Inspection report on compliance with HTA licensing standards
Inspection date: **04 April 2025**

Anglia Ruskin University

HTA licensing number 12515

Licensed under the Human Tissue Act 2004

Licensed activities

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose	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
Hub site East Road Campus, CB1 1PT	Licensed	Not Licensed
Satellite site Compass House, CB5 8DZ	Licensed	Not Licensed
Satellite site Chelmsford Campus, CM1 1SQ	Licensed	Not 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, three minor shortfalls were found against standards for Governance and quality systems. These shortfalls related to document control, audit follow-up and staff training records.

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

All applicable HTA standards have been assessed as fully met.

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
b) There is a document control system.	The establishment did not have a robust system for managing document control for standard operating procedures (SOPs). There was no system in place to show a list of SOPs, who authored, reviewed, and approved them, or when they are due for review. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	

GQ2 There is a documented system of audit		
b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.	The establishment did not have a consistent approach in place that specifies responsible parties for follow-up actions and outlines timeframes for completing these actions. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

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.	The establishment did not have staff training records available for inspection. There was no documented evidence of staff attendance at relevant training sessions. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**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 practices:

Number	Standard	Advice
1.	GQ3(a)	The establishment has a structured training programme for new staff, which introduces them to the Human Tissue Authority (HTA) and the scope of the HTA licence. To further strengthen this, the DI is advised to include reference to HTA Code A (Guiding Principles and the Fundamental Principle of Consent) and HTA Code E (Research) in staff training. This will help ensure staff are aware of both the regulatory requirements and the principles underpinning licensed research activities.
2.	GQ6(a)	To ensure that risks are appropriately mitigated and that suitable controls are in place to prevent adverse events, the DI is advised to ensure that risk assessments include preventative measures and controls for each identified risk.
3.	PFE2(c)	To help ensure a prompt and effective response in the event of an emergency—particularly out of hours or if primary contacts are unavailable—the DI is advised to add the names and contact details of additional persons to the freezer.

4.	PFE2(c)	To strengthen the establishment's preparedness for emergencies and ensure a coordinated response, the DI is advised to include more detailed information in the contingency plan, such as specific roles and responsibilities, response timelines, and escalation procedures.

Background

Anglia Ruskin University is licensed for the storage of relevant material which has come from a human body for use for a scheduled purpose, under the Human Tissue Act 2004 (HT Act). The institution supports a range of research activities across multiple campuses, primarily involving the collection and storage of saliva samples. Human tissue work is overseen by the Human Biological Material Committee (HBMC), and the ARU Biomarker Laboratory currently serves as the main licensed storage site.

Anglia Ruskin University has been licensed by the HTA since 2008. This was the fourth inspection of the establishment; an evaluated self-assessment took place in October 2023.Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence

Description of inspection activities undertaken

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

Standards assessed against during inspection

There are 47 standards in the Research sector, of which 46 were assessed. Standard PFE2(b) could not be assessed as the establishment does not store bodies or body parts (standards published 3 April 2017).

Review of governance documentation

The assessment included a review of documentation relevant to the establishment's licensed activities. This included policies and procedural documents relating to licensed activities, agreements with suppliers, equipment maintenance records, risk assessments, arrangements for temperature monitoring for the storage units, a review of the sample tracking system and audits, and incidents.

Visual inspection
No site visit was undertaken as part of this inspection. The establishment provided images of the storage facilities that allowed for assessment of security measures and the signage on the individual units

Audit of records
There were no sample audits carried out. A number of audits carried out by the establishment staff, which included audits covering processes and traceability of specimens, were reviewed.

Meetings with establishment staff
The inspection included discussions with the DI, PDs and other staff working under the licence. This included a Research Assistant, a Research Fellow and Laboratory Manager, a Biomedical Scientist, the Head of Security, a manager from Facilities and an Estates and Facilities Head Technician.

Report sent to DI for factual accuracy: 25 April 2025

Report returned from DI: 13 May 2025

Final report issued: 13 May 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.