Site visit inspection report on compliance with HTA licensing standards
Inspection date: **10 September 2019**

Imperial War Museum

HTA licensing number 12550

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 Imperial War 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 Imperial War Museum (the establishment) had met the majority of the HTA's standards, two minor shortfalls were found against standards for Governance and Quality.

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 governed by documented policies and procedures		
c) Regular governance meetings are held; for example, health and safety and risk management committees, that have agendas and minutes.	While a number of governance meetings occur between staff undertaking licensable activities, the last documented meeting that covered matters relating to licensable activities was in July 2017.	**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.	While there are a number of health and safety associated risk assessments, there are no risk assessments specific to licensable activities.	**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.	C1(a)	The establishment plans to store and publicly display exhibits that are subject to the consent requirements of the Human Tissue Act 2004 (HT Act). If this does happen, the DI should introduce a process for obtaining consent that is in accordance with the requirements of the HT Act and HTA Codes of Practice.
2.	GQ2(a)	The DI may wish to consider performing more frequent audits of the electronic database to ensure all records are completed and updated accordingly.
3.	GQ3(b)	The DI is advised to review the information provided to staff performing licensable activities to help to ensure that they have sufficient understanding and knowledge of the requirements of the HT Act and HTA Codes of Practice.
4.	PFE1(a)	The DI is advised to inform visitors that some exhibitions include material of human origin. The DI is also advised to clearly display the HTA licence. This will help to ensure that visitors can make an informed choice of if they enter these exhibition areas.

Background

The Imperial War Museum is a charitable foundation. The establishment has been licensed by the HTA since September 2009. This was the second site visit inspection of the establishment; the most recent previous inspection took place in June 2013.

Since the previous inspection, there has been a change of Designated Individual (DI). The current DI has been in post since August 2015. There have been no significant changes to the licence arrangements or the activities carried out under the licence.

At the time of the inspection, three items of relevant material were on public display, of which only one was displayed under the HTA licence. A further 14 items were stored under the licence. These items include blood-stained objects, bones and hair from the deceased. All items stored and on public display under the HTA licence at the time of the inspection were ‘existing holdings’ and so exempt from the consent requirements of the 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 C1(a), C1(b), C1(c), C2(a), C2(b), PFE2(a) and PFE2(b) were not assessed during the inspection as they are not applicable to the licensed activity undertaken. The remaining 29 HTA licensing standards (standards published 3 April 2017) were assessed.

Review of governance documentation

The inspection included a review of the establishment's governance documentation relating to licensed activity. This included policies and procedural documents relating to licensed activities, audits, risk assessments, minutes of governance meeting and staff training records.

Visual inspection

The inspection included a visual inspection of all areas where relevant material is on public display and the two areas in which material is stored under the HTA licence.

Audit of records

The electronic database was reviewed as part of the site visit inspection. This database is the main traceability record for samples. The inspection included five forward and three reverse audits of exhibits against the electronic database. The disposal records for three samples were found to be incomplete. The establishment provided paper records to evidence the date and method of disposal of these exhibits. The HTA has advised the establishment to strengthen traceability records (see *Advice,* Item 2).

Meetings with establishment staff

The inspection included an interview with the DI and a roundtable discussion with staff carrying out procedures related to licensed activities.

Report sent to DI for factual accuracy: 20 September 2019

Report returned from DI: N/A

Final report issued: 07 October 2019

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 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 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 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 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 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.