

Inspection report on compliance with HTA licensing standards

Inspection date: **28 October (remote) and 5 November (site visit) 2025**



Anglia Ruskin University

HTA licensing number 12683

Licensed under the Human Tissue Act 2004

Licensed activities

Area	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	Storage of an anatomical specimen
Anglia Ruskin University School of Medicine	Licensed	Licensed	Licensed	Licensed

Summary of inspection findings

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

Although the HTA found that Anglia Ruskin University ('the establishment') had met the majority of the HTA's standards, one minor shortfall was found against standards for traceability.

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.

Compliance with HTA standards

Minor Shortfalls

T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail.		
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.	One audit carried out during the inspection identified that the traceability of one whole body had not been fully maintained. The body was in the mortuary; however, the inventory register listed it as being stored in a classroom for teaching. <i>The establishment submitted sufficient evidence to address this shortfall before the report was finalised</i>	Minor

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, 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.

Advice

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

Number	Standard	Advice
1.	PFE2(c)	The establishment has a fridge that is used intermittently for the short-term storage, typically for periods of up to two days. To ensure that appropriate storage conditions are maintained whenever the unit is in use, the DI is advised to implement temperature monitoring for this fridge during periods of operation.

Background

Anglia Ruskin University provides anatomy teaching to undergraduate students as well as training for healthcare professionals. Activities include the receipt, preparation, storage, use, and disposal of donated bodies for anatomical examination and education. Anglia Ruskin University has been licensed by the HTA since October 2018. This was the second inspection of the establishment; the most recent previous inspection took place in October 2018. Since the previous inspection, a new Designated Individual (DI) has been appointed, along with four new Persons Designated (PDs).

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during the inspection:

Standards assessed against during inspection

40 out of 47 HTA licensing standards were covered during the assessment (standards published 3 April 2017). Some standards relating to consent procedures (C1(a), C1(d), C1(e), and C1(f)) and standards relating to consent training (C2(a), C2(b) and C2(c)) were not applicable as the establishment does not directly seek consent from donors.

Review of governance documentation

Policies and procedural documents relating to all licensed activities, including standard operating procedures and traceability systems were assessed. Documents detailing adverse events, incidents, risk assessment, governance meetings, agreements with the establishments providing donated material and audits were also reviewed.

Visual inspection

The inspection included a visual inspection of the anatomy suite including the areas where staff receive and store embalmed bodies, prosections and relevant material, and the areas where relevant material and specimens are used for training and anatomical examination.

Audit of records

An audit was undertaken of records and labelling for seven embalmed bodies and five prosections. In the storage area, Traceability was not maintained for one whole body, as the recorded storage location did not match the actual location of the body at the time of inspection (see Minor shortfall, T1(c))

Meetings with establishment staff

The inspection included discussions with the DI and two PDs.

Report sent to DI for factual accuracy: 24 November 2025

Report returned from DI: 28 November 2025

Final report issued: 28 November 2025

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI 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 DI 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 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.

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 Human Tissue Act 2004 (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 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:

- A notice of proposal being issued to revoke the licence
- 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.
- A notice of suspension of licensable activities
- Additional conditions being proposed
- 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 Codes of Practice, 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 review or at the time of the next inspection.

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 the final inspection report.

Establishments 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 inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.