Inspection report on compliance with HTA licensing standards
Inspection date: **27 January 2022**

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*
Pathology lab			*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, seven major and ten 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
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 lack sufficient detail. Key steps are included but these do not specify the individual actions that need to be undertaken to accomplish each step. These include, but are not limited to, SOPs detailing the process for: • admitting, storing and release of bodies; • post-mortem examination; • identification of deceased for viewing of bodies; and • out of hours release of bodies. This is not an exhaustive list of the SOPs requiring amendment. To fully address this shortfall the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate and contain sufficient detail to reflect current practice. *See advice item 1*.	**Major**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The scope of the audit schedule for activities conducted under the licence is limited. The audit schedule does not include sufficient vertical and horizontal audits to check compliance with documented procedures, the completion of records, and traceability of bodies and samples.	**Major**
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	Audit findings have not been investigated fully. This means it is difficult to understand the root cause of the failure to comply with the establishment's procedures. Audit findings do not state who is responsible for the root cause analysis or who is responsible for implementing corrective actions. No dates for completion of findings have been included.	**Major**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	External staff e.g. Porters and Site Managers have had initial training which has been signed for attendance. However, the establishment could not provide documentation showing that staff had received refresher training and competency (re)assessment.	**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 establishment's procedure for release of bodies out of hours does not make clear that documentation brought by Funeral Directors must include a minimum of three identifiers of the deceased.	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The bay area prevents Funeral Directors from reversing their vehicles into the area. There is a risk that passers-by at ground level, residents of flats overlooking the bay area and those on the walkway above could view movement of bodies in and out of the mortuary. During the inspection it was observed that the cover placed over the body on a trolley nearly came free on the slope whilst a Funeral Director was collecting the body.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

a) Storage arrangements ensure the dignity of the deceased	The establishment uses the base of the freezer unit for body storage. The body trolley does not lower to the level of the storage trays used; this means that bodies stored in this location are subject to additional manual handling when being placed into and removed from the body storage units. This practice poses an increased risk of accidental damage to the deceased. The Funeral Director's route from the mortuary to the transport vehicle is via a steep uneven slope. The width of the slope prevents Funeral Directors from transporting bariatric bodies via this route and instead requires the body to be transported via public access routes. There is an increased risk of accidental damage to the deceased and this does not ensure the dignity of the deceased is preserved.	**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	Staff have initially signed that they have read and understood the SOPs, however the latest versions of the SOPs have not been signed.	**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 licensed activities in the mortuary has not been reviewed regularly. The risk assessment was last reviewed in 2019.	**Minor**
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).	At the time of the inspection the establishment does not receive confirmation of receipt of toxicology samples that are sent away for analysis.	**Minor**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
d) The method and date of disposal are recorded	The method and date of disposal is not recorded for blocks and slides.	**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	The body store and PM room are showing slight signs of wear and require some maintenance to remain fit for purpose. There are small areas of damage to walls and doors, leading to exposed porous plaster and wood. The seal was coming away from the walls in some areas of the body store and PM room resulting in gaps between the floor covering and the walls. This means that these areas are difficult to clean and disinfect adequately.	**Minor**
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	Due to the temporary Nutwell in place in the PM room, the pass-through fridges are not in use. Bodies have to be transferred from the PM room to the body store on trolleys to place them back into refrigerated storage. No cleaning or decontamination of the trolleys takes place between the movement of the bodies from the PM room following or during PM examinations.	**Minor**
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)	There are no CCTV cameras facing the Funeral Director's entrance.	**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 lower temperature alarm trigger point for the fridges is not set at an appropriate temperature to ensure that the alarm will trigger when the storage temperature deviates from acceptable ranges.	**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 hoists are suffering from slight signs of wear and tear; small areas of rust and peeling paint were seen making it difficult to clean and decontaminate sufficiently.	**Minor**
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The ventilation records were not seen by the inspection team at the time of the inspection.	**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.	GQ1 (a)	Many SOPs have been in the review folder for a significant length of time. Changes to practices have been made during the time the documents have been under review, however, staff do not have up to date SOPs from which to work from. The procedures for hospitals under the Trust have been combined

		under one governance framework; the DI is advised when reviewing SOPs to consider amalgamating the parts of the procedure that apply to both hospitals.
2.	GQ5 (a)	The DI is advised to have aide memories on the labour and gynaecology wards where storage of tissue and bodies occurs to ensure all staff know how to identify and report incidents that are reportable to the HTA.
3.	T1 (b)	The DI is advised to add the fridge number to the electronic spreadsheet of any bodies transferred from the fridge to freezer for auditable purposes.
4.	T1 (c)	The DI is advised to add a further identifier to the body tag for babies to ensure that three identifiers can be sourced from tags, mortuary register and electronic spreadsheet.
5.	PFE2 (c)	The DI is advised to risk assess the long-term freezer storage capacity for bariatric bodies to ensure that contingency plans are in place in the rare occurrence that the establishment needs to transfer a bariatric body to a freezer.
6.	PFE2 (f)	The DI is advised to introduce a formal system to review and record trends in storage temperatures of fridges in the body store and on the labour and gynecology wards.
7.	N/A	The DI is advised to consider bringing Barnet hospital onto this licence (12013) as a satellite site instead of a separate licence as they are under the same NHS Foundation Trust and have the same governance framework.

Background

Royal Free Hospital (RFH) has been licensed by the HTA since 2010. This was the fourth inspection of the establishment; the most recent previous inspection took place in November 2017.

Since the previous inspection, post-mortem examinations have resumed in 2019.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection

All 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

The inspection included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records for the mortuary and post-mortem room, records servicing of equipment, audits, risk assessments, meeting minutes, reported incidents and staff training records.

Visual inspection

The inspection included a visual inspection of the mortuary body store, PM room, viewing room and maternity fridges.

Audit of records

Audits were conducted for four bodies in refrigerated storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and electronic database. No discrepancies found.

Audits of traceability were conducted for tissue blocks and slides from four PM cases, including audits of the consent documentation for the retention of these tissues. No discrepancies found.

Meetings with establishment staff

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

Report sent to DI for factual accuracy: 23 February 2022

Report returned from DI: 4 March 2022

Final report issued: 21 March 2022

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 21 June 2023

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as ‘Critical’, ‘Major’ or ‘Minor’. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the Human Tissue Act 2004 (HT Act) or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the HT Act or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   - A notice of proposal being issued to revoke the licence
   - Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or

- indicates a breach of the relevant Codes of Practice, the HT Act and other relevant professional and statutory guidelines, or
- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

   This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk-based review or at the time of the next inspection.

   In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. Establishments must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

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