Site visit inspection report on compliance with HTA minimum standards

Natural History Museum

HTA licensing number 12186

Licensed under the Human Tissue Act 2004 for the

- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose; and**
- **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**

17 February 2016

Summary of inspection findings

The HTA found the Designated Individual, the Licence Holder, the premises and the practices to be suitable in accordance with the requirements of the legislation.

The Natural History Museum (the establishment) was found to have met all applicable HTA standards.

Advice has been given to the establishment in relation to audit procedures.

Particular examples of good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual 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.

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. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, 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 given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

The Natural History Museum (the establishment) holds a number of items of human origin, some of which are currently on public display and others are stored in the establishment's secure storage areas. Of the human tissue held by the establishment, the majority of items do not fall under the Human Tissue Act 2004 (HT Act) due to their age and there having been 100 years since the death of the person from whom they came. The establishment has not acquisitioned any human tissue specimens in recent years and all these specimens are considered to be existing holdings. As existing holdings, the consent requirements of the HT Act do not apply to them. Although not all the human tissue held at the establishment falls under the HT Act, the establishment's collections management procedures treat all human remains in the same way and to the same standards.

The establishment has been licensed since July 2007 and this was its second routine site-visit inspection to assess whether it is continuing to meet the HTA's standards. The timetable for the site visit was developed in consideration of the establishment's last self-assessed compliance information, as well as pre-inspection discussions with the DI and review of the

previous inspection findings. During the site visit, a visual inspection of the premises, review of documentation and interviews with establishment staff were undertaken.

The HTA viewed all areas where human tissue specimens are displayed and stored. All human tissue specimens which were on public display at the time of the inspection were in dedicated display cases which can only be accessed by appropriate members of the museum's staff. Additionally, the establishment has a CCTV system covering the areas where tissue is on display and security staff patrolling the public areas. Environmental monitoring is undertaken, with records being kept of temperature and humidity which helps to assure the DI that human tissue specimens are being stored appropriately.

A traceability audit was undertaken during the inspection in both the comparative anatomy and osteology departments collections. The establishment maintains traceability records for all museum specimens on an electronic database, which contains details of human tissue that is on display and tissue that is being stored in the establishment's secure archive. Additionally, a local inventory of human tissue specimens is maintained in the establishment's secure storage areas.

In the comparative anatomy department collection, details of two specimens of human tissue were taken from their respective containers and were cross checked against the local inventory of tissue listing all of the specimens within the collection. Details on the tissue matched the details on the inventory and no anomalies were found.

In the osteology department collection, details were taken from three specimens of human tissue and again, these were cross checked against the local inventory of samples. No anomalies were found.

In some of the areas where human tissue is being stored, annual audits of the specimens takes place, both to verify that all of the exhibits can be accounted for and that their condition remains satisfactory. Where the audit shows that there has been some deterioration in the condition of the specimens, or their containers, they are identified for remedial action to restore their condition where possible. Although all departments storing human tissue reported that they audited the exhibits periodically, not all audits are undertaken annually. Generally, the frequency of audits relates to the frequency of access to the collections, which means that those collections which are not accessed regularly or often are audited less frequently. The audits that are being undertaken are not being documented as audits and therefore any actions arising from them are also not documented. Advice has been given below regarding audit procedures (see advice item 1).

Although the establishment was not actively acquiring new specimens at the time of the inspection, systems and processes have been developed for seeking consent for the public display of human tissue from tissue donors. The consent form that the establishment has developed requires witnessed first person consent for the public display of tissue, which is in accordance with the requirements of the HT Act.

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation.

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 practices:

No.	Standard	Advice
1.	GQ1	The DI is advised to consider the frequency of and processes governing audit of human tissue specimens. Although the frequency of audits depends upon how often collections are accessed, more regular audits, perhaps to an annual cycle, may help to provide the DI with assurance that all exhibits can be accounted for and that their condition remains satisfactory. The DI is advised that any audits of human tissue that are undertaken should be documented and records made of their outcomes and any actions arising.

Concluding comments

The establishment demonstrated a culture of continuous improvement, with many of its documents and procedures having been reviewed during recent months. Following a recent re-structure of the departments and directorates, the DI and her team have created new documented procedures covering the use of human tissue across the establishment.

The DI also described efforts to improve communication between different groups within the museum, such as the setting up of the anthropology and human remains panel, which focusses on matters relating to the use of human tissue.

The HTA has given advice to the Designated Individual with respect to audits.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 15 March 2016

Report returned from DI: 29 March 2016

Final report issued: 19 April 2016

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• Consent forms comply with the HTA's Codes of Practice • If the establishment obtains consent, a process is in place for acquiring consent in accordance with the requirements of the HT Act and the HTA's Codes of Practice, and records of consent are maintained • Where applicable, there are agreements with third parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice
C2 Information about the consent process is provided and in a variety of formats
• Standard operating procedures (SOPs) detail the procedure for providing information on consent • Agreements with third parties who provide material for public display contain information about consent requirements
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• Standard operating procedures (SOPs) detail the consent process • There is evidence of suitable training of staff involved in seeking consent • Records demonstrate up-to-date staff training • Competency is assessed and maintained

Governance and quality system standards
GQ1 The establishment's work on public display is supported by ratified documented policies and procedures as part of the overall governance process
• Policies and procedures are in place, governing the storage and public display of bodies and relevant material • There is a system of risk management in place • Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes • There is a complaints system in place

GQ2 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Qualifications of staff and training is recorded
- There are orientation and induction programmes for new staff
- There is a documented training programme (e.g. health and safety, fire, risk management, infection control), including developmental training

GQ3 There is a systematic and planned approach to the management of records

- There are documented procedures for the creation, amendment, retention and destruction of records
- There is regular audit of record content to check for completeness, legibility and accuracy
- There is a back-up / recovery facility in the event of loss of records
- Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

GQ4 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- There is an identification system which assigns a unique code to each donation and to each specimen, and to each of the products associated with it

GQ5 There are systems to ensure that all adverse events are investigated promptly

- There is a system for reporting adverse events
- Corrective and preventive actions are taken where necessary and improvements in practice are made

GQ6 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- There are documented risk assessments for all practices and processes
- Risk assessments are reviewed when appropriate
- Staff can access risk assessments and are made aware of local hazards at training

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- A risk assessment has been carried out of the premises to ensure that they are appropriate for the licensed activities
- There are policies in place to review and maintain the safety of staff, students and visitors
- Where appropriate, policies are in place to ensure that the premises are of a standard that ensures the dignity of the deceased

- The premises have sufficient space for procedures to be carried out safely and efficiently
- Policies are in place to ensure that the premises are secure and confidentiality is maintained

PFE 2 Equipment is appropriate for use and environmental controls are in place to avoid potential contamination

- There are documented cleaning and decontamination procedures
- Staff are provided with appropriate protective equipment and facilities that minimise risks from contamination
- There is a contingency plan for equipment failure

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells.

- Bodies and relevant material are stored in suitable secure environments and precautions are taken to minimise risk of damage, theft or contamination
- Critical storage conditions are monitored and recorded
- There are systems to deal with emergencies out of hours

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- A system is in place to ensure that traceability of specimens is maintained during transport
- Records of transportation and delivery are maintained
- Records are kept of any agreements with courier or transport companies

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented disposal policy
- There is compliance with health and safety recommendations

D2 The reason for disposal and the methods used are carefully documented

- There is a system for tracking the disposal of relevant material, including recording the method and reason for disposal
- Where applicable, disposal arrangements reflect specified wishes

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 Human Tissue Act 2004 (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:

   (1) A notice of proposal being issued to revoke the licence

   (2) 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.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) 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 CoPs, 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 or 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. You 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 desk-based or site-visit inspection.

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