Licence application assessment visit report on compliance with HTA licensing standards
Site visit date: **14 & 15 November 2024**

Chelsea and Westminster Hospital NHS Foundation Trust
Proposed HTA licensing number 12783

Application for a licence under the Human Tissue Act 2004

Activities applied to be licensed.
The table below shows the proposed activities this establishment is to be licensed for and the proposed activities to be 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 **Chelsea and Westminster Hospital**	Not applied to be licensed	Not applied to be licensed	Applied to be licensed
Mortuary			*Applied to be carried out*
Satellite site **West Middlesex University Hospital**	Not applied to be licensed	Not applied to be licensed	Applied to be licensed
Mortuary (satellite site)			*Applied to be carried out*

Summary of visit findings

The HTA found the proposed Designated Individual (DI) and the proposed Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Chelsea and Westminster Hospital NHS FT (the establishment) had met the majority of the HTA's standards, two cumulative major, six major and four minor shortfalls were found against standards for Consent, Governance and Quality, 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 site visit.

Compliance with HTA standards

Major shortfalls

Standard	Visit 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 consent policy does not reflect the requirements of the Human Tissue (HT) Act 2004 and the HTA's codes of practice.	**Cumulative Major**
b) There is a documented standard operating procedure (SOP) detailing the consent process	There are no documented standard operating procedures (SOPs) which detail the process for seeking consent for perinatal post mortem (PM) examinations at West Middlesex Hospital	
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	No evidence of consent training was submitted for staff involved in the consent seeking process for perinatal PM examinations at West Middlesex Hospital which addresses the requirements of the HT Act and the HTA's codes of practice.	**Cumulative Major**

b) Records demonstrate up-to-date staff training	The establishment does not have a process to identify which staff have received consent training and when refresher training is due.	
d) Competency is assessed and maintained	Competency in seeking consent has not been assessed and maintained.	
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
c) Staff are assessed as competent for the tasks they perform	Although staff have been initially 'signed off' on completion of training, there is no on-going competency assessments for staff at both Chelsea and Westminster Hospital and West Middlesex Hospital.	**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	All procedures relating to licensed activities have not been risk assessed.	**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	Three identifiers are not obtained from those wishing to view the deceased. The procedure for conducting viewings does not include steps to check a minimum of three identifiers: • When transferring the deceased into the viewing room; and • of the deceased provided by relatives against the identification on the body before a viewing takes place.	**Major**
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	Issues were identified with the maintenance of the establishment, making it difficult to adequately clean or decontaminate this area, posing a potential health and safety risk to mortuary staff and visitors. Issues include but are not limited to: <u>West Middlesex Hospital</u> • seal at base of fridges is deteriorating. • Mould present on seals of the fridges. • Rust of a number of fridges latches. • Small areas of exposed plaster in body store. <u>Chelsea and Westminster Hospital</u> • Seal at base of fridge deteriorating. • Area of rust at base of fridge; and • Exposed plaster in body store.	**Major**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The area that the funeral directors park to admit and collect bodies is next to the entrance to the hospital in the public car park. The car park is in constant use and there is a risk that the public and Trust staff can oversee into the garage area to the where additional fridges are situated when the doors are open. This activity has not been risk assessed and does not ensure the dignity of the deceased.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	Long term storage of bariatric deceased is not sufficient to meet needs.	**Major**

Minor Shortfalls

Standard	Visit findings	Level of shortfall
GQ4 There is a systematic and planned approach to the management of records		
b) There are documented SOPs for record management which include how errors in written records should be corrected	The inspection team noted that the mortuary register had blocked out corrections which means that the register cannot be audited satisfactorily.	**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 include all mitigating controls that are in place.	**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	At the time of the inspection fridges on the maternity unit are not alarmed. The establishment is currently in the process of procuring alarms.	**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 hydraulic trolleys at both Chelsea and Westminster Hospital and West Middlesex Hospital have large areas of rust. This makes the equipment difficult to clean and decontaminate.	**Minor**

Advice
The HTA advises the proposed DI to consider the following to further improve practice:

Number	Standard	Advice
1.	C1(g)	The proposed DI is advised to review the perinatal consent form to ensure that references to the codes of practice are up to date.
2.	GQ2(a)	The proposed DI is advised to include the auditing of consent forms in the audit schedule.
3.	PFE1(d)	The proposed DI is advised to look at installing swipe card access to the body store doors at West Middlesex Hospital. The proposed DI is advised to introduce a schedule of changing the key codes as part of the security risk assessment.
4.	PFE2(f)	The proposed Di is advised to include an audit of the maternity fridge temperatures while an alarm system is procured to ensure that temperatures do not fall outside of the optimum range.

Background
Chelsea and Westminster Hospital NHS Foundation Trust (FT) and West Middlesex University Hospital are under one NHS Trust umbrella. The hub site would be Chelesea and Westminster Hospital NHS FT with West Middlesex University Hospital being the satellite site.

Description of activities undertaken during visit
The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during the visit:

Standards assessed against during visit.
Standards GQ1(b), GQ2(c), T1(g), T2 (a-d), PFE3(c) and PFE3(e) were not assessed as they are not applicable to the activities undertaken. The remaining 63 HTA licensing standards (standards published 3 April 2017) were assessed.

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, records of equipment servicing, audits, risk assessments, meeting minutes, temperature monitoring records, staff training records and reported incidents.

Visual inspection
The inspection included a visual inspection of the mortuary body store and viewing room.

Report sent to proposed DI for factual accuracy: 19 December 2024

Report returned from proposed DI: 7 January 2025

Final report issued: 24 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 site visit 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, and.
- 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, or.
   - 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 site visit.

   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 the 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 site visit inspection.
- a request for information that shows completion of actions.
- monitoring of the action plan completion.

- follow up at next routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.