Inspection report on compliance with HTA licensing standards
Inspection date: **18 January 2023**

Queen Mary University of London
HTA licensing number 12004

Licensed under the Human Tissue Act 2004

Licensed activities

Area	Carrying out of an anatomical 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 a body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose	Storage of an anatomical specimen
Hub site **Queen Mary University of London**	Licensed	Licensed	Licensed	Licensed
Satellite site **The Whitechapel Galleries**	Licensed	Licensed	Licensed	Licensed
Satellite site **Bart's Pathology Museum**	Licensed	Licensed	Licensed	Licensed

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 Queen Mary University of London ('the establishment') had met the majority of the HTA's standards, four minor shortfalls were found against standards for Governance and quality systems, Traceability and Premises, facilities and equipment. The shortfalls related to Standard Operating Procedures, documenting staff training, records for the collection held at The Whitechapel Galleries, and the lack of an assessment of the premises at The Whitechapel galleries.

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

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		

a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.	Establishment Standard Operating Procedures (SOPs) did not provide sufficient detail for all licensable activities. For example: • SOPs related to the receipt and handling of human cadavers did not detail checks to be made when receipting a body, or what to do if there is an inconsistency with the records provided; • SOPs related to releasing a cadaver did not state that organs and tissue removed from the body need to be placed in the coffin; • While staff are trained in embalming, and follow a specified process, this had not been detailed in a documented SOP; and • There was no SOP detailing the cleaning and decontamination procedures followed by the establishment. In addition, SOP 1: Security, SOP 2 Health and Safety Procedures, and SOP 10 Recognising and Recording Adverse Events - related to The Whitechapel Galleries - were last reviewed in November 2020 and were due for review in December 2022. ***The establishment submitted sufficient evidence to address this shortfall before the report was finalised.***	**Minor**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
a) Qualifications of staff and all training are recorded, records showing attendance at training.	An external party provides training on embalming to establishment staff. Attendance at, and scope of, the training had not been documented for individual staff members. ***The establishment submitted sufficient evidence to address this shortfall before the report was finalised.***	**Minor**

T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail.		
b) A register of donated material, and the associated products where relevant, is maintained.	At the time of inspection, although the establishment was generating a catalogue of the specimens held in storage at The Whitechapel Galleries, this was incomplete.	**Minor**

PFE1 The premises are secure and fit for purpose.		
a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.	The establishment has been unable to provide an assessment of the premises for The Whitechapel Galleries.	**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 practices:

Number	Standard	Advice
1.	GQ1(a)	SOP 1 Bart's Pathology Museum: Security refers to an area which is no longer licensed. To prevent confusion and the possibility of material being stored in areas not covered by the licence, the DI is advised to update documents to ensure they refer only to areas currently licensed.
2.	GQ1(a)	To improve consistency and strengthen governance arrangements, the DI is advised to ensure that document review dates are added to all SOPs.
3.	GQ2(a)	The DI is advised to consider implementing a formalised schedule of procedural horizontal audits in addition to the vertical audits of records and specimens currently being undertaken. This may help to ensure that SOPs accurately reflect the practices being carried out.
4.	GQ6(a)	Establishment staff have identified areas of risk associated with licensable activities, and these are detailed in establishment SOPs. For example, 'SOP1: Security' outlines who has access to specific areas of the anatomy laboratory, security arrangements (including CCTV coverage and access log retention), and response to adverse events (including fire or security breaches at the Centre). The DI is advised to highlight risk assessments; for example, in a specific section of the relevant SOP, or in separate documented risk assessments. This may facilitate a wider understanding of the potential risk/s for each activity and the mitigating actions.
5.	PFE2(c)	The establishment begins the embalming process when bodies are received. Occasionally, a body may be received too late to begin embalming immediately, and may be stored overnight in a

		refrigerated body store. The DI is advised to implement a process to provide an assurance that the refrigerated store is working within expected parameters.
6.	PFE3(a)	The DI is advised to consider obtaining a second formaldehyde meter to enable measurement of formaldehyde when the current unit is sent for calibration, and as a contingency for the current meter.

Background

The establishment is licensed for the full suite of anatomy sector activities. The establishment receives bodies through the London Anatomy Office (LAO) which are embalmed on site. The anatomy laboratory is able to accommodate 60 students, supervised by up to 10 staff members.

Queen Mary University of London has been licensed by the HTA since 2007. This was the second inspection of the establishment; the most recent previous inspection took place in November 2012. In addition to using donated bodies for anatomical examination, the establishment also retains prosections that are prepared on site, 'potted' specimens and skeletal material. While the anatomy suite is at the establishment's hub site, there are also two satellite facilities for the storage of anatomical specimens and other relevant material, which may be used for training medical students. At the time of the inspection, only 'potted' specimens were being held at the Whitechapel site and the DI confirmed there was no storage of anatomical specimens or other relevant material at the Bart's Pathology Museum site.

Since the previous inspection, the establishment had ceased activities in two of the three Whitechapel Galleries, and had appointed a new DI, and several new Persons Designated.

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
40 out of 47 HTA licensing standards were covered during the assessment (standards published 3 April 2017). Some standards relating to consent procedures (C1(a), C1(d), C1(e), and C1(f)) and standards relating to consent training (C2(a), C2(b) and C2(c)) were not applicable as the establishment does not directly seek consent from donors.

Review of governance documentation
Policies, procedural documents, and records relating to licensed activities, including standard operating procedures, risk assessments, audits, traceability systems, adverse incidents, staff training records, visitor management policies and visitor codes of conduct were assessed.

Visual inspection
The inspection included a visual inspection of the anatomy suite at the hub site and the area where relevant material is stored at The Whitechapel Galleries satellite site. The visual inspection at the hub site included a review of the area where funeral staff deliver and collect bodies, the temporary body storage and embalming area, the anatomy laboratory where anatomical training is undertaken, storage areas for prosections and other relevant material, and staff offices where records are kept. At The Whitechapel Galleries, a review was undertaken of the area where potted specimens were stored.

Storage of material at the Bart's Museum satellite site occurs in an area also licensed for Public Display activities under the Bart's Pathology Museum (HTA licensing number 12625). This licence was inspected in October 2022 and, in consideration of the lack of activity occurring under the Queen Mary University of London (HTA licensing number 12004), the Bart's Pathology Museum satellite was not inspected on this occasion. Findings related to the premises may be reviewed in the published inspection report for HTA licensing number 12625.

Audit of records
An audit was undertaken of records and labelling for one embalmed body in the storage area, two bodies in the anatomy laboratory (one in use for undergraduate training and one for postgraduate training), two potted specimens, and one prosection in the anatomy laboratory. No discrepancies were identified. The most recent audit of the anatomy laboratory was also reviewed (see Advice, item 3).

Meetings with establishment staff
The inspection included discussions with the DI, the Director of Anatomy, Persons Designated working under the licence, the establishment's Learning Resources Manager (the DI for HTA licence 12625), and the assistant curator for the Bart's Pathology Museum.

Report sent to DI for factual accuracy: 23 February 2023

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 4 April 2023

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: 30 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 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 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.