Inspection report on compliance with HTA licensing standards
Inspection date: **24 and 25 September 2025**

UCL Hospitals NHS Foundation Trust

HTA licensing number 12054

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 College Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Maternity	-	-	*Carried out*
Satellite site **National Hospital for Neurology and Neurosurgery (NHNN)**	Not licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*Carried out*

Satellite site **Department of Clinical Parasitology**	Not licensed	Not licensed	Licensed
Mortimer Market	-	-	*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 UCL Hospitals NHS Foundation Trust ('the establishment') had met the majority of the HTA's standards, one critical, 7 major and 9 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
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	Systems in place do not robustly ensure the traceability of tissue taken at post mortem. During the HTA audit of retained tissue many records were found to be incomplete • Post-mortem tissue consisting of blocks and slides retained for a scheduled purpose were discovered to have been stored for an indeterminate period on unlicensed premises. The Designated Individual (DI) had neither oversight of nor awareness that this tissue was being stored on unlicensed premises, which represents a serious failure in governance and regulatory compliance. • Records did not consistently document the number of blocks and slides present for all patients. • The inspection team identified instances where tissue was additional to that recorded or missing. • Tissue from the living had been incorrectly recorded as post mortem tissue and stored for return to the mortuary. • There were no documented procedures for the management of deceased tissue following histological examination and return to the mortuary from the histology laboratory. *The establishment took immediate action to relocate all tissue to licensed premises and implement a documented procedure for the return of tissue to the Mortuary.*	**Cumulative Critical**
h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements	See T1g above	

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		
c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice	Written information for those giving consent was not provided. While consent forms reference the requirement to have read and understood *A Simple Guide to Post Mortem 2003*, this document is outdated and does not sufficiently reflect the requirements of the Human Tissue Act (HT Act) or the Human Tissue Authority's (HTA) Codes of Practice. This includes but is not limited to: • The guide does not outline the hierarchy of qualifying relationships, which is essential for determining who is legally able to give consent. • It lacks information on the process for withdrawing consent, including the timeframe within which relatives may change their minds. • The document does not include organisation-specific details regarding the post-mortem process or how tissue may be handled following the procedure.	**Cumulative Major**
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	See shortfall against standard C1(c) above	

will be taken if no decision is made by the relatives		
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		

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.	SOPS relating to licensable activities undertaken on the maternity unit were not provided.	**Cumulative Major**
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	The DI has no oversight of HTA related activities within Maternity. There is no Person Designate (PD) within the Maternity unit. This poses a risk of lack of oversight and failure to ensure incidents are reported. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	
GQ2 There is a documented system of audit		

a) There is a documented schedule of audits	Although a documented schedule of audits is in place, it does not include sufficient vertical and horizontal audits of mortuary procedures, that reflects level of activity undertaken at the establishment. The lack of targeted audits limits the ability to monitor compliance effectively across sites and identify associated risks.	**Cumulative Major**
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	The establishment undertake an annual tissue audit on a small sample of cases, of stored tissue in which discrepancies have been identified. The inspection team are not assured that the establishment is aware of what relevant material is being held under the licence or that its retention and disposal is in accordance with both the Human tissue Act 2004 (HT Act) and the families wishes.	
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 inspection team are not assured that there is adequate management of the retained tissue taken at PM which means that tissue may not be disposed of in line with the families wishes.	**Cumulative Major**
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	There is no documented procedure for the management of retained tissue that demonstrates effective systems are in place for communication with the Coroner's Office. In the absence of such procedures, there is a risk that tissue may be retained longer than necessary.	
c) Disposal is in line with the wishes of the deceased's family	The inspection team were not assured that robust procedures are in place to ensure disposal is in line with the relatives wishes.	

d) The method and date of disposal are recorded	The method and date of disposal were not recorded on some of the records relating to stored tissue provided.	
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	**Hub Site** A recent review of swipe access to the mortuary identified 140 personnel are provided with access to the mortuary. This includes, but is not limited to: • Portering staff • Bed Management Team • Site Teams • Logistics Staff • Waste Management Staff • Contractor Access Card • Operations Team • Pathology Business Manager Staff have indicated that they have limited control over access permissions due to the building being managed under a Private Finance Initiative (PFI). However, it remains the responsibility of the DI to ensure that access is authorised, appropriate, and limited to those with a legitimate right of access, both during and outside of standard working hours. A door from the main physiotherapy department waiting area leads directly into the mortuary. Although swipe access is required, it is unclear who has access via this route and whether this entry point is included in routine security audits. Visitors' logs are not used to record attendance of visiting UCL staff furthermore these are not included in the security audits. The inspection team were unable to establish if a suitable back up system is in place for electronic locks on mortuary access doors in the event of a power failure. The main mortuary corridor serves as the emergency exit route for the pharmacy. The inspection team found that one emergency exit security dome	**Major**

	on the door had been removed and one broken permitting access into the mortuary corridor. Funeral directors are currently granted access to toilet facilities located within the high-risk changing rooms. This area connects directly to the post-mortem (PM) room, presenting a risk of unauthorised access or inadvertent observation of post-mortem activities. Additionally, the main male and female changing rooms also provide direct access to the PM room. This also poses a risk unauthorised access or inadvertent observation of post-mortem activities. The panic alarms situated in the office, viewing rooms and relatives' room are not routinely tested. **Maternity** Although swipe access is required to enter the area is unclear to how this is managed. Evidence to demonstrate access is audited was not provided. **NHNN** The mortuary facility is located in an area with minimal footfall and no external CCTV coverage. Currently, access to the mortuary is controlled via physical keys, with swipe card access scheduled for implementation by December 2025. Internal CCTV coverage is in place at the mortuary's entrance and exit points, and footage is reviewed by staff Monday to Friday. Audit findings have identified instances where agency portering and domestic staff accessed the mortuary using keys who were not listed as those authorised to do so. Additionally, the mortuary is not fitted with panic alarms and due to the isolated location, this poses a risk to staff lone working *See advice PFE1(e) below*	
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	**Hub Site** Although the upper temperature trigger point for the fridges is tested, current procedures do not include testing of the lower temperature trigger point. Additionally, alarm testing of the fridge and freezer units outside of normal working hours (OOH) is not undertaken. This does not provide assurance that alarms will trigger correctly or that OOH procedures are effective in the event of a failure. Staff were unable to confirm the alarm parameters and trigger points. Furthermore, the parameters recorded in the engineer's annual maintenance report suggest that the current settings pose a significant risk of accidental damage to the deceased should a failure occur. **NHNN** Testing of fridge alarms is not undertaken, and staff were unable to advise of the current alarm parameters. **Maternity** Evidence to demonstrate fridges are alarmed or testing of alarms is undertaken was not provided.	**Major**

f) Temperatures of fridges and freezers are monitored on a regular basis	**Maternity** Although temperature recording sheets were present on both fridges for July and August, they had not been completed. No evidence of temperature monitoring within the maternity unit was provided. Additionally, staff were unable to confirm whether the fridges are equipped with audible alarms or if the fridge temperatures are remotely monitored. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Matters relating to Human Tissue Authority (HTA) licensed activities are discussed at mortuary meetings, however this is not a standing agenda item. Furthermore, these meetings do not include staff working in other relevant areas, such as maternity services. This limits the opportunity for effective communication, shared learning, and oversight across all areas where licensable activities occur. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**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	The procedure document titled *Incident Handling and Reportable Incidents MOR 932* does not contain up-to-date information regarding HTA reportable incidents. A previous incident involving equipment failure was initially assessed as not meeting the threshold for HTA reporting. However, a review of the establishment's incident log revealed discrepancies between the internal records and the information submitted to the HTA. The internal documentation suggests that the incident would have met the threshold for reporting. Additionally, while maternity staff are aware of the Trust's general incident reporting requirements, they are not familiar with the definition of HTA reportable incidents or the obligation to report such incidents or near miss to the HTA.	**Minor**

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	The Risk assessment relating to security at both sites is currently in draft format and incomplete. The process for release from NHNN has not been risk assessed to include the route through the laundry area and oversight by offices overlooking the loading area.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		

b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records)	Although the three identifiers provided by funeral staff at the time of release are verified against the patient file and wristband, the mortuary register which undertakers are required to sign to confirm identity and receipt contains only one of these identifiers. This limits the ability of funeral directors to confirm that the patient's identity matches all the identifiers provided. Wristbands containing patient identifiers are attached to the zips of body bags. This practice presents a risk that staff may, when busy, rely solely on the wristband attached to the bag for identification, rather than conduct physical checks of identifiers directly on the body. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised*	**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	At the time of inspection, the majority of areas appeared to be clean and well maintained, however the inspection team identified the following areas that require attention: **Hub Site – Main Post-Mortem (PM) Room** • Areas of lime scale were observed on the floor. • Tissue debris was present on one of the PM tables. • Heavy lime scale deposits and rusting were noted on the dictation system pedals. • Decommissioned equipment remained in situ, preventing effective decontamination of surrounding surfaces. • Equipment was stored in an unused sink, indicating inappropriate storage practices. **Hub Site – High Risk Suite** • Brown residue was present around organ bowls. • Brown staining was visible on the PM table. • A strong odour was present, emanating from the drainage system. **Transition Area Between PM Rooms** • Dust and debris were present on the flooring in the transition area, suggesting inadequate cleaning protocols. **Satellite Site – NHNN** • At the time of inspection, lighting in the entrance/relatives' area was not operational, potentially impacting the environment for bereaved families.	**Minor**

	• In the body store, an area was visible where the flooring upstands had separated from the wall, exposing a porous surface. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised*	
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	**Hub Site** Cleaning records for the main pm room were provided, however this is only undertaken when post mortems are conducted and can be left for significant periods of time without any additional cleaning taking place. Cleaning records for the High-risk suite were not available. **Satellite site NHNN** Cleaning records are not completed for this site. **Maternity** Although at the time of inspection fridges appeared clean records to demonstrate regular cleaning is undertaken were not provided.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

a) Storage arrangements ensure the dignity of the deceased	**<u>Hub Site</u>** The opening of the body store doors internally is via a motion sensor located on the wall. The sensitivity of the motion detector causes the doors to open when not required. *See advice item PFE2(a)* **<u>NHNN</u>** There is a gap in the doors when closed between the viewing room and the body store allowing for oversight to the body store which can also observed through a gap in the doors from the hospital corridor. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised*	**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 inspection team identified the following that require attention • The extraction unit was not used routinely with the necropsy saw in the main PM room line with *HSE guidance Managing infection risks when handling the deceased.* • Damaged wooden edging on fridges exposing porous surface in body store • Patches of rust and flaking pain present on the hoist in the High-Risk PM room • Rusting present on necropsy saw unit in the High-risk PM room • The numbering of fridges on some banks does not correlate with the number of spaces present. The current method employed to record occupancy of the unnumbered space is not robust. **NHNN** • Flaking paint and areas of rusting were observed on the hoist.	**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	Records were not provided to indicate that the fridges on the maternity are subject to regular servicing or maintenance	**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 use the information in the HTA's Code A 'Guiding principles and the fundamental principle of consent' and the HTA's model consent form to help produce the information given to relatives for adult consented PM examinations
2.	T1(b)	DI is advised to review content to ensure the identifiers provided for patient identification are included within the mortuary register.
3.	GQ4(c)	The mortuary registers include detailed information relating to the deceased's cause of death and medical history. The DI is advised to review the content of the register and consider the inclusion of sensitive personal patient information and its relevance.
4.	PFE 1(e)	The DI is advised to improve lone working measures to reduce risks to staff when working at the satellite site considering the use of panic alarms or lone worker devices.
5.	PFE2(a)	The DI is advised to consider replacement of the motion sensor to ensure the doors from the body store open only when required to prevent any unauthorised oversight of activity.
6.	PFE3(a)	Whilst the mortuary ventilation is subject to regular testing and maintenance the sound levels exceed that of the recommended safe volume. Additionally, the recent report suggest replacement should be considered in line with HTM03-01 requirements. The DI is advised to consider the findings provided within the recent servicing report.

Background
UCL Hospitals NHs Foundation Trust has been licensed by the HTA since 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in April 2024

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, cleaning records for the mortuary, contracts for servicing of equipment and records of servicing, audits, risk assessments, meeting minutes, staff training and competency records and reported incidents. Documentation relating to some licenced activities undertaken in the maternity unit were not provided.

Visual inspection

The inspection team undertook a visual inspection of the premises at the hub, and satellite sites under the licence. This included. body storage, PM room, viewing areas, maternity and the funeral director loading area at the Hub and satellite.

During the visual inspection the inspection team also observed admission and release of the deceased.

Audit of records

The inspection team undertook audits of traceability of six bodies in storage including one in long term storage. Traceability details were crosschecked between the identification bands on the body, information on the body store door, patient documentation and the mortuary register. No discrepancies were identified.

A tissue audit identified discrepancies in the recording of blocks and slides, the outcome of which resulted in the inspection team attending the histology laboratory where post-mortem tissue consisting of blocks and slides retained for a scheduled purpose were discovered to have been stored for an indeterminate period on unlicensed premises.

Meetings with establishment staff

The inspection team conducted interviews with the Designated Individual and staff carrying out processes under the license. This included the Mortuary Manager, Anatomical Pathology Technician, Mortuary Assistant, portering staff and portering supervisor and a bereavement midwife. An adult hospital consent taker was not available for interview

Report sent to DI for factual accuracy: 12/11/2025

Report returned from DI: 27/11/2025

Final report issued: 23/12/2025

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.