Site visit inspection report on compliance with HTA licensing standards
Inspection date: **11 March 2020**

British Museum

HTA licensing number 12526

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
Hub site **The British Museum**	Licensed *Carried out*	Licensed *Carried out*
Satellite site **Frank's House**	Licensed *Not carried out*	Licensed *Not 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 the British Museum (the establishment) had met the majority of the HTA's standards, three minor shortfalls were found against standards for Governance and Quality 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

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
a) There is a documented system of audit, which includes records of traceability and specimens.	Audits of the exhibits on display and stored under the licence are not performed regularly or included in an audit schedule.	**Minor**
GQ6 Risks associated with the establishment's practices and processes in relation to the storage and display of human material are assessed and monitored		
a) Risk assessments are documented.	There are no risk assessments covering licensed activities. Risk assessments relate to health and safety risks only. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
PFE1 The premises and facilities are secure and safeguard the dignity of the deceased and the integrity of human tissue		
d) A documented risk assessment has been carried out of the premises to ensure that they are appropriate for the licensed activities.	The establishment could not provide a documented risk assessment of the suitability of the premises for the licensed activities conducted. *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. 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 include exhibits stored under the licence in the museum contingency plan.
2.	GQ3(b)	The DI is advised to record staff attendance at meetings where the discussion is focused on the care of exhibits of human origin. The DI is also advised to record that staff have read and understood the policy for the care of exhibits of human origin.
3.	PFE1(a)	The DI is advised consider ways of informing visitors that some exhibitions include material of human origin. This will help to ensure that visitors can make informed choices of whether to enter these exhibition areas.

Background

The British Museum has been licensed by the HTA since 2008. This was the second site visit inspection of the establishment; the most recent previous inspection took place in October 2013.

Since the previous inspection, all relevant material is now stored at the hub site in a purpose-built store. The establishment has decided to keep the satellite site licensed, for contingency purposes.

At the time of the inspection, three exhibits of relevant material were on public display. A further 155 exhibits were stored under the licence. All items stored and on public display under the licence at the time of the inspection are ‘existing holdings’, and so are exempt from the consent requirements of the Human Tissue Act 2004 (HT Act).

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
Standards under C1 and C2, and standard T2(c) were not assessed during the inspection as they are not applicable to the licensed activity undertaken. The remaining 30 HTA licensing standards were assessed 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, audits, risk assessments, minutes of governance meetings and staff training records.

Visual inspection
The inspection included a visual inspection of all areas where relevant material is on public display and the areas in which exhibits are stored under the licence at the hub site. This included areas where relevant material may be temporarily stored whilst being conserved. The inspection also included visual inspection of the satellite site premises; no relevant material was on display or stored at the satellite site, at the time of the inspection.

Audit of records
The electronic database was reviewed as part of the inspection. This database is the main traceability record for items of relevant material. A unique reference number is assigned to exhibits and recorded on the item, on labels or packaging with the item, or on signs relating to the items whilst on public display. The inspection included audits of three exhibits on display and three exhibits in storage. The unique reference number and the description of the exhibits audited were cross-checked against the electronic database; there were no discrepancies.

Meetings with establishment staff
The inspection included a meeting with the DI and a roundtable discussion with staff carrying out procedures related to licensed activities.

Report sent to DI for factual accuracy: 08 April 2020

Report returned from DI: 27 April 2020

Final report issued: 27 April 2020

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: 13 May 2020

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 HT Act. 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 site visit 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 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 site visit.

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

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