Site visit inspection report on compliance with HTA minimum standards

University of Leicester

HTA licensing number 12399

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.**

18 April 2012

Summary of inspection findings

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

The HTA found that the University of Leicester (the establishment) had met the majority of the HTA standards. Only one minor shortfall was found, which related to the traceability of some prosections and bones. Following the inspection, the HTA was informed that each prosection will be labelled using a unique identifier.

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 Paragraph 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

A site visit inspection of the medical school at the University of Leicester was undertaken on 18 April 2012. This was the first site-visit inspection of the establishment and was classified as routine.

The medical school at the University of Leicester undertakes the embalming of around 35 donated bodies each year. These bodies are used to teach medical students, biological science students, surgeons at nearby hospitals and students of physiotherapy, podiatry and occupational health. The medical school has an embalming suite, a storage area with 64 fridge spaces, a large dissection room used for teaching, several rooms where archival material is stored and a museum containing bones and plastinated tissues. The establishment uses ledgers and a bequest database to store information on donations and stored tissue. The establishment also retains forms which record consent, receipt of bodies, death certificates, cremation records and information from GPs. These forms are also scanned and stored within the bequest database. The establishment does not import any cadaveric material.

The Bequest Secretary at the medical school receives enquiries from people who wish to donate their bodies for anatomical examination and other scheduled purposes. A bequest pack is sent which contains a consent form, guidance on how to complete the form and information on body donation. When the donor dies, relatives call a 24 hour telephone service so that arrangements can be made to transfer the body to the medical school.

The DI and Persons Designated (PD) decide on whether or not a donated body can be accepted into the establishment. The establishment does not usually accept bodies where the deceased has a history of cancer, dementia other than long standing vascular dementia,

transmissible diseases, severe deformity, when the body has to undergo a post-mortem examination or if organs are to be removed or have been removed for transplantation (apart from the removal of corneas). Once a decision is made to accept the body, staff arrange for an undertaker to collect and bring the body to the medical school. Bodies which are not accepted by the establishment are offered to other Anatomy schools which may have different acceptance criteria.

Bodies are received and stored in fridges once the identity and paperwork have been checked. The embalming procedure, is started within ten days after death, and begins when the medical school receives confirmation that the death has been registered.

The premises are secure. Students, professionals, and visitors are allowed to enter the dissection room once the DI has given permission and they are informed of the Dissection Room rules. The entrance is monitored by CCTV cameras and staff identify visitors and students before they are given access to the Dissection Room. Visitors and students are not allowed to enter the embalming suite or the storage area. The temperature in the fridges is continuously monitored and linked to an audible alarm. Staff monitor the formaldehyde levels in the dissection room every thirty minutes when the room is in use by students and take action if the level exceeds a threshold level.

The site visit inspection of the establishment included interviews with the Lecturer in Anatomy and Physiology who is the DI, the Dissecting Room Manager, Consultant Pathologist, who is a member of the teaching staff and the Bequest Secretary. A document review was carried out, which included: bequest files, transport procedures, standard operating procedures (SOPs) relating to obtaining consent for anatomical examination, embalming and dissection of cadavers and monitoring of formaldehyde levels. Records reviewed included disposal records, audit reports, risk assessments, maintenance agreements, temperature monitoring records and a museum catalogue.

Seven audit trails were undertaken. The records relating to an embalmed body in the fridge, an embalmed body in the dissection room, a prosection in the fridge used for surgical training, prosection in the storage area, a specimen of bone stored in the museum, a body which was cremated and a limb which was incinerated. The labels or tags on the bodies or tissues, the relevant paper records in the bequest ledger, consent forms, death certificates, location of tissues in the fridge, location of body in the dissection room and the disposal records including cremation records were audited. Computer records in the bequest database, which included scanned copies of the relevant forms, were also audited. No discrepancies were found. However it was noted that an archival collection of bones in the storage room were not labeled and it was standard practice for all prosections from a body to be labeled with the same identifier.

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

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ5 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	Some bones in a collection of archival material do not have unique identifiers, which means they cannot be accurately traced if used for teaching within the establishment or if they are loaned to other establishments for education and training. In addition, the lack of unique identifiers means that the establishment is not able to accurately audit the collection. Where consent is in place, staff occasionally remove and store more than one prosection from a body, All prosections from one body are labelled with the same identifier as the donor body. There is no system to label individual prosections with unique identifiers, which means that traceability for each prosection is not possible when multiple prosections are retained from one body. The bequest database assigns a unique number in these cases, but this is not recorded on the label attached to each prosection. *Following the inspection the establishment changed their procedure so that each prosection is labelled using the unique identifier assigned by the bequest database.*	**Minor**

Advice

The HTA advises the DI to consider the following to further improve practices:

No.	Standard	Advice
1.	GQ3	The DI is advised to encourage staff who have worked in the establishment for several years to attend professional meetings and additional training events to ensure that they keep abreast of good practice in their areas of expertise.
2.	GQ4	The establishment currently destroys all paper records, apart from the ledger of bodies received, five years after the cadaver or any cadaveric material has been disposed of. The establishment does not have a policy on retention for computer records. The DI is advised to implement a policy for retention for computer and paper records, taking into account the requirement to maintain traceability.
3.	PFE2	The DI is advised to seek advice on Health and Safety on the need to monitor and record formaldehyde levels in the body storage area on a regular basis. There is a strict schedule for monitoring formaldehyde levels in the dissection room where students work, but formaldehyde levels in the body storage area are not monitored on a regular basis in order to assess the level of exposure of staff to formaldehyde. Staff wear respirators when working in the embalming suite which reduces the risk of exposure to formaldehyde, but are exposed to formaldehyde in the body storage areas.

4.	PFE4	The undertaker who delivers the body to the establishment completes a delivery note which includes the date and time of delivery. The DI is advised to include the place from which the body is collected in order to further improve traceability in the event that an adverse incident occurs during transportation of the body.
5.	D1	The DI is advised to review the collection of bones in the archive and decide whether or not they would be useful for education and training. Any bones which are surplus to the needs of the medical school can be disposed of in accordance with the HTA's code of practice 5 on Disposal (http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code5disposal.cfm). Bones which are retained should be individually labelled (or coded) and catalogued in order to ensure traceability.

Concluding comments

There is good communication between staff, who attend regular HTA governance group meetings with other HTA licensed groups at the University of Leicester. The establishment uses a bequest database to track donations from the initial enquiry to receipt of a body and cremation following anatomical examination and storage or disposal of prosections. There are good systems in place to ensure secure access to the dissection room. Students and visitors are supervised whilst they are on the premises and must adhere to the code of conduct. Mobile phones and cameras of any description cannot be used in the dissection room. These practices help to ensure that the deceased are treated with respect. Overall, the HTA was impressed by the dedication and professionalism shown by staff who work under the licence.

One minor shortfall against HTA standards was identified. The establishment is required to ensure that a robust system of labeling and cataloging of prosections and bones is in place in order to improve traceability. The HTA requires that the DI addresses this shortfall by submitting a completed corrective and preventative action (CAPA) plan 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.

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 shortfall identified during the inspection.

Report sent to DI for factual accuracy: 15 May 2012

Report returned from DI: 23 May 2012

Final report issued: 13 June 2012

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 and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 26 July 2012

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.