Site visit inspection report on compliance with HTA licensing standards

University of Birmingham, Department of Anatomy

HTA licensing number 12236

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.**

22 June 2017

Summary of inspection findings

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

The University of Birmingham (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

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

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.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

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. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, 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 provided.

HTA inspection reports are published on the HTA's website.

Background to the establishment

This report refers to the activities carried out at the University of Birmingham, Department of Anatomy (the establishment).

The Designated Individual (DI) named on the licence is Professor of Anatomical Sciences and Head of the Human Anatomy Unit. The Corporate Licence Holder (CLH) is the University of Birmingham and the CLH contact is the Pro-Vice-Chancellor (Research and Knowledge). There are two Persons Designated (PD) under the licence: an Emeritus Professor of Immunology and a Senior Technical Manager. Other staff working under the licence include a Senior Lecturer, Lecturer, Bequeathal Secretary, Deputy Bequeathal Secretary, Senior Technical Manager, Senior Prosectorium Technician, Senior Teaching Support Technician and a Prosectorium Technician (post currently vacant). There are typically 11 full time Anatomy Demonstrators during term time.

The Human Anatomy Unit is part of the Institute for Clinical Sciences (ICS) in the College of Medical and Dental Sciences (CMDS). The anatomy facilities, located in the Medical School Building, are used to teach a variety of undergraduate and postgraduate courses including medical, dental, pharmacy, science, and clinical anatomy. Outside of term time, the establishment facilitates a Pain Management/X-ray course twice a year for a range of health care professionals from the UK and overseas. Occasionally, they facilitate additional courses for health care professionals.

The establishment receives approximately 20 whole body donations per year. The establishment does not loan specimens to others, import or receive specimens from other locations. They operate a bequeathal process and obtain donated bodies from donors who fit established acceptance criteria. Occasionally, they receive referrals from other anatomy schools; for example, when other schools have sufficient bodies. The Bequeathal Secretary and Deputy Bequeathal Secretary at the establishment seek consent from the donors (see Advice, item 1). Donated bodies are used for the purpose of anatomical examination, through demonstration and dissection. Prosections, bones, and plastinated specimens are also used for teaching.

Delivery of bodies is arranged, in advance, with a contracted funeral director. On arrival, the funeral director telephones the establishment and staff meet them at the reception area, which is located in a secluded part of the medical school. After receipt of the body, and identification checks, the body is prepared for embalming. The Senior Prosectorium Technician (SPT) is responsible for embalming the body and preparation of prosected specimens (see Advice, item 5). The SPT prepares the embalming fluid, examines the body and notes down any relevant information on the embalming record (e.g. condition of body, scars). All bodies are labelled with a unique identification number, which the establishment refers to as the ‘BM number’. Six tags with the BM number are put on every donor: both

wrists, both ankles and both ears. The BM number is also written, in permanent marker, on the soles of the feet. The HTA has given advice regarding writing on the deceased (see Advice, item 6). Additionally, an electronic microchip, which also contains a unique code, is injected in the sole of the right foot, just below the big toe. The BM number and unique code are written in the accompanying paperwork of the donor.

After the embalming is completed, and if there is a requirement for prosected specimens, the SPT dissects and prepares the specimens. Prosections are labelled with a BM identification number and a code which relates to the region/type of body part. Depending on the size and suitability of the specimen, an electronic microchip is also inserted. Two technicians are present when parts are labelled. A form is completed with the BM number and electronic code and signed off by both technicians. Once forms are completed, they are kept in the bequeathal office. Prosected specimens are kept in sealed containers with the body and stored on a body tray in a locked storage area.

There is also a locked storage cabinet within the preparation room that holds specimens where consent is in place for retention beyond disposal of the rest of the body. Other relevant material such as bones and plastinated parts are stored in an additional locked storage room. Bones are also stored in locked cabinets in the anatomy tutorial rooms.

Depending on the type of course, students dissect whole bodies or use prosections for their training. Students may also use bones or plastinated specimens. Before undertaking any training, students are required to attend a lecture given by the DI, which includes the history of the Human Tissue Act (HT Act), an overview of the regulatory framework, and respect for the dignity of the donors. They are also required to read and sign a code of conduct. Students cannot work with the bodies or prosections without attending the lecture. Students must sign a register when attending classes. They are also required to wear appropriate personal protective equipment (PPE) or they will not be allowed into class.

Training is carried out in the dissection room, the prosectorium, or in any of the 11 dedicated anatomy tutorial rooms.

The dissection room is adjacent to the preparation room and contains four downdraft tables. A technician provides supervision and is always present in the room when students are dissecting. A group of approximately four students are assigned to each table and remain with the same body throughout their course. Any tissue removed during dissection is kept in a metal tray on the table, put into labelled containers, and kept with the body. At the end of each day, bodies are either covered or put back into storage depending on when the next course runs. If any maintainence or repair work needs to be carried out in the room, this is arranged ahead of time and work is done when courses are not in session.

The prosectorium is located on another floor within the department. The technicians transfer prosections to the prosectorium in a covered container along with a prosection form. There is a dedicated lift for the transfer of specimens. There are 10 downdraft tables, with approximately four students allocated to each table. Students are supervised by three circulating demonstrators and a technician. Students remain in the same group and rotate through the tables to look at the prosected specimens. At the end of each day, specimens are collected and transferred back to storage.

The 11 anatomy tutorial rooms are used by students using bones or plastinated specimens for their training. There is always a member of academic staff or a Demonstrator supervising students during training. After the training session is finished, specimens are collected and transferred back into storage.

Disposals are arranged in advance and bodies are put into individual coffins provided by the funeral director. Bodies are kept for approximately three years before disposal. If there is no permission for retained parts, these are reunited with the rest of the body prior to disposal. Families are given the option to attend the cremation and a ceremony is provided if requested.

Disposal of retained material is organised by the Senior Technical Manager and carried out by a contracted company. All disposal of retained parts is witnessed by the DI or PD from the establishment.

A disposal form is completed and the date, method and reason for disposal is recorded in the paperwork and kept with the donor file in the bequeathal office.

Every year, the university holds a memorial service which they refer to as a 'Thanksgiving service'. This is attended by students and staff. Afterwards, a transcript ot the service is sent to the families of the donors.

Description of inspection activities undertaken

This was the second routine site visit of the establishment by the HTA. The last inspection took place in 2013. This inspection included a visual of the areas where tissue is received, prepared, and stored; a visual inspection of the prosectorium, dissection room and anatomy tutorial rooms; interviews with members of staff; and a review of governance documentation. An audit trail was also conducted. Details are included below.

A traceability audit was conducted by the inspection team on:

- A whole body;
- a prosected left ulnar nerve;

- a prosected left lung attached to a heart;
- two plastinated hearts; and
- a box of existing holdings containing 43 left radius bones.

Labels and electronic coding on the specimens were checked against relevant paperwork, consent forms and computer records. No anomalies were found.

Inspection findings

The HTA found the Licence Holder, the Designated Individual and the premises 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.	C1e	During the inspection, staff at the establishment raised the issue of accepting donations from donors whose first language is not English and where the responsibility lies in terms of ensuring the accurate translation of information to the donors. Establishments need to assure themselves that valid and appropriate consent has been obtained, which may be challenging in cases where the first language of the potential body donor is not English, especially where that language is not commonly used. In such cases, establishments may need to take a flexible and risk-based approach, working with relatives or others (such as those involved in language translation) to ensure that any consent obtained is valid and appropriate. Whatever approach is taken, it is important that decisions are documented and that there is good record-keeping. Looking to the future, the establishment may wish to consider translating their consent forms into languages common to non-English speaking communities of that area.
2.	GQ1a	In the document for students 'Rules and Compliance/Background', there is a reference to the HTA licensing images. The making and displaying of images

		(including photographs, films and electronic images) fall outside of the scope of the HT Act and cannot be formally regulated by the HTA. The DI is therefore asked to correct this section and consider whether published guidance from the HTA on this matter could be usefully added.
3.	GQ1d	Staff at the establishment currently have ad hoc meetings but these are not recorded. Overall governance processes should be supported by regular meetings with staff at the establishment who are engaged in licensed activities. Formal meetings should be minuted and the actions should be noted and followed up. Documented minutes of meetings should be distributed to all relevant staff to help to ensure that they are aware of all important information relating to licensed activities at the establishment. National and local information relevant to activities should also be disseminated.
4.	GQ2b	The establishment has a documented audit schedule and conducts traceability, consent and process audits several times a year. However, some of the audits are not recorded. The DI is advised to formalise the process of audits. Audit findings should include who is responsible for follow-up actions and the timeframes for completing these. Audit processes can benefit from being undertaken by a person who is not normally involved in the activity at the establishment. In addition, outcomes of the audits should be used to review and update existing SOPs where the processes have evolved or changed so they reflect current practice.
5.	GQ6a	Currently, there is only one member of staff who can embalm. If this staff member is off sick or away, there is no one to cover and the establishment cannot accept donations. Inability to accept donations because of a lack of staff trained in embalming, opens up the possibility of fewer donations which creates a risk of not having enough material for students. The DI is advised to undertake a risk assessment to clearly define the risks inherent in this situation and identify possible mitigations.
6.	T1a	In addition to labelling the donor with six tags containing the BM number, it is also written on the soles of their feet. To maintain the dignity of the donors, the HTA requests that this practice is stopped.
7.	PFE3a	Some equipment is old and may not be optimal for current practices and requirements; for example, the embalming table is not adjustable. The DI is advised to review the equipment throughout the department, perhaps supported by auditing and risk assessment. This should help to identify any areas or equipment that may benefit from refurbishment or upgrade.

Concluding comments

All HTA licensing standards were assessed as met.

In terms of strengths, staff at the establishment have many years of experience, are dedicated and sensitive to the needs of families. They appear to have a good working relationship with the funeral director.

In terms of good practice, the DI has put together a thorough presentation for students, which includes references to relevant statutory and regulatory requirements. Also, traceability audits include noting the condition of specimens and any follow up actions that may be required.

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

Report sent to DI for factual accuracy: 11 July 2017

Report returned from DI: 20 July 2017

Final report issued: 21 July 2017

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
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice. b) Consent forms are available to those using or releasing relevant material for a scheduled purpose. c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice. d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice. e) Language translations are available when appropriate. f) Information is available in formats appropriate to the situation.
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
a) There is suitable training and support of staff involved in seeking consent. b) Records demonstrate up-to-date staff training. c) 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
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities. b) There is a document control system. c) There are change control mechanisms for the implementation of new operational procedures. d) Matters relating to HTA-licensable activities are discussed at regular governance meetings, involving establishment staff. e) There is a system for managing complaints.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits covering licensable activities. b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
a) Qualifications of staff and all training are recorded, records showing attendance at training. b) There are documented induction training programmes for new staff. c) Training provisions include those for visiting staff. d) Staff have appraisals and personal development plans.

GQ4 There is a systematic and planned approach to the management of records
a) There are suitable systems for the creation, review, amendment, retention and destruction of records. b) There are provisions for back-up / recovery in the event of loss of records. c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).
GQ5 There are systems to ensure that all adverse events are investigated promptly
a) Staff are instructed in how to use incident reporting systems. b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice. b) Risk assessments are reviewed regularly. c) Staff can access risk assessments and are made aware of risks during training.

Traceability standards
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it. b) A register of donated material, and the associated products where relevant, is maintained. c) An audit trail is maintained, which includes details of when and where the bodies. or tissue were acquired, the consent obtained, the uses to which any material was put, when and where the material was transferred, and to whom. d) A system is in place to ensure that traceability of relevant material is maintained during transport. e) Records of transportation and delivery are kept. f) Records of any agreements with courier or transport companies are kept. g) Records of any agreements with recipients of relevant material are kept.
T2 Bodies and human tissue are disposed of in an appropriate manner
a) Disposal is carried out in accordance with the HTA's Codes of Practice. b) The date, reason for disposal and the method used are documented.

Premises, facilities and equipment standards
PFE1 The premises are secure and fit for purpose
a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose. b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained. c) There are documented cleaning and decontamination procedures.
PFE2 There are appropriate facilities for the storage of bodies and human tissue
a) There is sufficient storage capacity. b) Storage arrangements ensure the dignity of the deceased. c) Storage conditions are monitored, recorded and acted on when required. d) There are documented contingency plans in place in case of failure in storage area.
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored
a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept. b) Users have access to instructions for equipment and are aware of how to report an equipment problem. c) Staff are provided with suitable personal protective equipment.

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.