Site visit inspection report on compliance with HTA minimum standards

University of Bristol

HTA licensing number 12135

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.**

6 October 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 HTA found the University of Bristol ('the establishment') had met the majority of the HTA standards. A major shortfall regarding consent for anatomical examination, and a minor shortfall regarding disposal of retained specimens, were found.

Examples of strengths 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 ('the HT Act'). 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 licenses 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 Centre for Comparative and Clinical Anatomy ('CCCA') at the University of Bristol ('the establishment') accepts approximately one hundred bequeathals of bodies each year. Of these, 10-15 bodies each year are used to prepare anatomical specimens for undergraduate medicine and dentistry courses. Although some medical undergraduates may perform dissection in a Special Study Module, teaching is normally carried out using prosected specimens. The majority of bodies are used for surgical training courses by surgeons in the Vesalius Clinical Training Centre ('VCTC') at CCCA (the Scheduled Purpose of 'Education or training relating to human health'). CCCA also houses a medical museum containing potted and resin-encased pathological specimens (refer to advice item 3).

Bodies can be bequeathed through a donor's will or using the establishment's bequest form. The bequest form allows donors to opt for their body and body parts to be retained for a maximum of three years, and in addition to opt for body parts to be retained for a longer period, for use for the scheduled purposes of anatomical examination, education or training relating to human health and research in connection with disorders, or the functioning, of the human body.

When notified of a potential donor's death, consent documentation is reviewed by the establishment and, if this is satisfactory, the donor's medical practitioner is asked to confirm the donor's medical history and cause of death. If all acceptance criteria are met, a

nominated funeral director delivers the body to CCCA and its identity is verified by two members of staff. Bodies are given a unique traceability number upon acceptance, which tracks the body and all body parts in the establishment's records. A CCCA Body Usage Chart records usage of a body, and body parts from it, for surgical training. A CCCA Body Map records usage of a body, and body parts from it, for anatomical examination.

Bodies for anatomical purposes are embalmed and stored in a cold room for some months, and are dissected by academic and technical staff. The prosections generated are stored in formalin either collectively in tanks or individually in small pots, depending on the nature of the specimens, and are tagged with the unique donor identification number or microchipped if tagging is unfeasible (e.g. for brains). Prosections are visually inspected each week for signs of damage or mould. Prosections for use in classes are retrieved from storage and placed on tables in the Human Dissection Room by technical staff, and returned to storage after use. Anatomical specimens can be used for comparative anatomy teaching, however human and non-human specimens are never stored together. A collection of potted pathology specimens that pre-date the HT Act is also used for teaching.

The establishment ensures undergraduates treat donated bodies and body parts with dignity and respect. Undergraduates attend a lecture on expected behaviours, and are required to sign the 'Human Dissection Room Rules and Regulations' sheet, which sets out rules to be followed, before admission to the dissection room is permitted (refer to advice item 2).

Bodies and body parts for surgical training are stored at -20 ^{o}C. Each body is normally used for up to three courses prior to its cremation. Information on appropriate behaviours is disseminated to attendees through the person booking the course (refer to advice item 2).

The -20 ^{o}C freezer in which bodies for surgical training are stored, and the coldroom for storage of embalmed bodies, have alarms which ring locally and to the Estates Office (refer to advice items 4, 5). Most areas in CCCA where bodies and body parts are stored have access restricted to establishment staff only. Students are permitted to enter the Human Dissection Room once they have read the 'Human Dissection Room Rules and Regulations' sheet (refer to advice item 2).

Specimens may be loaned to other establishments under documented loan agreements. 'Duty of care' visits are performed annually to ensure loaned specimens are being stored and used appropriately.

Prior to disposal, all body parts are reviewed against traceability records, including the Body Map or Body Usage Chart (as appropriate). Following reconciliation of body parts, bodies are cremated and the ashes may be returned to the family if that is requested. Annual thanksgiving services are attended by staff, students and families of donors. Where a donor had consented to continued retention of body parts for teaching and research use, such parts are returned to storage and traceability records updated.

Prior to commencement of the HT Act, the establishment was inspected by HM Inspector of Anatomy. The establishment has been licensed by HTA since September 2007. One previous site visit inspection took place in March 2008. This report describes the second, routine, site visit inspection of this establishment in October 2015. The inspectors met staff involved with licensable activities, visually inspected areas where bodies and body parts are stored and used for teaching or surgical training, and reviewed documentation. Two bodies and six prosected specimens in storage were selected and their traceability records audited. Starting from consent documents, traceability records for a further two donors were audited. One anomaly relating to consent documentation for one donor was identified (refer to shortfall against standard C1).

The University of Bristol holds other HTA licences under the HT Act (licensing numbers 12248, 12512). Activities taking place under those licences were not reviewed at this inspection.

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

Consent

Standard	Inspection findings	Level of shortfall

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.	For one body donation audited during the inspection, the donor's will had stated their wish for their body to be used for research. After the donor had died, their solicitor wrote to the establishment reiterating the donor's wishes. This letter also refers to research. Neither the donor's will, nor their solicitor's letter, uses the term 'anatomical examination' or a similar one such as 'medical teaching'. At the time of donation, bodies could either be accepted for research or anatomical examination. Although some of the establishment's traceability records state this body was accepted for use for research, the body was in error used for anatomical examination. It is unclear how this error occurred. While the body has now been cremated, some prosected specimens were retained for continued use for teaching. There is no documented consent for storage and use of this donor's body and body parts for anatomical examination. Hence, the HT Act's consent requirements have not been met for this donor. This has been classified as a major shortfall. To address this shortfall, pending the formalisation of a CAPA, the establishment has been asked to take the following steps: • ensure all remaining body parts from this donor are either retained for research use only or disposed of immediately in line with local disposal procedures; • report this internally as an adverse incident, and; • audit all body donations accepted through a donor's will in that calendar year to determine if there are any other cases where valid consent for anatomical examination is not in place. The HTA will be notified of the outcome of this audit. *(Following the inspection, the DI informed HTA all remaining body parts from this donor had been removed from teaching pending disposal, an adverse incident had been logged, and an audit of bequeathals through wills from that calendar year found no further discrepancies. The HTA acknowledges the establishment's proactive response to this shortfall, and will seek documentary evidence through the corrective and preventive action plan.)*	**Major**

Disposal

Standard	Inspection findings	Level of shortfall
D2 The reasons for disposal and the methods used are carefully documented.	The traceability of retained specimens for disposal needs strengthening: • The 'Disposal of retained Cadaveric Specimens from Southwell Street Site' standard operating procedure (SOP) does not specify how to record in the traceability database when retained specimens have been placed into the disposal freezer pending collection for incineration. • Prior to collection of retained specimens for incineration, the DI completes a form listing which donors these parts came from, using their traceability number. However, it is not always logged on this form what specimens have come from each donor. Without robust record keeping of disposal of retained specimens, there is a potential risk these are not fully traceable. *(Following the inspection, the DI informed HTA of changes being made to the recording of disposal of retained specimens. The HTA acknowledges the establishment's proactive response to this shortfall, and will seek documentary evidence through the corrective and preventive action plan.)*	**Minor**

Advice

The HTA advises the DI to consider the following to further improve practices:

No.	Standard	Advice
1.	GQ3	The DI is advised: • to maintain records to confirm staff have read and understood all standard operating procedures (SOPs) relevant to their role, so she can be further assured they are aware of the correct procedures to follow, and; • the date of biennial staff training sessions on HTA standards should be written on attendance certificates.
2.	GQ4	Undergraduate students of University of Bristol and other universities who use the Human Dissection Room are required to read the 'Human Dissection Room Rules and Regulations' sheet prior to admission. University of Bristol students are required to sign the sheet to confirm they have read and will abide by these

		rules, but there is no requirement for visiting students to do so. The DI is advised that all undergraduate students should sign the 'Human Dissection Room Rules and Regulations' sheet before permitting access to the Human Dissection Room. While the DI receives in advance of surgical training courses the names of expected attendees, a contemporaneous attendance list is not kept in all cases. Late changes to attendees, for example, could potentially be missed. The DI is advised to keep contemporaneous attendance lists for all surgical training courses.
3.	PFE1	There is restricted access to most areas within CCCA where bodies and body parts are stored or used. However, there is open access to the Medical Museum. The University has a central booking system for teaching rooms so a wide range of staff and students could attend CCCA for classes and, potentially, enter the Medical Museum. Particularly at weekends, when establishment staff are not on the premises, there is a potential risk to the integrity of specimens and dignity of the deceased from uncontrolled access to the Medical Museum. Also, as the number and identity of persons who could enter the Medical Museum is unknown, the specimens could in principle be considered to be in use for public display, for which the establishment is not licensed. The DI is advised to consider how access to the Medical Museum may be controlled, for example, by swipe card access.
4.	PFE3	Regarding storage of bodies in the -20 ^{o}C freezer and cold-room, the DI is advised: • to develop a documented procedure and schedule for regular testing of alarms, and ; • to periodically review temperature monitoring records, for trending purposes.
5.	PFE5	The DI is advised she should ensure that she receives copies of any reports of maintenance visits of critical equipment such as freezers or body trolleys from the Estates Department. This will enable her to have assurance that these visits take place to a regular schedule and that equipment remains fit for use.
6.	PFE5	The DI is advised to confirm if the formaldemeter requires periodic calibration. The formaldemeter is not currently calibrated to a regular schedule.

Concluding comments

Despite the shortfalls, strengths were identified. The commitment of staff to the care and dignity of the deceased was very apparent. There was good evidence of close team working and communication amongst those working under the licence. The premises are clean and modern. The university has a well-developed governance framework spanning all of its HTA licences, which includes annual audits against HTA licensing standards.

Some areas of practice require improvement, including one major and one minor shortfall. The HTA has given advice to the DI with respect to record keeping, facilities and equipment, and disposal.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 28 October 2015

Report returned from DI: 2 November 2015

Final report issued: 5 November 2015

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 22 November 2015

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
PFE2 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
PFE4 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.