Inspection report on compliance with HTA licensing standards
VRA and site visit: 24 April and 26-27 April

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	Not licensed	Not licensed	Licensed

Department of Clinical Parasitology			
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.

UCL Hospitals NHS Foundation Trust ('the establishment') was found to have met all HTA standards.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

Number	Standard	Advice
1.	C1 (a)	<u>Hub site</u> Perinatal deaths which require a PM examination are transferred to another HTA licensed premises. The other establishment provides consent forms and training to UCLH staff. The maternity department may wish to consider a review of the agreement to ensure it details the frequency of refresher training and how this will be monitored and communicated to staff at UCLH.

2.	C1 (a)	Department of Clinical Parasitology The establishment is advised to confirm that written consent is obtained wherever possible for all activities involving deceased tissue. If verbal consent is obtained, this should be clearly documented in the patient's records.
3.	C2 (d)	Hub site Competency checks are completed of consent forms, however these are not recorded. The establishment is advised to formalise this process.
4.	GQ1 (h)	Hub site and NHNN The establishment is advised to formalise the process of refresher training for porters.
5.	T1 (c)	NHNN The instruction card in the mortuary for viewings should be updated to include the requirement to check a minimum of three identifiers of the deceased on the body and check this against the details provided by the family members when they arrive to the mortuary for viewings.
6.	PFE1 (a)	Hub site The establishment is advised to continue with their plans to refurbish the viewing room.
7.	PFE2 (a)	Hub site Mortuary staff are advised to review the upper and lower trigger points for fridge temperature alarms to ensure there is no risk of bodies deteriorating or being frozen when in refrigerated storage. Staff in maternity should confirm with the appropriate department the range at which the alarm will trigger when temperatures deviate. This is to ensure themselves that temperatures are set within an appropriate range.
8.	PFE3 (a)	NHNN

		Staff occasionally use a wooden measuring stick to measure the deceased. Mortuary staff are advised to discontinue use as this cannot be easily cleaned or disinfected.

Background

The establishment has been licensed by the HTA since May 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in February 2018.

Since the previous inspection, the establishment has revoked the satellite sites at the Department of Pathology and Ormond House which are no longer conducting licensable activities.

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 assessment 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 were reviewed. Traceability audits, risk assessments, meeting minutes, incidents, consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the premises at the hub and satellite sites under the licence. This included the mortuary body storage area, the temporary body storage units, the PM room and viewing room at the hub site and the mortuary body storage area at the National Hospital for Neurology and Neurosurgery (NHNN). A visual inspection was also undertaken of the premises at the Department of Clinical Parasitology.

Audit of records

Audits were conducted for two bodies in refrigerated storage and one in freezer storage at the hub site and one body in refrigerated storage at NHNN. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and relevant documentation. No discrepancies were found.

Audits of traceability were conducted for tissue blocks and slides from three hospital consented PM cases, including audits of the consent documentation for the retention and disposal of these tissues. A traceability audit was also conducted of a relevant material that was removed at the hub site and sent to NHNN. In addition a traceability audit was conducted of relevant material from the deceased at that the Department of Parasitology. No discrepancies were found.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including the DI, Anatomical Pathology Technologists, porters involved in mortuary activities, consent seekers and staff involved in licensable activities at NHNN and the Department of Parasitology.

Report sent to DI for factual accuracy: 26 May 2023

Report returned from DI: No factual accuracy comments received

Final report issued: 15 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.