Site visit inspection report on compliance with HTA minimum standards

University of East Anglia, Norwich

HTA licensing number 12005

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.**

28 January 2014

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.

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

The establishment undertakes a wide range of activities associated with anatomical examination. Establishment staff are all trained to seek consent and answer enquiries from potential donors or their families. The establishment has a dedicated phone number and rota to ensure that staff are available to answer enquiries out-of-hours. Consent forms and donor associated paperwork is kept in the anatomy office in secure fireproof safes. Documents are also transcribed into the database proforma and backed up electronically in an encrypted database with restricted access.

The establishment has recently undergone expansion and is now embalming on site with a contingency arrangement with a local undertaker. Upon receipt at the establishment, the body is embalmed in a designated mortuary facility. If embalming is not possible immediately upon receipt for example, if staff are unavailable, bodies can be frozen.

Access to the anatomy suite is restricted, by patented keys which are held by the anatomy staff. A spare key is held by security. The facility is alarmed and has motion detection sensors.

Sequential unique identification numbers are assigned to each body and six tags (both ears, both wrists and both big toes) are used to ensure identification and traceability. Once embalmed, bodies are stored in the mortuary in fridges. When bodies are required for teaching they are removed to individual tables with lids that are held in place by tight catches, these are then stored in a walk in refrigerated room.

Where prosections are created, an identification system with unique numbers links these to the body from which they were prepared. Prosections are also stored securely in the refrigerated room in steel cabinets or plastic pots. The establishment also has a small collection of slides, bones and potted samples which are catalogued, regularly audited and stored in a designated store room.

If required, the establishment will accept bodies from neighbouring anatomy schools but will only accept a maximum of 11 bodies into storage at any time.

The dissecting room is set up so that tables are designated to specified groups of students and therefore their activities can be closely monitored. Dissection log books are associated with each trolley for students to record laboratory activity.

No comparative anatomy is taught at the establishment.

At the end of each academic year, bodies are cremated or buried according to the wishes of the next of kin. Relatives and students are invited to attend a memorial service held by the university for all bodies used the previous year.

The establishment has been licensed since November 2007. This was the first routine inspection and covered the areas of bequeathal, body receipt, embalming, storage as well as dissecting room activities. The inspection also involved a review of documentation and meetings with individuals working under the licence. Interviews were conducted with both current and incoming DIs, technical staff and teaching staff.

Audits were conducted of one embalmed body in the body store; one body currently used for teaching in the anatomy laboratory store; two potted specimens and one prosection. All relevant material were traced back to original consent forms. These 5 sets of donor records were checked for completeness, accuracy and crosschecked against the electronic database. Full traceability was seen and 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.

Advice

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

No.	Standard	Advice
1.	GQ1	Staff at the establishment have regular discussions, to continually assess activities. The DI is advised to ensure the continued documentation of these discussions in order to maintain a record of governance meetings.
2.	PFE3	The establishment has a contingency freezer facility for the storage of bodies that cannot be embalmed upon receipt. The DI is advised to define the length of time a body can be maintained in satisfactory condition if the power was to fail.
3.	PFE4	The DI is advised to improve the access used by the undertaker to deliver and collect bodies, to ensure that the transfer cannot be seen by passers on the path, road or building that overlooks the entrance.

Concluding comments

There is a strong ethos of teamwork at the establishment and the incoming DI has supported the current DI for a number of years. Technical and teaching staff are actively encouraged to take ownership of their work within the department and to develop their roles further. Although some changes have taken place, the team is settled and processes are in place to ensure the smooth transition of the DI roles and additional activities. The establishment is well supported by the university.

Regular risk assessments are performed across all aspects of the licensable activity and the establishment has clear concise operating procedures.

Bodies used for dissection are kept on stainless steel trollies which are covered by stainless steel lids and secured in a lockable refrigerated room to ensure their dignity. Additionally, the establishment covers bodies with damp cloths and uncovers only the area to be dissected at any time. This further ensures the dignity of the deceased is preserved and also ensures that they remain in good condition throughout the academic year.

During teaching, the establishment retains tight control of activities; there is a system of blue coats for dissection and white coats for observation. The laboratory remains paper-free whilst students are present to ensure that cuttings and trimmings are not contaminated with paper waste.

The establishment has restricted the storage of material to that used for teaching purposes only. Regular audits are performed of all human tissue held.

Prior to disposal, an audit is performed of body parts and a checklist is used and signed by the DI to ensure that no tissue is accidentally retained. No out-of-hours activities are conducted in the anatomy suite, staff working under the licence are responsible for cleaning thus mitigating the risk of cleaners in the facility. Maintenance workers are always supervised and no human material is left on display when maintenance is required.

There is a good working relationship with the local undertakers allowing for contingency for viewing suitability of bodies for donation, storage and embalming.

Report sent to DI for factual accuracy: 6 February 2014

Report returned from DI: 14 February 2014

Final report issued: 19 February 2014

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.