Site visit inspection report on compliance with HTA minimum standards

The School of Biomedical and Health Sciences

HTA licensing number 12123

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.**

3 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.

The School of Biomedical and Health Sciences (the establishment) was found to have met all HTA standards.

Particular examples of 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 describes the first site visit inspection of the establishment, which has been licensed by the HTA since 2007. Prior to this the establishment was inspected by Her Majesty's Inspector of Anatomy.

The Department of Anatomy & Human Sciences is part of the School of Biomedical and Health Sciences at King's College London. Donated bodies are used for the purpose of education and training of undergraduate and postgraduate students enrolled on courses including medicine, dentistry, physiotherapy and biomedical sciences. Approximately 1300 students per academic year are taught using donated bodies and other specimens. The premises are also used for surgical skills training courses undertaken by external trainers.

The department receives approximately 60 donated bodies per year, and has an extensive collection of prosections, bones, and anatomical models. The training facilities include two large dissection rooms and a large multidisciplinary teaching laboratory.

The bequeathal process is undertaken by the London Anatomy Office (LAO), which includes obtaining consent, and arranging the transport of donated bodies to and from the establishment by contracted funeral directors. The LAO consent procedures have been reviewed previously by the HTA and have been demonstrated to comply with the HTA Code

of Practice for consent. The DI has assured himself, through agreements with the LAO, that consent is in place.

This was a routine inspection and included a review of documentation relevant to the establishment's activities, a visual inspection of the premises, and interviews with key members of staff including: the Designated Individual, who is a Professor of Anatomy and the Head of Department; and Persons Designated including the Academic Manager of the Dissecting Room; the Technical Manager of the Dissecting Room; and the Technical Manager of the Multidisciplinary Teaching laboratories.

A traceability audit was conducted across a range of specimens including a fresh frozen limb for surgical training, one potted specimen, two brain specimens, three prosections, and one complete donated body. The identity and storage location of each item was traced through to both paper and electronic records of consent where applicable. Traceability was maintained throughout and no discrepancies were identified in the accompanying documentation.

Inspection findings

The HTA found the Designated Individual and the Licence Holder, the premises and the practices 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	Kings College London has a Human Tissue Governance Group that oversees all of the college's HTA licences. The Group's meetings are documented and attended by representatives from each of the respective licences. The DI is advised to consider whether departmental meetings should adopt a similar format, with attendance by all key academic and technical staff involved in licensable activities. Documented meetings with standing agenda items covering, for example, teaching services, materials required for teaching, scheduling of external surgical skills training courses, staff availability, and on-going management of the dissection rooms, will help to ensure that discussions are captured for reference and tracking of any ongoing actions.
2.	GQ2	Standard operating procedures (SOPs) are in place for all licensable activities, however many departmental SOPs are not included in the document control system. The DI is advised to review SOPs to ensure they reflect current practice, and to amend documents as necessary to include the appropriate document control information, such as 'effective from' date, date for review, and the author.
3.	GQ5	The establishment has a coding and records system, and procedures in place to maintain tissue traceability. As discussed during the inspection, the DI is advised to maintain traceability of the sets of bones currently used for teaching purposes. The establishment is reviewing the collection of bones in storage. Once those to be retained are identified they should also be incorporated into the system for maintaining traceability.
4.	GQ7	The establishment has a risk assessment process in place, with an emphasis placed on health and safety assessments. The DI is advised to formalise the risk assessments specific to human tissue, including potential risks such as loss of traceability, loss of tissue, the risk of receiving tissue without appropriate consent documentation, and the actions to be taken in such circumstances.
5.	PFE4	Records are maintained of material sent to other establishments for loan or permanent transfer. The DI is advised to ensure that the release and receipt procedure is fully documented to maintain traceability, and ensure that staff are aware of the procedure.
6.	PFE5	The establishment has a contingency procedure in place with another licensed establishment in the event of equipment failure. The DI is advised to review and update the Memorandum of Understanding where necessary and ensure that it is signed by both parties.

Concluding comments

The establishment was found to have met all applicable HTA standards.

The establishment is managed by a highly experienced and dedicated team. It was evident throughout the inspection that importance is placed on respect and dignity of the deceased, and procedures and processes are in place to safeguard the integrity and security of donated material.

There were many areas of good practice observed, some of which are documented below.

There is a good induction procedure for both students and demonstrators. Induction packs include a local 'Code of Conduct' form that must be signed prior to admittance to the dissection rooms. These packs also place emphasis on the privilege of being able to perform anatomical examinations as part of training, that the respect and dignity of the deceased are of upmost importance, and that regulations are strictly adhered to.

The establishment benefits from the overarching governance framework provided by the King's College London Human Tissue Governance Group. An example of this includes the system of audits introduced. An annual audit is conducted by the DI of another HTA licence held by the College, and an external peer audit is conducted by the DI of another HTA licenced anatomy establishment.

There are some areas of practice that may benefit from further improvement and the HTA has given advice and guidance to the DI with respect to these.

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

Report sent to DI for factual accuracy: 23 September 2013

Report returned from DI: 27 September 2013

Final report issued: 3 October 2013

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below. Individual standards which are not applicable to this establishment are shown in grey text.

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.