



Site visit inspection report on compliance with HTA minimum standards

Leeds Institute of Medical Education

HTA licensing number 12279

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.**

17 December 2015

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.

The University of Leeds (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

This report refers to the activities of the University of Leeds (UoL; the establishment) licensed under the Human Tissue Act 2004 (HT Act). UoL has been licensed since July 2007 and this is their second on-site HTA inspection. The previous inspection was conducted in January 2008.

Staff at the establishment are trained in the requirements for obtaining consent and to answer any enquiries from potential donors or their families. The establishment arranges the collection of donated bodies, which are received into a designated mortuary for embalming and long-term storage. To ensure identification and traceability, a unique number is assigned to each body upon receipt. Identification tags include this ID code; tag colour- and letter-coding indicate cases where consent for retention of material and/or photography have not been given. The same unique identification number is used to label any prosecutions. Colour-coded body bags and covers are used to indicate the intended use of cadavers.

The Establishment undertakes two types of embalming: formalin fixation is used for teaching anatomy and Theil fixation is used for specialist training where tissue flexibility is required; for example, in surgical training. Bodies that have been fixed in formalin are stored in temperature-monitored mortuary fridges; Thiel fixed bodies are stored at ambient temperature in bespoke storage racks.

During the academic year, the establishment teaches anatomy to approximately 1000 students who work in one of two dissecting rooms:

- The 'small' dissecting room has 12 dissecting tables
- The 'large' dissecting room has 24 dissecting tables. The dissecting tables in the large dissection room can hold two bodies on separate platforms that rotate to maximise storage. Each body per rotating table is labelled with a number and an A or B suffix to denote the labelled shelf.

Students undertake training about the Act, local regulations and appropriate conduct before being allowed access to the dissection rooms. Access to dissection rooms and the museum are controlled by a card entry system; the card also identifies students who have attended a class. In order to receive their access cards, students must sign a form to confirm that they have read and agree to the local code of conduct for the dissection rooms. A changing room separates the corridor from the dissection room to control access.

The establishment has a small dissection room, a large dissection room and a museum used for teaching.

The museum houses two collections: an 'anatomy' collection and a 'pathology' collection. Specimens in the museum date as far back as the first half of the 19th Century, though most were collected during the 20th Century. Electronic and paper inventories of the collections are maintained.

The establishment's documents are held electronically on two shared network data stores. One, which holds bequest data, is located on a secure server and is accessible only by the DI and the Anatomy Facilities Manager; the other, which is available to all anatomy teaching and administrative staff, holds documents such as local regulations, risk assessments, standard operating procedures etc.

At the end of each academic year, bodies are cremated or buried according to the wishes of the next of kin. Relatives are invited to attend an annual memorial service held by the University for all bodies used the previous year. A Remembrance cabinet details all donations for each academic year.

No comparative anatomy is taught at the establishment.

A total of eight traceability audits were conducted:

- One formalin fixed cadaver from the small dissection room
- Two cadavers from the large dissection room: one formalin fixed and one Thiel fixed
- Two prosected parts: one ankle stored at room temperature and one thorax stored in the designated fridge.
- A cadaver undergoing formalin fixation in the mortuary
- A formalin fixed cadaver stored in the fridge
- A Thiel fixed cadaver stored at room temperature

The audits were conducted against paper and electronic records and were checked for appropriate consent. 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.	C3	<p>Currently the bequeathal process is the responsibility of only one member of staff.</p> <p>The DI is advised to consider undertaking a risk assessment to cover contingency arrangements in the case of key staff absences, particularly in relation to embalming and bequeathal activities.</p> <p>The DI is also advised to consider providing a checklist or more detailed standard operating procedures to ensure bequeathal documentation is completed as required.</p>

Concluding comments

The DI demonstrated a good oversight of licensable activities and is supported by the HTA Manager and Persons Designated (PDs).

The DI discusses HTA matters at regular HTA group meetings involving the DIs for all licenses held in Leeds. In addition, anatomy specific activity is discussed at meetings of the HTA anatomy sub-group and relevant information shared with staff.

The DI has procedures to ensure good oversight of the anatomy suite: of a total of eight trained demonstrators (PhD students), six are always present for each anatomy class. A member of the academic team is also present during these classes.

Other areas of good practice seen were:

- Good document control including documentation to mitigate loss of traceability;
- Good set of risk assessments;
- Use of colour coded bags to ensure traceability and good condition of cadavers;
- A photographic record of dissections to ensure correct selection and preservation of teaching material.

The HTA has given advice to the Designated Individual with respect to documentation and contingency for staff absence.

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

Report sent to DI for factual accuracy: 19 January 2016

Report returned from DI: 2 February 2016

Final report issued: 2 February 2016

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
<ul style="list-style-type: none">• 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
<ul style="list-style-type: none">• 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
<ul style="list-style-type: none">• 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
<ul style="list-style-type: none">• 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
<ul style="list-style-type: none">• A document control system, covering all documented policies and standard operating procedures (SOPs).

<ul style="list-style-type: none"> • Schedule of audits • Change control mechanisms for the implementation of new operational procedures
<p>GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills</p>
<ul style="list-style-type: none"> • 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
<p>GQ4 There is a systematic and planned approach to the management of records</p>
<ul style="list-style-type: none"> • 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)
<p>GQ5 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail</p>
<ul style="list-style-type: none"> • 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
<p>GQ6 There are systems to ensure that all adverse events are investigated promptly</p>
<ul style="list-style-type: none"> • 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)
<p>GQ7 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately</p>
<ul style="list-style-type: none"> • 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.