Site visit inspection report on compliance with HTA minimum standards

Keele University School of Medicine

HTA licensing number 12190

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.**

26 September 2013

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.

Keele University School of Medicine (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 Medicine, Keele University. It receives and stores bodies and prosected parts of bodies, principally for use for anatomical examination in the teaching of anatomy to medical, nursing and midwifery, physiotherapy, osteopathy and biomedical science students. The anatomy teaching facility has recently undergone a comprehensive refurbishment during the academic summer recess, including the addition of dedicated facilities for future use in planned post graduate surgical training and had been operating in its current form for a period of only a few weeks prior to the inspection.

The establishment provides detailed information about bequeathal on its web site. 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. After initial discussion, 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. Each potential donor is allocated, and provided with, a unique identification number, which

helps locate the appropriate records when the establishment is contacted following the death of the donor.

When the establishment receives confirmation that a potential body donor has died, a member of staff retrieves the original consent and relevant records and makes contact with the next of kin or executor to obtain further details in order to determine whether the deceased's body is suitable for bequethal.

A contracted funeral director transports those bodies accepted for anatomical examination to the establishment and, on receipt, each body is given a further unique identifier, consisting of year of acceptance and sequential number. Anonymity of bodies is maintained within the establishment by the use of unique identifiers alone with only certain staff members having access to bequest records.

The body store has 50 fridge spaces available to store embalmed bodies and prosections for use in teaching anatomy, and 15 freezer spaces, 10 of which can convert to refrigeration, which may be used to store frozen bodies or prosections.

On the day of inspection, the freezer spaces were operating but empty. As the dissection room had been set up for the current undergraduate teaching term, most bodies had been moved from store onto dissection tables.

The dissection room has sufficient space for a maximum of 16 groups of 12 students to carry out anatomical examination simultaneously and is supported by the body store and embalming facilities and a resource room where prosections and other display specimens or models are available for study. There are also extensive on-line teaching materials, available to students on a secure, password protected, intranet.

On the date of inspection, the dissection room had been set up for teaching, with 12 tables being used for the current undergraduate intake.

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 included with the information pack presented to medical students when they are accepted into the university and is posted on various walls throughout the establishment.

Following use in teaching, when the body is to be sent for cremation, staff review all of the relevant documentation within the bequest file, prepare the coffin and repatriate any trimmings or separated prosections 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 and paper copies of records are placed in the relevant bequest file.

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. Paper records are maintained in secure, fire resistant cabinets, and electronic records are backed up to memory sticks and a back-up server.

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, and a staff member with responsibility for quality documentation was present for much of the document review. A member of IT staff demonstrated a new database, currently in development, to the HTA

An audit of documentation and traceability was carried out:

- Two bodies were located within the body store and tag details compared to those on the fridge inventory sheet. The related documentation was reviewed for presence of consent documentation, death certificate and registration, traceability forms and copies of letters and documentation sent to and received from next of kin or executors.
- Two prosections were located within the body store, their location checked against the inventory records and the documentation relating to the source bodies checked for the documentation mentioned in the preceding paragraph.
- One body being used for teaching was selected within the dissection room, and the relevant consent documentation, death certificate and registration, traceability forms and copies of letters and documentation sent to and received from next of kin or executors reviewed.
- A display teaching specimen on long term loan to the establishment was selected and the relevant inventory record checked to confirm the source and age of the specimen, which was an existing holding pre-dating the Human Tissue act 2004, and its recorded location.
- A box of slides in the slide store was selected and the relevant inventory records checked.

No discrepancies, other than one minor typographical error in a record form, 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 ensure that all meetings of staff involved in the licensed activity are minuted. While the HTA notes that some meetings are minuted, not all staff involved in the licensed activity attend these or are recipients of the minutes. By recording all formal meetings and circulating minutes to all staff involved in the licensed activity the DI will help to ensure that relevant information is

		distributed to all staff.
2.	GQ1	The DI is advised to institute a system whereby staff are recorded as having read updated SOPs or other governance documents. The HTA notes that all staff acknowledge having read SOPs and policy documentation as part of their induction training, but by extending this procedure to incorporate updates of documentation, the DI will help to ensure that staff are working to the appropriate, current, procedural documents and using correct record forms.
3.	GQ2	The DI is advised to formalise the internal audit schedule to include horizontal audits of traceability, consent and other relevant documentation. The HTA notes that audit procedures were in place in advance of the recent refurbishment work and changes to the governance system, and that there is provision for a comprehensive annual external audit. The HTA further notes that the revised governance documentation scheduling internal audits is yet to be finalised. By ensuring that the planned internal audit schedule and procedures are formalised, the DI will help to ensure that any systemic issues identified by the audit may be addressed at an early stage, and this will assist in the further refinement of procedural documentation and improvements to service.
4.	GQ7	The DI is advised to extend the current suite of risk assessments to ensure all regulatory risks pertaining to the licensed activity, including the use of bodies and body sections for surgical teaching, are included. The HTA note that a comprehensive set of Health and Safety based risk assessments, as well as some relating to regulatory matters have been carried out, and that SOP drafting has been informed by risk assessment. However, not all of the risk assessments undertaken have been formally documented. By documenting regulatory risk assessments, including risk of retention in excess of time periods consented for, loss of traceability, storage damage to bodies and those risks which may arise in relation to use of bodies for surgical training, risks may be identified, staff made aware, and this will help to inform development of procedures and relevant documentation.

Concluding comments

The HTA saw various examples of good practice during the inspection. Staff appear to communicate well and operate as a team, and focus on the dignity of the donor and the feelings of relatives. Good relationships have been created with the contracted funeral directors, local registrar and the local crematorium, which helps staff manage the relevant procedures efficiently with minimum delay, to the benefit of relatives. This is evidenced by many letters from relatives complimenting the staff involved on their sensitivity in dealing with bequests.

Governance documentation has been reviewed during the recent refurbishment and the formats used are clear, content is appropriate and document control well managed. There is extensive use of carefully considered flowcharts, which detail relevant forms and SOPs, and also extensive use of checklists, all of which aid staff in providing consistent information to enquirers and in the recording of relevant details.

In recognition of the importance of governance, particularly in light of the extension of the

licensed activities to include post graduate surgical training, a staff member with skills in quality management has had protected time allocated to concentrate on this area.

The establishment has arranged for annual external audits to be carried out and acts on the findings thereof. The database used by the establishment is being updated to add extra functionality which will help staff conduct vertical and horizontal audits of traceability and various documentary records.

Training for staff and students includes training on the ethical and legal background to the licensed activity and the involvement of the HTA.

A lesson plan system has been created, which includes dissection and resource room layout plans detailing the specimens to be used and their physical location on tables used for teaching. This not only assists staff in setting up for classes, but also helps minimise the risk of any prosection or display item being misplaced.

During the refurbishment, staff have been heavily involved with the university Health and Safety department to refine the systems used to record the presence of formaldehyde and other hydrocarbons in the embalming and dissection rooms so as to minimise risk of exposure to staff. A staff member has devised a method of minimising loss of embalming fluid from body orifices during the embalming process, which helps minimise exposure of staff to embalming fluids and also reduces the amount of waste produced.

The HTA has given advice to the Designated Individual with respect to some elements of governance documentation.

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

Report sent to DI for factual accuracy: 4 October 2013

Report returned from DI: 15 October 2013

Final report issued: 15 October 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.