Site visit inspection report on compliance with HTA minimum standards

University of Southampton Faculty of Medicine

HTA licensing number 12555

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.**

13 June 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.

University of Southampton Faculty 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 (DI) are set out 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

University of Southampton Faculty of Medicine ('the establishment') was, prior to the introduction of the Human Tissue Act 2004 ('the Act') in September 2006, inspected by Her Majesty's Inspector of Anatomy. Upon the Act's commencement, the establishment was licensed by the HTA under licensing number 12075, when it was located at the Boldrewood campus of the University. The establishment re-located from Boldrewood to the purpose-built Centre for Learning Anatomical Sciences (CLAS) at Southampton General Hospital in September 2009, and was re-licensed under HTA licensing number 12555.

The establishment accepts bequeathals from donors for body donation. Criteria for acceptance of a donation include suitable donor medical history, body size and time after death, as embalming must occur within a certain timeframe. A donation that has been declined on the basis of the donor's medical history may, in certain circumstances and only with the family's consent, be offered to other UK medical schools for anatomical examination.

Up to twenty bodies of deceased persons are accepted for anatomical examination each year. Bodies are delivered by a contracted funeral director to the hospital mortuary where, following stringent checks on identity and bequeathal documentation, they are stored overnight. The following day, the bodies are collected by CLAS staff for embalming at the Anatomical Sciences Laboratory (ASL) which is based within the CLAS. Bodies are embalmed and dissected by CLAS staff, and the embalmed prosections are stored at 16 ^{o}C in

the ASL body store. The prosected specimens have a barcoded tag affixed to them to enable tracking of their movement in and out of storage. The prosections are used for teaching purposes, and dissection is not normally performed by students except for a small number of students in later years of their programme.

The CLAS is used by undergraduate students studying medicine, physiotherapy, podiatry and occupational therapy, and also by registered medical practitioners undertaking surgical training courses. Anatomical specimens used in teaching including formalin-fixed prosections, bones and articulated skeletons, and potted and plastinated specimens. A museum collection of potted pathology specimens, which are considered existing holdings, as they were in the collection prior to the commencement of the Act, are also stored under this licence and are used for teaching.

Entrance to CLAS is by swipe card access to authorised staff and students only. All areas within CLAS are monitored by closed circuit television. Only CLAS staff are permitted to enter the ASL body store. Before they are permitted entry to the CLAS, new undergraduates have an introductory lecture when appropriate behaviours are explained, and there are notices within the ASL to reinforce this. Undergraduate students, and attendees at postgraduate surgical training courses, in the ASL are closely supervised at all times by CLAS staff.

The wishes of the donor's family for disposal of anatomical specimens are sought at the time of acceptance of the donation. There is a regular schedule of collection of body parts which are due for disposal.

This report describes the first, routine, HTA site visit inspection of the establishment in June 2013. The inspectors met with establishment staff, reviewed documentation and visually inspected the ASL and pathology museum. An audit of traceability records, consent forms and bequeathal documentation, for one embalmed body and three, separate, smaller body parts revealed no anomalies. An audit of storage records for two pathology museum specimens revealed a minor discrepancy in the location of one specimen, although this did not affect traceability as the specimen was in the correct storage cabinet, and evidence was seen to confirm that traceability records were being updated for the annual specimen audit.

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	Two detailed quality documents set out the procedures for several activities, including accepting body donations and the storage, use, transportation and disposal of anatomical specimens. The DI is advised to consider writing separate standard operating procedures (SOPs) for each specific activity. This would simplify the regular review and risk assessment of documented procedures, and align operating procedures which cover these activities with the anatomical

		dissection procedures, for which there are SOPs for each practical technique.
2.	GQ2	The storage location and physical condition of each anatomical specimen is audited annually, and any signs of damage or deterioration are documented. However, the completion of corrective actions following each audit is not recorded. The DI is advised to keep a record of the completion of corrective actions, as an assurance that these have been carried out.
3.	GQ5	Upon application, specimens may be loaned temporarily to other centres using a loan authorisation form. Loans of current specimens are tracked through the ASL database. However, when museum specimens are loaned out, the specimen spreadsheet is not updated, so the only record of the loan is the authorisation form. This poses a potential risk to traceability that, if a loan form is mislaid, there is no other record of the loan. The DI is therefore advised to record the loan and return of museum specimens in the specimen spreadsheet.
4.	GQ7	The DI is advised to also consider the following aspects in documented risk assessments of practices and premises: • contingency arrangements for storage of anatomical specimens if the ASL body store were to be rendered unusable; • the ongoing storage of skeletal material in cardboard boxes within the ASL; • security arrangements for the dry prep room where specimens for disposal are stored.
5.	PFE2	The DI is advised that the hospital's Estates Department should provide written confirmation when the annual servicing and calibration checks of the ASL formaldehyde sensors are carried out. The DI is also advised that, as the portable formaldehyde sensor has not been used for a significant period of time, it should be re-calibrated prior to its next use.
6.	-	The DI is informed of the names of all undergraduate students who will enter the ASL, but does not always receive in advance the names of attendees at postgraduate training courses held there. The DI is advised that event organisers should provide her with the names of attendees of postgraduate training courses, in advance of such events, so she can be fully aware of all individuals who will be using the ASL. This will provide further reassurance that the dignity of the deceased is being upheld.
7.	-	The DI is advised to verify, periodically, the ongoing suitability of the hospital mortuary storage facilities and its practices.

Concluding comments

The establishment has met all HTA licensing standards. Several strengths were identified during the inspection. The commitment of staff to the dignity of the deceased in their care, and the preservation of the integrity and traceability of anatomical specimens, was apparent throughout the inspection. The establishment's working practices are well-embedded and are clearly understood by all staff. Records of donor documentation, and the computer database used for tracking the location of current anatomical specimens, are rigorous. The CLAS is spacious and modern.

The HTA has given advice to the Designated Individual with respect to recording of audits and loaned specimens, procedures, additional risk assessments and the management of the formaldehyde monitoring equipment.

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

Report sent to DI for factual accuracy: 10 July 2013

Report returned from DI: 15 July 2013

Final report issued: 16 July 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

GQ6There 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.