilation system is working to the required standard and the lack of suitable RPE, there is a risk to the health and safety of staff working in the PM room.	

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.	Not all relevant Standard Operating Procedures (SOPs) reflect practice or consistently refer to checking three points of identification at different stages of a procedure. SOPs should include what the identifiers could be and what they are checked against. Examples include but are not limited to: • MO LPR78 Deceased patient transfer to temporary freezer/fridge unit. • MO LPR92 Paediatric PM examinations. • MO LPR9 Retaining, disposal and transfer of PM samples. • MO LPR73 Admission for stillbirth, neonatal deaths, foetuses and foetal tissue. The inspection team were informed that this procedure has been updated but this is not reflected in the current SOP. There is no SOP outlining the process for the rapid release of bodies by site managers/modern matrons. SOP MO LPR44 Identification and viewing of deceased patients does not contain sufficient detail of all stages of the process from the point of booking a viewing appointment to the checking of identification before relatives view a body. Out of hours, the SOP refers to porters checking the identification of bodies for viewing but in practice the site managers/modern matrons do this. Currently there is no identification check using three identifiers immediately before relatives view a body (See shortfall relating to standard T1(c)) SOP MO LPR74 Procedural overview of admission of deceased patients includes how bodies of unknown identities are dealt with from the hospital but not from the community. In addition, the SOP states that bodies may come in from the community with less than three identifiers but no information on how this would be followed up. SOPs that refer to the transfer of bodies internally are not clear on what documentation/identification details of bodies funeral directors bring with	**Major**

	them to check at the point of release of transfer to help mitigate the release of a wrong body. The process for following up and confirming receipt of specimens sent off site is not documented in an SOP.	
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 HTA reportable incidents (HTARIs) and near-miss HTARIs that should have been reported to the HTA.	**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	Although the establishment have recently undertaken a fundamental review of risk assessments relating to mortuary activities, not all risk assessments have been included. This has meant some activities have inaccurate risk ratings and may not include all relevant information or reflect current practice. Risk assessments do not always detail the correct groups of people for who might be harmed in the activity being assessed. For example, risk assessments relating to PM examination do not include the deceased as being at risk of harm. The risk assessment relating to HTARI categories is only in draft format. To fully address this shortfall, a further review of all risk assessments is required. *See advice item 8*	**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 current procedures for carrying out viewings in and out of hours is not robust. In hours, there is no handover from the bereavement staff who meet relatives prior to a viewing and mortuary staff who prepare the deceased and conduct viewings. There is no final identification check of the deceased using three identifiers provided by the relatives when they attend for a viewing. For out of hours viewings, it is not clear how a minimum of three identifiers of a deceased are obtained, recorded and checked for preparation and conducting a viewing with relatives. This presents a risk of viewing a wrong body.	**Major**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	When specimens are retained during PM examination, they are placed into plastic baskets numbered with the corresponding PM table. These baskets are placed on a bench away from the tables next to each other. Specimens are not labelled until a PM session has been completed. There is a risk that specimens may be placed into the wrong basket and labelled incorrectly. The record of the number and types of tissue retained at PM examination for histological examination is not kept by the mortuary or written on the histology specimen card sent to the laboratory with tissue. Therefore, laboratory staff are unable to confirm if the tissue they receive in the laboratory for processing is correct. The mortuary have a spreadsheet to record tissue taken at PM examination. However, this has not been completed for tissue retained at coronial or consented PM examination. Although the retention of tissue is recorded in the paper record for each case, there is no way to easily identify which cases have tissue retained, making oversight and tissue traceability audits difficult.	**Major**
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 CCTV camera that is supposed to cover the mortuary external door used by funeral directors is obscured by a fence meaning activities and access to this area cannot be sufficiently monitored. The mortuary body store is used by the surgical training centre staff to transfer donor material into the training centre during working hours via an access door from the body store. Access through this door is controlled by training centre staff; mortuary staff are not notified when access is required to the body store. There is a risk that mortuary activities maybe overseen by unauthorised staff and the dignity of the deceased could be compromised. There is no documented record of which training centre staff have accessed the mortuary body store and when. The condenser units for the establishment's fridges and freezers are not secured to prevent them being tampered with or switched off. *See advice item 11*	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The mortuary's bin store is located off an internal mortuary corridor. The trust's waste team are granted access to this corridor by mortuary staff using video intercom to verify access during working hours. The waste team have a key to access the bin store from the corridor, however, there is another door leading directly into the main PM room which is not secured at any time, including when the PM room is operational. In addition, the fridges are not routinely locked out of hours. There is currently no way to monitor activity in the internal corridor once access has been granted. There is also no system in place to alert staff should there be a security breach into this area, in or out of hours. There is a risk of unauthorised persons accessing the PM rooms and the body store fridges. *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		
e) There is a system for recording that staff have read and understood the latest versions of these documents	Not all staff working in the mortuary have read and understood the latest versions of SOPs relevant to their work.	**Minor**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	The DI does not currently hold meetings with PDs overseeing activities carried out under the licence.	**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 require attention. The inspection team identified: • Areas of flaking plaster within the main PM room; • Dark fluid on the drawers of a unit in the main PM room; • Debris and hair in the drains in the main PM room; and • Tissue debris under the table tops of two PM tables. For one table this was caused by a blocked drain that had not been addressed.	**Minor**

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 establishment do not currently test the lower alarm trigger points for the body store fridges to provide assurance they will trigger should temperatures drop too low.	**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 used to present deceased for viewings is old and does not have a mechanism to secure a fridge tray in place. In addition, the brakes on the trolley are not sufficient to prevent the trolley moving during a viewing. There is a risk of accidental damage to the deceased should the trolley and/or tray move. The inspection team identified rust on storage trollies and the barrier used for demarcation purposes in the main PM room. Therefore, these items cannot be adequately cleaned or disinfected. The wooden cross stored on the floor in the body store is porous and cannot be adequately cleaned and disinfected.	**Minor**
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	The fridge in the gynaecology ward used to store foetuses for PM examination is not regularly serviced.	**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 have information relating to consented PM examinations (adult and paediatric/perinatal) available in different languages for relatives.
2.	C1(d)	The DI is advised to include in the information leaflet for relatives for consented PM examinations that where tissue is retained for scheduled purposes, it will be disposed if after three months should it not be used for that purpose within that time frame.
3.	C1(g)	The DI is advised to liaise with the 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.
4.	GQ1(a)	The DI is advised to liaise with staff involved in Sudden Unexpected Death in Childhood (SUDIC) procedures to ensure the working instruction for the process is updated to remove information and forms that are not required as they are causing confusion for staff involved in the process.
5.	GQ1(g)	The DI is advised to appoint a Persons Designated (PD) in the gynaecology ward as storage activity is occurring in this area.
6.	GQ2(c)	To improve the process for mortuary tissue audits the Mortuary Manager is advised to utilise the existing tissue retention spreadsheet for coronial and hospital cases and review the spreadsheet to ensure it contains sufficient detail to aide with tissue audits.
7.	GQ3(a)	The Mortuary Manager is advised to ensure that funeral service staff involved in mortuary activities out of hours maintain training and competency and new staff attend the mortuary for training when required.

8.	GQ6(a)	The DI is advised to include staff training and competency as a control measure in relevant risk assessments and also include references to SOPs.
9.	T1(b)	Although the mortuary has an electronic database system, paper records are still used and kept to refer to information the system does not hold. The DI may wish to consider options for a system that can help to streamline processes and store information in one place.
10.	PFE1(b)	The Mortuary Manager is advised to consider alternative methods to demarcate between dirty, transitional and clean areas in the mortuary.
11.	PFE1(d)	The DI is advised to: • increase CCTV coverage in the mortuary to include current 'blind spot' areas to have oversight of activities in these areas. • consider using existing CCTV cameras in the PM room no longer used for teaching purposes to monitor access to the fridges that can be accessed from the PM room. • highlight to the Trust the area used by funeral directors to admit and collect bodies is also used by staff and others as a smoking area.
12.	PFE1(e)	The DI is advised to: • have oversight of the key used by the trust waste team to access the mortuary bin store, including how many keys are in circulation and the use of the key(s) is recorded. • have the old PM room observation window frosted to prevent oversight of activities in the PM room should the door to this area be open during a PM session.
13.	PFE3(a)	The Mortuary Manager is advised to remove any items of equipment from the isolation PM room not required to be in there and relocate to a more appropriate location in the mortuary.
14.	PFE3(c)	The DI is advised to:

		• ensure that the ventilation system report is made available to the Mortuary Manager in a timely manner. This will help ensure oversight if any issues are identified requiring action and provide assurance that the system is working to the required standard. • identify who in the Trust can assist with face-fit testing staff who work in the PM rooms for FFP3 masks and explore other RPE options for those staff who are unable to wear them.

Background

University Hospital Coventry has been licensed by the HTA since November 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in June 2023 which was a targeted unannounced visit focusing on certain standards. The most recent full inspection took place in January 2022.

Since the previous inspection, there has been additional permanent body storage added on site to help alleviate storage capacity issues during peak times.

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 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, Research Tissue Bank (RTB) and research tissue collections were reviewed. This included standard operating procedures, risk assessments, audits, incidents, meeting minutes, equipment servicing reports and training and competency assessment documents. Consent seeking procedures and information for families giving consent for PM examinations were also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the premises which included the mortuary body storage areas, viewing rooms, PM rooms, the fridge storage area in the gynae ward and the storage area of the RTB and research tissue collections.

Audit of records
The inspection team undertook audits of traceability for five bodies in storage, in both body storage areas. This included a perinatal case, bodies with same/similar names and a body in long term storage. Traceability details were crosschecked between the identification bands on the bodies, information in the mortuary register, paperwork and mortuary electronic record. The bodies with same/similar names were not identified as such. This was not sufficient to amount to a shortfall, but oral advice was given to the establishment at the time of the inspection.

The inspection team undertook traceability audits of the research material held for ten cases in the Arden Tissue Bank. Traceability details were crosschecked between the identifiers on the material and paper records through to consent documentation. For three of the cases audited the consent documentation was not fully completed.

Meetings with establishment staff
The assessment team met with staff carrying out activities under the licence, including mortuary staff, histopathology staff, quality manager, a portering staff member, a pathologist, staff involved in the consent seeking process for PM examinations, the research tissue bank manager and the DI.

Report sent to DI for factual accuracy: 15 January 2025

Report returned from DI: 31 January 2025

Final report issued: 31 January 2025

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.