Inspection report on compliance with HTA licensing standards
Inspection dates: **27 and 28 May 2025**

University Hospital Coventry
HTA licensing number 30019

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
University Hospital Coventry (Hub site)	Licensed	Licensed	Licensed	Licensed
Halo Medical Solutions Limited (Satellite site)	Not licensed	Not licensed	Not 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 University Hospital Coventry ('the establishment') had met most of the HTA standards, five shortfalls were identified against Governance and quality system standards. These were in relation to documented procedures, audits, records management, risk assessments and 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

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		
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.	The establishment's standard operating procedures (SOPs) did not contain sufficient details to enable a new member of staff to follow procedures from start to end. Furthermore, there were no SOPs in place for the receipt of cadaveric material or preparation of cadaveric material for surgical training.	**Minor**

GQ2 There is a documented system of audit		
b) There is a documented schedule of audits covering licensable activities.	The establishment uses an audit proforma template to document audits undertaken. Completed audit reports were reviewed during the inspection and were found not to contain sufficient detail about the information that was reviewed at the time the audit was carried out.	**Minor**

GQ4 There is a systematic and planned approach to the management of records		
b) There are provisions for back-up / recovery in the event of loss of records.	Hard copy donor files are held in a locked, fire-proof room. There are no back-up provisions in the event of loss of these records.	**Minor**

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.	The establishment has carried out risk assessments against licensable activities but these did not contain sufficient information about the control measures in place at the hub and satellite sites.	**Minor**

T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail.		
b) A register of donated material, and the associated products where relevant, is maintained.	The establishment did not have an up-to-date inventory record of plastinated specimens.	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ1(b)	The establishment carries out regular reviews of their SOPs. If there are no changes required, they do not document that the procedure was reviewed. To strengthen the governance around this, the DI is advised to record when any formal review has been undertaken in the revision history.
2.	GQ6(a)	The DI is advised to ensure that site-specific risks are considered and included in risk assessments This will help to improve the approach to risk management and oversight of risks at both sites

Background

University Hospital Coventry ('the establishment') hosts the West Midlands Surgical Training Centre, which has 8 fully equipped surgical stations to represent a clinical training environment. The establishment imports fresh-frozen cadaveric specimens from the USA, under an agreement, which are then stored and used in surgical training a few times a week throughout the year. The establishment is licensed under a hub-and-satellite licensing arrangement and specimens are stored at the satellite either for re-use in surgical training or sensitive disposal.

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
Of the 47 HTA standards 39 were assessed (standards published 3 April 2017). Standards C1(a),(b),(d),(e) and (f) and C2(a),(b) and (c) were not applicable as the establishment is not involved in seeking consent.

Review of governance documentation
A number of documents were reviewed during the inspection which included, but were not limited to, agreements confirming consent from the supplier, standard operating procedures for licensable activities, key policies, traceability audits, meeting minutes, staff training records, and incident reports.

Visual inspection
A visual inspection of the premises where human material is stored and used was undertaken during the site visit inspection.

Audits
Audits reviewed during the inspection focussed on storage of cadaveric material, consent, transport and disposal records.

Hub site: day one traceability audits

Forward and reverse audits of three cadaveric specimens were undertaken. This included review of delivery notes, packing slips as well as specimen movement forms. All specimens were fully traceable and no discrepancies were noted.

A records audit was undertaken of two cadaveric specimens shipped across to the satellite site for disposal. This included review of delivery notes, packing slips and specimen movement forms. All specimens were fully traceable and no discrepancies were noted.

There were three plastinated specimens that were identified from the inventory spreadsheet but were not in storage as these had been transferred under agreement to another HTA-licensed premises. The inventory record had not been updated appropriately *(Minor shortfall, T1c*).

Further audits of two plastinated specimens were undertaken. These were traced from a recent inventory audit record to their storage locations. All specimens were fully traceable.

Satellite site: day two traceability audits

Forward audits of three cadaveric specimens were undertaken from storage locations through to records. All specimens were fully traceable and no discrepancies were noted.

Reverse audits of two cadaveric specimens were undertaken, identifying parts from records through to their storage locations. All specimens were fully traceable and no discrepancies were noted.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff which included the DI, Persons Designated (PD) at the hub and satellite sites and Surgical Technicians.

Report sent to DI for factual accuracy: 20 June 2025

Report returned from DI: 20 June 2025

Final report issued: 23 July 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.