Site visit inspection report on compliance with HTA licensing standards

University of East Anglia

HTA licensing number 12005

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.**

27 June 2019

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.

University of East Anglia 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

University of East Anglia (the 'establishment') undertakes a wide range of activities, including anatomy courses for students and surgical skills training for health professionals. The establishment stores and uses embalmed and fresh frozen bodies.

Establishment staff are trained to seek consent and answer enquiries from potential donors or their families. The establishment has a dedicated phone number and rota to ensure that staff are available to answer enquiries out-of-hours. After staff speak to a potential donor, an information booklet is sent to them with a consent form. Once the consent form is sent back to the establishment, staff check the paperwork to ensure everything is filled out correctly.

Consent forms and donor associated paperwork is kept in the anatomy office in secure fireproof safes. Documents are also scanned into the database, which has restricted access.

At the time of donation, staff arrange arrival times directly with contracted funeral directors. After the body is received by staff at the establishment, it will either be embalmed or frozen.

Bodies are given unique numbers and six tags are attached to each (both ears, thumbs/or fingers and both big toes). If the body is embalmed then it will be stored in the fridge. For frozen bodies, they will remain in the freezer until needed for courses. All fridges and freezers are locked and access is restricted to anatomy staff only.

Where prosections are created, an identification system with unique numbers links the prosections to the body from which they were prepared. Prosections are also stored securely in the refrigerated room in steel cabinets, plastic containers or freezers. Staff reported it was sometimes difficult to access these prosections due to the current arrangements of the walk in fridge. The establishment also has a small collection of slides, bones and potted samples which are catalogued, regularly audited and stored securely.

When bodies are required for teaching, they are moved to individual tables with lids that are held in place by tight catches. They are stored in a walk in refrigerated room when not in use.

Access to the anatomy suite is restricted by patented keys which are held by the anatomy staff. A spare key is held by security. The facility is alarmed and has motion detection sensors.

If required, the establishment will accept bodies from neighbouring anatomy schools. The anatomy facility has capacity for 35 bodies.

The dissecting room is set up so that tables are designated to specified groups of students and therefore their activities can be closely monitored. Dissection log books are associated with each trolley for students to record laboratory activity.

No comparative anatomy is taught at the establishment.

At the end of each academic year, bodies are cremated or buried according to the wishes of the next of kin. Relatives and students are invited to attend a memorial service held by the university for all bodies used the previous year.

Description of inspection activities undertaken

The establishment has been licensed since November 2007. This was the second routine inspection and covered the areas of bequeathal, body receipt, embalming, storage as well as dissecting room activities and disposal. The inspection also involved a review of documentation and meetings with individuals working under the licence. Interviews were conducted with the Designated Individual and staff involved in licensable activities.

Audits were conducted of two embalmed bodies in the fridges; one body currently used for teaching in the walk in fridge; one fresh frozen body; one potted specimen and one prosection. All relevant material was traced back to original consent forms. Donor records were checked for completeness, accuracy and crosschecked against the electronic database. Full traceability was seen and no discrepancies 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.	GQ1 (b)	The establishment has Standard Operating Procedures (SOPs) for all activities under the licence, which are reviewed and updated regularly. The DI is advised to add the review date to the documents so they can identify when a document is approaching its required 'review by' date.
2.	PFE2 (d)	There is a documented contingency plan, but this is not wide ranging in consideration of the possible risks. The DI is advised to re-examine the contingency plan and re-evaluate the risks to see if the plan is still appropriate and meets the needs in the unlikely event of a complete loss of service (e.g. fire damage).

Concluding comments

During the site visit inspection of the establishment, several strengths and areas of good practice were noted. These were:

- Staff are experienced and knowledgeable about the activities carried out at the establishment. They also demonstrated a good understanding of the Human Tissue Act 2004 and how it relates to their activities
- The preparation and dissection areas are cleaned to a high standard
- There appears to be a good relationship between staff at the establishment with funeral directors. Staff provide training for funeral directors that relates to the activities conducted in the anatomy department so that funeral directors are familiar with procedures when bringing bodies to the department In addition, staff at the establishment participated in a tour of the funeral directors facilities and completed training in bereavement to famliarise themselves with the process
- Despite the pressures on staff, a good working practice, high standard and dignified service is maintained

Report sent to DI for factual accuracy: 16 July 2019

Report returned from DI: 19 July 2019

Final report issued: 2 August 2019

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.