Site visit inspection report on compliance with HTA licensing standards

Anglia Ruskin University

Proposed HTA licensing number 12683

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.**

04 October 2018

Summary of inspection findings

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

Anglia Ruskin University (the establishment) was found to have met all HTA standards.

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

Anglia Ruskin Medical School is a brand new facility that opened to students in September 2018. Within the Medical School, the establishment proposes to open anatomy facilities for anatomical examination of Thiel embalmed cadavers in order to teach gross anatomy to undergraduate Medical students. The establishment has applied for a HTA licence.

The proposed Designated Individual (DI) is a Senior Human Anatomy Technician. The Corporate Licence Holder (CLH) is Anglia Ruskin University and the CLH contact (CLHc) is the Chief Legal and Governance Officer for the University. There are two proposed Persons Designated (PD) under the licence: a Senior Anatomy Lecturer and an Anatomy Technician and Demonstrator.

The anatomy suite includes an embalming room and an anatomy laboratory. Access is restricted to six key members of staff. There is closed circuit television (CCTV) and a swipe card entry system on all doors leading to the anatomy suite. Records of cards that have attempted access are available and are reviewed. Out of hours the premises is alarmed.

The first intake of cadavers will be imported, pre-embalmed from Scotland and anatomical examination will begin in November 2018. The establishment intends to receive all subsequent bodies from London Anatomy Office and plans to embalm them on site. There is a Service Level Agreement (SLA) with London Anatomy Office who will undertake the bequeathal process (including obtaining consent) on their behalf. Cadavers will be delivered from a contracted Funeral Director and brought to the facility to be embalmed using the Thiel embalming method. On receipt of a body, identification and consent documentation will be checked and all bodies are to be labelled with a unique identification number (ID). Three tags with the unique ID will be put on every donor. The establishment plans to use a database for tracking bodies from arrival to use to disposal.

Access to the embalming room is restricted to Anatomy staff only. Within the embalming room there are two large embalming tanks that can take up to four bodies each and one smaller tank that can take two bodies. Cadavers will be perfused with embalming fluid and then submerged in the Thiel tanks for a period of three to six months. Bodies will be checked weekly. Following submersion, the cadavers will be sealed using a vacuum sealer and plastic tubing and will be stored in room temperature racking until they are used for anatomical examination. There are spaces for 60 cadavers on the racking in the embalming room. There is also a refrigerated storage facility and a freezer that can hold up to four bodies each. As the Thiel embalming procedure will begin immediately after the bodies arrive there are no plans to use the temperature controlled storage facilities.

With appropriate consent, prosections may be retained from some cadavers. Prosections will be labelled with the bodies unique ID and a code which relates to the body part. This will be tracked on the database and stored within the racking area in the embalming room.

Anatomical examination by Medical students will take place in the anatomy laboratory. The Medical students will undertake a systematic dissection of a whole cadaver over the course of three years. During dissection classes, students will be supervised by teaching staff, technicians and demonstrators. Before undertaking any practicals, students are required to attend an 'Introduction to Anatomy' lecture which includes information about the Human Tissue Act 2004 (HT Act) and an overview of the regulatory framework. Students are also required to read and sign a Code of Conduct. Students cannot work with the bodies or prosections without attending the lecture. Students register electronically when attending classes. They are also required to wear appropriate personal protective equipment (PPE).

There are 16 fully-equipped dissection tables. A group of approximately 6 students will be assigned to each table. Any residual tissue removed during dissection is kept bagged and stored in a metal tray underneath the table. The material remains at the associated station with the relevant cadaver until it is reunited with the body prior to disposal. All organs and limbs that are dissected are also stored with the body in their correct anatomical positions. At the end of each day, stations are cleaned and bodies are covered. During term time the cadavers will be stored in the anatomy laboratory and transferred to the racks in the embalming room out of term time.

Bodies are kept for approximately one to three years before disposal. Disposals will be arranged in advance and bodies are picked up by agreed Funeral Directors. For the first set of bodies imported, bodies will be transferred back to the receiving establishment. For subsequent bodies received from London Anatomy Office, bodies will be sent for cremation as per SLA.

Inspection findings

The HTA found the LH, the DI 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 proposed DI to consider the following to further improve practices:

No.	Standard	Advice
1.	GQ3(a)	The proposed DI is advised to ensure that all staff involved in undertaking licensed activities are aware of the requirements of the HT Act and the HTA's Codes of Practice.
2.	GQ3(a)	Currently, there is only one member of staff who is fully trained to perform Thiel embalming. The DI is advised to train up other members of the anatomy team to ensure that body donations can be accepted and embalmed if the Senior Human Anatomy Technician is away.
3.	PFE1(a)	As the body store fridge and freezer are identical, the DI is advised to clearly label them to ensure that staff do not inadvertently store a body at the wrong temperature.

Concluding comments

This report describes the licence application assessment of the suitability of Anglia Ruskin University to be licenced under the HT Act 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.

All HTA licensing standards were assessed as met and the HTA found the proposed DI, LH and CLHc suitable. The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 10 October 2018

Report returned from DI: 16 October 2018

Final report issued: 17 October 2018

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.