Inspection report on compliance with HTA licensing standards
Inspection date: **27-28 October 2022**

Bart's Pathology Museum

HTA licensing number 12625

Licensed under the Human Tissue Act 2004

Licensed activities

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose	Use, for the purpose of public display, of the body of a deceased person, or relevant material which has come from the body of a deceased person
Bart's Pathology Museum	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 Bart's Pathology Museum ('the establishment') had met the majority of standards, a cumulative major shortfall was found against standards for 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 shortfall

PFE1 The premises and facilities are secure and safeguard the dignity of the deceased and the integrity of human tissue		
a) Areas used for storage or public display provide an environment that is safe for staff and visitors and preserves the integrity of the material and the dignity of the deceased.	The ceiling of the room that stores potted specimens has significant water damage. This has created a hole in the ceiling and staff were unable to provide documented evidence at the time of inspection there were no water leaks. In addition, the conservation laboratory and the museum itself also had water leaking into the room where specimens are stored.	**Major (cumulative)**
d) A documented risk assessment has been carried out of the premises to ensure they are appropriate for licenced activities.	The establishment has not risk assessed the following: • Flooding in the areas where specimens are stored and potential damage to specimens • Equipment and Personal Protective Equipment (PPE) required for work in the conservation laboratory	

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)	The DI is advised to update SOP 4 ‘Access and Display’ to specify that storage of relevant material also takes place under the anatomy licence by agreement.
2.	T1 (a)	The DI is advised to continue a centralised approach to manging traceability of specimens. This is to ensure all staff working under the licence are aware of the traceability records held and how to access them if needed.
3.	PFE1 (f)	The DI is advised to incorporate regular audits of swipe card access into the museum.

Background

The establishment has been licensed by the HTA since July 2014. This was the second inspection of the establishment; the most recent previous inspection took place in December 2014.

The establishment stores relevant material for the use for public display and for training and education to support teaching and public engagement.

Since the previous inspection, the following changes have been made to the licensing arrangements: the current DI was approved in September 2018. Following this, the establishment decided to revoke the licence at the satellite site in June 2021 and storage of relevant material is now under an agreement with another HTA licensed establishment.

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
31 out of 36 licensing standards were covered during the inspection (standards published 3 April 2017). Standards relating to consent procedures (C1(a), C1(b), and C1(c)) and standards relating to consent training (C2(a) and C2(b)) were not applicable as the establishment has not received any new acquisitions and does not directly seek consent from donors.

Review of governance documentation
The following documents were reviewed: policies and procedural documents relating to licensable activities, audits, risk assessments, adverse incidents, staff meetings and staff training records.

Visual inspection
A visual inspection was conducted which included storage areas, display locations and the conservation laboratory.

Audit of records
Foreword and reverse audits were conducted for specimens and relevant material (records to location and location to records). This included seven forward and three reverse. No discrepancies were found.

Meetings with establishment staff
The inspection included discussions with staff carrying out processes under the licence. This included the DI, voluntary technical staff and the Technical Curator for Public Engagement.

Report sent to DI for factual accuracy: 24 November 2022

Report returned from DI: 02 December 2022

Final report issued: 28 December 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: 12 October 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.