

Inspection report on compliance with HTA licensing standards

Inspection date: **04 August 2023**



## **Natural History Museum (London)**

HTA licensing number 12186

Licensed under the Human Tissue Act 2004

### **Licensed activities**

<b>Area</b>	<b>Storage of relevant material which has come from a human body for use for a scheduled purpose</b>	<b>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</b>
<b>Natural History Museum (London)</b>	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.

The Natural History Museum (London) ('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.	GQ6 (a)	The DI is advised to consider all areas in the museum where relevant material is stored. This is to determine if there are any additional risk assessments that should be undertaken which may be specific to the area of storage.

### **Background**

The establishment has a large collection of human specimens including historical material. There are four human specimens on display to members of the general public, only two of these specimens fall within the legal requirements of the Human Tissue Act 2004.

The establishment has been licensed by the HTA since July 2007. This was the third inspection of the establishment; the most recent previous inspection took place in February 2016.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence.

### **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 of the 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 and has not acquired any new specimens for a number of years.

### *Review of governance documentation*

The following documents were reviewed: policies and procedural documents relating to licensed activities, audits, risk assessments, adverse incidents procedure and staff training records.

### *Visual inspection*

A visual inspection was conducted of locations within the establishment where relevant material is stored and displayed.

### *Audit of records*

Audits were conducted of relevant material in storage and for public display. Location of specimens were cross-referenced with records. No discrepancies were found.

### *Meetings with establishment staff*

The inspection included discussions with staff carrying out processes under the licence. This included the DI, Persons Designated and museum staff.

**Report sent to DI for factual accuracy: 11 August 2023**

**Report returned from DI: 11 August 2023**

**Final report issued: 14 August 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.