Site visit inspection report on performance against HTA quality standards
Queen's University Belfast
HTA licensing number 12113

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.**

15 August 2013

Executive Summary

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.

Queen's University, Belfast (the establishment) was found to have met all HTA standards.

Advice and guidance is provided in a number of areas where the HTA identified opportunities for improving existing systems and procedures. 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 is a major undergraduate and postgraduate teaching resource within the School of Medicine, Dentistry and Biomedical Sciences. The licensed premises comprise a mortuary reception area and body store, ‘main’ and ‘minor’ dissection rooms and a technical support room.

Donors who match established acceptance criteria are accepted into the bequeathal process, which includes obtaining consent in accordance with HTA’s consent standards. The establishment is also responsible for the respectful disposal of specimens in accordance with HTA’s disposal standards.

This is the first on-site inspection of the establishment by the HTA. The timetable for the inspection was developed following pre-inspection discussion with the Designated Individual (DI) and with due consideration of the results of desk-based assessments at the time of initial HTA licence application and the June 2011 self-assessment required of the anatomy sector under HTA Directions. Before the Human Tissue Act 2004 came into force, previous inspections were conducted by the Northern Ireland inspector of anatomy under the Anatomy (Northern Ireland) Order 1992.

The scope of this inspection included visual inspection of the facilities that are set aside for licensable activities, review of relevant documentation and interviews with representative members of staff undertaking the various licensable activities. The inspection also incorporated a number of traceability audits which were selected to encompass different types of specimens. Records relating to cadaveric material were checked against the establishment’s inventories and the respective bequeathal records. All of the selected specimens were fully traceable and had evidence of appropriate consent.

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.	GQ2	The DI is advised to extend the programme of periodic documented audits to include 'fresh eyes' review of the fabric and finish of the areas in which licensable activities are carried out. The aim of these periodic reviews should be to identify areas requiring rolling maintenance, refurbishment and / or upgrade.
2.	GQ7	The DI is advised to extend the programme of periodic documented risk assessments to include: • Planned preventative maintenance and, where applicable, calibration for all types of equipment in use within the establishment; • Coverage of the closed circuit television system.
3.	PFE1 & PFE5	The DI is advised to conduct a review of materials and equipment that are currently housed within the mortuary reception area with a view to relocating extraneous items, which are not needed to support activities in this area.
4.	PFE1 & PFE5	The DI is advised to review the equipment, fabric and finish of the mortuary reception area and the body store. Porous materials should be avoided or suitably sealed to minimise the risk of contamination and to facilitate effective cleaning.
5.	PFE2	The DI is advised to update the standard operating procedure (SOP) relating to the routine cleaning and maintenance of the areas set aside for licensable activities to include the requirement for the cleaning and maintenance to be recorded.
6.	PFE2 & PFE5	The DI is advised to implement an appropriate procedure for the logging of ad hoc requests for the repair and / or refurbishment of equipment and facilities within the areas set aside for licensable activities where this work is not to be carried out by members of staff working under the licence. The procedure should include an appropriate system for documenting the requests and for tracking requests through to completion of actions. The aim of this procedure should be to record the reporting of any problems and to provide an audit trail of events and actions.

Concluding comments

The HTA found the Designated Individual (DI), the Licence Holder, the premises and the practices to be suitable in accordance with the requirements of the legislation.

A number of strengths and good practices were identified during the inspection.

The DI has a wealth of relevant experience, a working practical knowledge and a full understanding of the licensable activities being conducted under the establishment's licence. The DI demonstrates knowledge, understanding and practical application of the HTA anatomy sector requirements. The inspection identified a number of areas of practice where the DI has developed ways of working and influenced and promoted compliance with licence requirements.

There is a sound overall structure to the governance of licensable activities. The establishment is subject to oversight from the Queen's University Research Governance Team. Matters relating to human tissue are discussed at the periodic Human Tissue Steering Group meetings. The DI attends Steering Group meetings and has regular formal and informal meetings with members of the Research Governance Team. There is a well established and robust bequeathal process supported by an experienced Bequeathal Secretary and the anatomy technicians. The processes supporting the acceptance and use of donated bodies are focussed on maintaining the dignity and respect of the deceased donors and to maintaining complete and accurate records of body donations and their use.

There is good use of the role of 'Persons Designated' to maintain oversight of licensable activities in accordance with applicable HTA standards and codes of practice. Members of staff who are involved in licensable activities demonstrate a good knowledge of regulatory requirements. There is evidence of good communication across both the internal team and, external, third parties whose services are relied upon as part of the overall process.

Access to the different areas of licensed premises is well managed and controlled, with access restricted to those who are involved in licensable activities. Undergraduate and postgraduate students are required to attend a programme of induction prior to gaining access to the dissection rooms.

The licensed premises were built during the late 1960s and have had minimal upgrade during the intervening years. This is particularly the case within the mortuary reception area and body store where design, layout, fabric and finish reflect the date of construction. In the short term, a number of pieces of advice are offered to the DI with regards to implementation of a rolling programme of review, risk assessment, maintenance and refurbishment. In the medium to longer term, the establishment should look to upgrade the mortuary reception area and body store in order to meet current standards of fabric, finish, design and layout.

Report sent to DI for factual accuracy: **10 September 2013**
Report returned from DI: **17 September 2013**
Final report issued: **16 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.