Site visit inspection report on compliance with HTA minimum standards

Faculty of Life Sciences, University of Manchester

HTA licensing number 12111

Licensed under the Human Tissue Act 2004 for the

- **carrying out of an anatomical examination;**
- **removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation;**
- **storage of a body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose; and**
- **storage of an anatomical specimen.**

5 September 2013

Summary of inspection findings

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

The Faculty of Life Sciences, University of Manchester (the establishment) was found to have met all HTA standards.

Particular examples of strengths and 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 establishment forms part of the Faculty of Life Sciences, University of Manchester, and receives and stores bodies and prosected parts of bodies, principally for use for anatomical examination as part of teaching anatomy to undergraduate medical, dental and life-science students. In the last year the faculty has set up the Manchester Surgical Skills and Simulation Centre (MSSSC), as a facility for use in teaching trainee surgeons, using fresh frozen cadaveric material.

In conjunction with the creation of the MSSSC, the existing anatomy teaching facilities, body store and dissection room were upgraded. The body store now has 80 fridge spaces used to store embalmed bodies and prosections for use in teaching anatomy, and 20 freezer spaces used to store fresh frozen bodies and body sections, principally for use within the MSSSC.

Students, staff and those visiting the establishment are presented with a talk on expected standards of behaviour and the code of conduct, a written copy of which is signed.

Enquiries from members of the public wishing to donate their body for use in the teaching of anatomy are received principally by telephone or e-mail, but also by letter. Information about bequeathal is then sent to the enquirer with a consent form for completion and return.

On return of the signed consent form, it is checked for completeness and apparent validity, and the name of the potential donor, together with other relevant details, is entered onto a database, the paper copy of the signed consent form being stored securely.

When the establishment receives confirmation from family or executors that a body donor has died, another trained member of staff checks the original consent and makes contact with the next of kin or executor. During the telephone conversation, if the body of the deceased would be considered suitable, the possibility of use for teaching within the MSSSC is also discussed and appropriate authorisation forms issued.

On receipt at the establishment, each body is given a unique identifier, the format of which differs depending on whether the body is to be used for anatomical examination or within the MSSSC.

Those bodies to be used for surgical training are frozen and stored within defined freezer spaces; those used for anatomical examination as part of teaching are embalmed within the department and placed into the fridges. Anonymity of bodies is maintained within the establishment by the use of unique identifiers alone.

Following use in teaching, when the body is to be sent for cremation, two members of staff review all of the documentation, prepare the coffin and repatriate any trimmings with the body. Where requested, next of kin are contacted in order that they may attend the cremation service. The database is again updated with reason, date and method of disposal.

The establishment has slightly different procedures in place for disposal of bodies used within MSSSC, depending on whether they are local bequests or have been imported from outside the UK, and also has defined procedures for disposal of sensitive materials, in conjunction with a local HTA licensed mortuary.

Security within the establishment is maintained by the use of secure swipe card access, which limits access depending on authority, and extensive CCTV coverage, both live and recorded.

This was the establishment's first HTA inspection, being routine and scheduled. It comprised a visual inspection of the body store, embalming room, dissection room and related offices. Governance documentation and records were reviewed, including a selection of policies and related standard operating procedures, environmental monitoring records, equipment maintenance and calibration records, staff training records and the electronic database which records details relevant to bequests. Key staff were interviewed, both in scheduled interviews and, informally, as part of the visual inspection.

An audit of documentation and traceability was carried out:

- One body allocated for use within the MSSSC was located within the freezer and paper and database records reviewed for the presence of signed consent and completed traceability and other relevant forms.
- One body allocated for use for anatomical examination was located within the dissection room. The unique identification number was located on the body, checked against the corresponding number on the dissection table, and the relevant paper and database records reviewed for the presence of appropriate consent, traceability records and other relevant forms.

- Three prosections were located, two within the fridges and one within the liquid storage tanks. The corresponding database records and paper documentation were reviewed to ensure consent for retention was in place. Disposal details for the corresponding bodies were reviewed within the database.
- One museum pot was selected and the corresponding database record detailing its type and location reviewed.

No discrepancies were found.

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 review the SOP - “Creation, amendment, retention and deletion of documents and records” to incorporate guidance to staff on how handwritten amendments to documents should be managed and recorded, by striking through, dating and initialling any changes.
2.	GQ1	The DI is advised to review the SOP – “Disposal of bodies after anatomical examination” to reflect current practice, where staff reunite any dissection trimmings with the body when preparing the deceased for cremation.
3.	GQ4	The DI is advised to record, as horizontal audits, the review of traceability, consent and other related documents which are carried out as part of the current vertical audit of traceability of bodies received by the establishment.
4.	GQ5	The DI is advised to document the current procedure where wrist, ankle or other banding is applied, in addition to the original tagging, when different parts of fresh frozen bodies are used in surgical skills courses.

5.	PFE3	The DI is advised to record the periodic testing of the body store fridge and freezer alarms so that audit of records to identify any failure to carry out periodic alarm testing will be possible.
6.	N/A	The DI is requested to ensure that the HTA logo is removed from documents used within the establishment, both internally and sent to those party to bequests, in line with the HTA policy on the use of its logo and branding: http://www.hta.gov.uk/termsandconditions/copyright.cfm

Concluding comments

The HTA saw various examples of good practice during the inspection.

Aide memoires and checklists are used when staff deal with initial enquiries about bequeathal and when confirming authorisation from next of kin. Different staff members deal with the initial enquiry and consent documentation, and the eventual bequest, which means important documentation is subject to review by two different individuals before a bequest is accepted.

The establishment has procedures in place to document the receipt of any updates of contact details relating to the potential donor, next of kin or executors, or other relevant changes to ensure that information is as current as possible.

The database used keeps records of bodies, prosections and museum type specimens, and there is an annual review of stored specimens

The consent form used has been subject to continuing review, for example being updated to provide clarity on the reasons why a potential bequest may not be accepted, rather than rely solely on the same information contained within the bequethal information sent to potential body donors. Authorisation forms sent to next of kin, where appropriate, provide information about use of bodies within the MSSSC and the resultant changes to timing of eventual disposal by cremation.

Security appears to have been well considered, and the establishment has comprehensive arrangements restricting levels of access, backed up by extensive CCTV coverage and the use of fireproof document storage cabinets which are secured by electronic PIN access locks.

There is a twice yearly audit meeting which covers all aspects of the licensed activities and includes review of SOPs, updating of the risk register and review of risk assessment, as well as consideration of any untoward events or incidents.

The establishment has an annual memorial service dedicated to those who have donated their bodies for teaching purposes, attended by establishment staff and students and to which relatives of donors are invited.

In considering the suitability of the DI, the HTA noted that he is at a very senior level within the university with other responsibilities, which has an influence on his direct day to day oversight of the licensed activities. However, the inspection revealed no concerns relating to communication between those carrying out the licensed activities and the DI, as there are several Persons Designated within the establishment, responsible for various elements of the activities carried out and with defined lines of communication to the DI. The HTA also took into account the involvement of the DI, and Corporate Licence Holder Contact, in the

governance of this and other HTA licenses as part of a governance group within the university. Accordingly, the HTA found the DI to be suitable.

The HTA has given advice to the Designated Individual with respect to some elements of governance documentation and on the recording of periodic alarm testing

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

Report sent to DI for factual accuracy: 17 September 2013

Report returned from DI: 23 September 2013

Final report issued: 23 September 2013

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 Code of Practice • Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose • Where applicable, there are agreements with third parties to ensure consent is obtained in accordance with the requirements of the HT Act 2004 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 • Independent interpreters are available when appropriate • Information is available in suitable formats
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 • 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 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process
• Policies and procedures are in place, covering all licensable activities • Appropriate risk management systems are in place • Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes • Complaints system
GQ2 There is a documented system of quality management and audit
• A document control system, covering all documented policies and standard operating procedures (SOPs).

- Schedule of audits
- Change control mechanisms for the implementation of new operational procedures

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Qualifications of staff and training are recorded, records showing attendance at training
- Orientation and induction programmes
- Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training
- Training and reference manuals
- Staff appraisal / review records and personal development plans are in place

GQ4 There is a systematic and planned approach to the management of records

- Documented procedures for the creation, amendment, retention and destruction of records
- Regular audit of record content to check for completeness, legibility and accuracy
- Back-up / recovery facility in the event of loss of records
- Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

GQ5 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 of the products associated with it
- An audit trail is maintained, which includes details of when and where the bodies / body parts were acquired, the uses to which the bodies / body parts were put, when the bodies / body parts were transferred and to whom

GQ6 There are systems to ensure that all adverse events are investigated promptly

- Corrective and preventive actions are taken where necessary and improvements in practice are made
- System to receive and distribute national and local information (e.g. HTA communications)

GQ7 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- 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 purpose • Policies in place to review and maintain the safety of staff, authorised visitors and students • Where appropriate, policies are in place to ensure that the premises are of a standard (and maintained to that standard) that ensures the dignity of deceased persons • 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 Environmental controls are in place to avoid potential contamination
• Appropriate separation of relevant material • Air classification system and maintenance of air quality, including control and monitoring of environmental conditions • Documented cleaning and decontamination procedures • Staff are provided with appropriate protective equipment and facilities that minimise risk of contamination
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.
• Relevant material, consumables and records are stored in suitable environments and precautions are taken to minimise risk of damage or theft and ensure the security of holdings • Critical storage conditions are monitored and recorded • System to deal with emergencies on 24 hour basis
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
• Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation • A system is in place to ensure that traceability of relevant material is maintained during transportation • Records of transportation and delivery • Records are kept of transfer agreements with recipients of relevant material • Records are kept of any agreements with courier or transport companies
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored
• Records of calibration, validation and maintenance, including any agreements with maintenance companies

- Users have access to instructions for equipment and receive training in use and maintenance where appropriate
- Staff aware of how to report an equipment problem
- Contingency plan for equipment failure

Disposal Standards
D1 There is a clear and sensitive policy for disposing of human organs and tissue
• Documented disposal policy • Policy is made available to the public • Compliance with health and safety recommendations
D2 The reason for disposal and the methods used are carefully documented
• Standard operating procedures (SOPs) for tracking the disposal of relevant material detail 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.