Site visit inspection report on performance against HTA quality 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**

18 November 2010

Executive Summary

A site visit inspection of the Natural History Museum (the establishment) was carried out by the HTA on 18 November 2010.

The establishment was found to meet the majority of the HTA standards across the four areas of: consent; governance and quality; premises, facilities and equipment; and disposal. Some shortfalls were found in relation to standards C1, GQ 1 and D1. Any particular examples of strengths or good practice are included in the concluding comments section of the report.

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.

All 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 is a national museum and is an international leader in scientific study of the natural world. The Science Directorate is one of the seven science departments at the museum and is the focus for the development of the museum's policies and for scientific research and collections management. The majority of the collections of human material is outside the remit of the Human Tissue Authority and the licence, primarily due to age (over 100 years at the time of the Human Tissue Act (HT Act) coming into force). Of the relevant material held under licence at the museum's site in London, most is held in the secure storage areas of the museum, where it is held for research and possible future public display. Some material is from the living (e.g. deciduous teeth). No material has been added to the collections since 2006 (i.e. all materials are existing holdings under the HT Act). The museum holds all its human remains collections to the same standard and systems, irrespective of age and status under the HTA licence.

This routine inspection, the first since the establishment was licensed in 2006, covered all areas of public display and storage for research and future display. Most material is held under the authority of the Keeper of Palaeontology. Some material is held under the authority of the Keeper of Zoology. The inspection included successful audit trails of material on display and of an appropriate selection of materials held in storage. As the bulk of human material held by the museum falls outside the remit of the Human Tissue Authority, with the permission of the staff some of these traceability audits were undertaken on material that is outside the licence (due to age) as the system used for traceability of material is common to both.

Meeting the HTA's licensing standards

The HTA developed its licensing standards with input from its stakeholders, in order to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA expects licensed establishments to meet these standards.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a licensing standard is not met, the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor' (see Appendix 3: Classification of the level of shortfall).

Unless otherwise advised, the establishment is required to inform the HTA within 14 days of the receipt of the final report of the corrective and preventative actions that will be taken to ensure that the improvements are addressed. A template for this purpose is provided as a separate Word document.

HTA standards not met

Consent

Standard	Inspection findings	Level of shortfall
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.	All material currently held is 'existing holdings' under the HT Act, so records of consent are not required. However, no current policy of the museum documents the consent requirements which should be followed, should new material be obtained by the museum. The establishment should review the overall donation/accessions policy, or other relevant document, and include reference to the HT Act (2004) and the HTA codes of practice on Consent and Import and Export to ensure that these would be followed appropriately, should new materials be obtained or offered to the museum in the future. The inclusion of this information could be cross referenced in the Policy on Human Remains of the establishment.	**Minor**

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 The establishment's work on public display is supported by ratified documented policies and procedures as part of an overall governance process.	At present, the establishment rarely loans any human material for public display, whether under the licence or not. However, the requirement that material held under the licence should only be loaned to another establishment holding an HTA licence for public display is not stated in any establishment documents. The appropriate policy should be updated to include the requirement that material held under the licence should only be loaned to premises holding an HTA licence covering public display.	**Minor**

Disposal

Standard	Inspection findings	Level of shortfall
D1 There is a clear and sensitive policy for disposing of human organs and tissue.	The establishment would only very rarely consider final disposal of material. However, the special nature of material held under the licence and the HTA code of practice on Disposal are not mentioned in the collections policy of the museum or the Policy on Human Remains. The requirements of the licence and the relevant content of the code of practice on Disposal should be referenced in appropriate policies and documentation to ensure that they are followed should the rare occurrence of final disposal occur in the future.	**Minor**

Advice

Below are matters which the HTA advises the DI to consider.

No.	Standard	Advice
1.	Governance and Quality	The Designated Individual is advised to note the review dates of all policies and procedures used at the establishment which affect material held under the licence, to ensure that appropriate updates and approvals are made as required.
2.	Premises, Facilities and Equipment	The Designated Individual is advised to consider if fluctuations in environmental conditions may adversely affect the material held under the licence, particularly that in storage rather than on active display, in the medium to long term.

Concluding comments

The establishment holds all human remains according to the same policies and procedures. This means that material under the licence benefits from systems and processes developed and carried out by a major national museum for the much larger amount of material of human origin held outside the licence. Examples of this include the exemplary security of the material and the specific, unique identification records allowing effective traceability. The establishment clearly appreciates the value, and respects the integrity of the material held under the licence.

Report sent to DI for factual accuracy: 29 November 2010

Report returned from DI: 5 December 2010

Final report issued: 18 January 2011

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.

Date: 29 July 2011

Appendix 1: HTA inspection process

The Human Tissue Authority regulates the removal, storage, and use of human bodies, body parts, organs and tissue for activities such as research, transplantation, and education and training. The legal requirements for establishments which carry out such activities are set out in the Human Tissue Act 2004 and The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

We license establishments in England, Wales and Northern Ireland that carry out these activities, and inspect them to make sure legal requirements are met.

Inspections

We use the term 'inspection' to describe when we:

- visit an establishment to meet with staff, view premises and facilities, and review policies and procedures (a site-visit inspection); or
- assess written information we have requested from an establishment (a desk-based assessment / inspection).

We carry out inspections to assess if the Designated Individual (DI) is suitable to supervise the activity covered by the licence, as it is their responsibility to ensure that:

- other staff working under the licence are suitable;
- suitable practices are used when carrying out the activity; and
- the conditions of the licence are met.

We also need to be satisfied that the licence applicant or holder, the establishment's premises, and the practices relating to licensed activities, are suitable.

To help us reach our decisions, we have developed standards under four headings: Consent; Governance and Quality; Premises, Facilities and Equipment; and Disposal.

After every site visit inspection, we write a report documenting our findings. Where we find a particular standard is not fully met, we will describe the level of the shortfall as 'Critical', 'Major' or 'Minor'. In most cases, it will be the responsibility of the DI to seek the HTA's agreement on how they will address the identified shortfalls. More information about the classification of shortfalls can be found in Appendix 3.

The majority of our site-visit inspections are announced. If we have concerns about an establishment, we can also undertake an unannounced site visit inspection.

You can find reports for site visit inspections which took place after 1 November 2010 on our website.

Appendix 2: HTA standards

Standards which are not applicable to this establishment have been highlighted.

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 in place 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 3: 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.

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.

Follow up actions

A template corrective and preventative action plan is available as a separate Word document. 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.