Inspection report on compliance with HTA licensing standards
Inspection date: **18 September 2024**

Royal Free Hospital

HTA licensing number 12013

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 Royal Free Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Maternity	-	*Carried out*	*Carried out*
A&E	-	*Carried out*	
Satellite site Barnet Hospital	Licensed	Licensed	Licensed
Mortuary (satellite site)	-	-	*Carried out*
Maternity	-	*Carried out*	*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 Royal Free Hospital ('the establishment') had met the majority of the HTA's standards, three major and two minor shortfalls were found against standards for 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
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	The inspection team were not assured significant risks on the corporate risk register are being actioned in a timely way. Whilst assurance was provided there are plans in place to recruit more staff, the mortuary has been operating on reduced staff numbers for the previous 12 months, which has led to staff regularly lone working. This poses the risk of a serious incident. *See Advice item one.*	**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	Family members are asked to provide three identifiers when attending the mortuary for a viewing. These do not correspond with information held on the ID bands. This poses the risk of a viewing of the wrong body. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
d) Fridge and freezer units are in good working condition and well maintained	Whilst fridge and freezer units are subject to regular maintenance, significant damage has been sustained to the fridge units at the satellite site. Additionally, the inspection team identified damage to some fridge door seals. This poses the risk of a major equipment failure. Furthermore, there is rusting to the fridge bases and internal racking which poses the risk of ineffective decontamination.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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	The post mortem (PM) suite at the hub site has some areas of exposed wood where door frames have been damaged. Additionally, there is some rusting at the base of the PM tables and on the scales used to weigh bodes. This poses the risk of ineffective decontamination.	**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	Whilst fridge and freezer alarms are regularly tested, a test of the lower set range is not carried out on mortuary and maternity fridge units. Furthermore, temperature trend analysis is not routinely undertaken to identify trends and the extent of any variations in storage temperatures. This poses the risk of an incident pertaining to the accidental damage to a body. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**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.	GQ6(a)	The DI is advised to consider the introduction of a “man down” alarm for staff to use when lone working at the hub and satellite sites.
2.	GQ6(c)	The DI is advised to undertake a staffing review and process mapping in preparation for the planned merging of mortuary services with another NHS Trust. This will mitigate the risk of insufficient staff to manage the anticipated increase in the volume and complexity of work.

3.	PFE2(b)	The DI is advised to look at the Integrated Care System population for bariatric and super-bariatric patients residing within the merged Trust catchment area. This will help with resilience and future-proofing the mortuary capacity.
4.	PFE3(c)	Whilst the Post Mortem (PM) suite at the satellite unit is not in use and the ventilation system is regularly serviced, the DI is advised to action the findings from the most recent maintenance and service report should the decision be made for PM examinations to recommence.

Background

Royal Free Hospital has been licensed by the HTA since 2007. This was the fifth inspection of the establishment and was unannounced; the most recent previous inspection took place in October 2022.

Since the previous inspection, Barnet Hospital has been added to the licence as a satellite unit. There have been no changes to key personnel.

There is a planned merger between Royal Free Hospital NHS Foundation Trust and North Middlesex University Hospital NHS Trust in January 2025, this will lead to a review of mortuary services and the activity undertaken at the Hub and Satellite sites.

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

69 out of the 72 post mortem standards were covered during the inspection. Three standards (GQ2(c), T2(a) and T2(d)) are not applicable. The establishment does not store or dispose of tissue blocks and slides.

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, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and training records for both the mortuary staff and porters.

Visual inspection
The inspection included a visual assessment of the mortuary body storage areas, PM room and viewing suite at both the hub and satellite sites. The inspection teams observed the processes for admission and release of bodies within the mortuary.

Audit of records
Audits were conducted onsite of four bodies in refrigerated storage and one body in long term frozen storage at the hub site. At the satellite site, an audit of one body in refrigerated storage and two bodies in long term frozen storage was carried out. The release of one body into the care of the Funeral Director was observed at the hub site. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork in addition to information held electronically. Two minor discrepancies were identified at the satellite site which were immediately rectified.

Meetings with establishment staff
Staff carrying out processes under the license were interviewed including the DI, Mortuary Manager, Trainee APT, Porter, Pathologist and Perinatal Consent Seeker.

Report sent to DI for factual accuracy: 22/10/2024

Report returned from DI: 04/11/2024

Final report issued: 08/11/2024

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: 25 February 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.