Site visit inspection report on compliance with HTA minimum standards

Cardiff School of Biosciences

HTA licensing number 12065

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.**

25 July 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 Cardiff School of Biosciences (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

The establishment undertakes a wide range of activities associated with anatomical examination. Bequeathal officers are trained to take consent and to answer any enquiries from potential donors or their families. Upon receipt at the establishment, the body is embalmed in a designated mortuary facility. Once embalmed, bodies are stored in mortuary fridges until required in the dissection room at the beginning of the academic year. In the dissection room, bodies are stored within heavy-duty bariatric body bags to maintain integrity. To ensure identification and traceability, a unique number is assigned to each body and six tags are used to label both ears, wrists and ankles; a further two tags are used to label the body bag and the trolley which will both remain with the body until completion of dissection. Where prosections are created, an identification system with unique numbers links these to the body from which they were prepared. Prosections are stored in a designated store room in sealed plastic containers. The establishment also has a collection of slides, bones and potted samples which have been catalogued and stored in designated store rooms.

During the academic year, the establishment has 300 medical students, 80 dentists, 45 scientists and hosts a number of other health care related courses. The dissecting room is set up so that tables are designated to particular groups of students and therefore their activities can be closely monitored. Within each group, students are assigned formal duties which ensures adherence to the dissecting room code of conduct.

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 a memorial service held by the university for all bodies used the previous year.

The establishment is currently preparing to undertake surgical teaching using frozen bodies.

All academic staff involved in dissection room teaching are Persons Designated (PDs) on the licence.

The establishment has been licensed since July 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. The DI, a former PD under the licence, has been in the role for 14 months.

Audits were conducted of two recently embalmed bodies in the body store; two bodies in the dissecting room; two potted specimens in storage; archived bones in storage; bones in the dissecting room used for teaching and four prosections, one of which was traced back to original consent form. Although full traceability was seen, minor transcription errors were noted (see Advice below).

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 perform regular risk assessments. Where these identify the requirement for additional control measures, the DI is advised to update the assessment to reflect the revised risk score once appropriate actions have been taken.
2.	GQ1	The DI is advised to ensure that standard operating procedures (SOPs) capture all activities and that they contain sufficient detail. For example, the SOP on body receipt could detail the paper checks involved and the mortuary SOPs could detail the temperature monitoring as performed.
3.	GQ2	Although the establishment undertakes audits, the HTA's audit of traceability highlighted examples of incomplete forms and transcription errors. When internal audits are performed, the DI is advised to also include audits of records.
4.	GQ3	Although technical staff are appropriately trained in techniques relevant to their work, the DI is advised to ensure formal personal development plans are discussed on an annual basis. Technical staff should be given opportunities to update their skills and to share good practice with others in the field.
5.	GQ4	The establishment has an SOP on writing SOPs. The DI is advised to ensure that current document control, such as completion of revision dates, reflects the practices outlined in this document. The DI should also consider implementing a uniform procedure for consistently

		correcting hand written errors in donor records.
6.	GQ7	The DI is advised to risk assess lone working in the mortuary with particular regard to health and safety.
7.	PFE3	Great care is taken to maintain the dignity of the deceased during dissection, only the area under study is uncovered at any time. Following the embalming process, the deceased are stored in mortuary fridges and covered by towels moistened in disinfectant placed to cover heads, pelvic area and feet. Since the inspection, the DI has purchased shrouds so that the deceased are covered completely while in the fridges.
8.	PFE5	The embalming mortuary employs wooden head-blocks and wooden-handled tools were seen in the dissection room. The DI is advised to replace these with those made of non-porous materials which are easier to keep clean.
9.	N/A	The undertaking of comparative study is not covered in the licensing or consent sections of the HT Act 2004. However, the DI is asked to consider appropriate separation of relevant material from animal tissue in the form of histological slides used for comparative anatomy.

Concluding comments

The HTA also saw several examples of good practice during the inspection.

Staff at the establishment are motivated and take great care to ensure that all donations are treated with dignity. The establishment has a good working relationship with the funeral director who also attends governance meetings.

A system of red kidney dishes for sharps and blue kidney dishes for non-sharp instruments is used in the dissection room to reduce sharps-related injuries. Stainless steel bowls are used to ensure that any cuttings from dissection are collected appropriately for sensitive disposal. The establishment employs a system of coloured ties which are bound to dissection tables to ensure that photographs are only taken where appropriate consent has been obtained.

Staff at the establishment regularly perform risk assessments and resulting corrective and preventative action plans have been implemented. Where used, the catalogue system used by the establishment enabled complete traceability.

There are a number of areas of practice that require improvement. The HTA has given advice to the Designated Individual with respect to governance and quality and premises, facilities and equipment.

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

Report sent to DI for factual accuracy: 11 September 2013

Report returned from DI: 16 September 2013

Final report issued: 16 September 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.