Inspection report on compliance with HTA licensing standards
Inspection dates: **4 June (remote) and 10-11 June (site visits) 2025**

Newcastle University
HTA licensing number 12148
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
Hub site Newcastle University	Licensed	Licensed	Licensed	Licensed
Satellite site Minimally Invasive Surgery Training Facility	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 Newcastle University ('the establishment') had met the majority of the HTA's standards, six minor shortfalls were found against standards for Consent, Governance and quality systems 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
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.		
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.	The donor information pack and consent form available at the time of inspection provided comprehensive details about the body donation process, including the purpose of donation and the ways in which donated material is used. However, the documentation did not include information on how a potential donor could withdraw their donation offer. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised*	**Minor**

GQ1 All aspects of the establishment's 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.	Procedures for managing the receipt of material from third-party suppliers are not fully documented or integrated within the establishment's governance framework. At the time of inspection, it was noted that the satellite site received cadaveric material from external providers. However, the Designated Individual (DI) had not been formally informed of these sourcing arrangements and had not reviewed or signed the relevant agreements. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised*	**Minor**
d) Matters relating to HTA-licensable activities are discussed at regular governance meetings, involving establishment staff.	The establishment did not hold regular governance meetings that covered the hub and satellite sites. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised*	**Minor**

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 approach to audit at the satellite site did not include how audit findings would be managed in accordance with this standard and there were no supporting documents or templates. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised*	**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 satellite site did not have risk assessments in place for all practices and processes relating to licensed activities. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised*	**Minor**

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.	Audits conducted during the inspection of the satellite identified that the traceability of two specimens was not maintained. The specimens were located in the 'thaw fridge'; however, the inventory register recorded them as being stored in 'Fridge 1'. (see *Audit of records*, below) *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.	GQ1(d)	The DI does not currently receive regular updates on incidents or audits from the satellite site. The DI is advised to implement formal arrangements to ensure routine sharing of incident reports, audit schedules, and findings. This will support governance and oversight of licensed activities, ensuring issues are identified, discussed and addressed in a timely manner.

Background

Newcastle University's Anatomy and Clinical Skills department provides teaching of human anatomy to undergraduate and postgraduate students and supports surgical training. Activities include the receipt, storage, use, and disposal of donated bodies for anatomical examination and surgical skills education. The establishment also supplies material to its satellite site, the Minimally Invasive Surgery Training Facility.

Newcastle University has been licensed by the HTA since 2007. This was the third inspection of the establishment; the most recent previous inspection took place in May 2016. Since the previous inspection, a new Designated Individual (DI) and Corporate Licence Holder (CLH) contact have been appointed, along with seven new Persons Designated (PDs). In addition, two previously licensed satellite sites have been formally revoked. There have been no other significant changes to the licence arrangements or the activities carried out under the licence. The satellite site, the Minimally Invasive Surgery Training Facility, is in the final stages of applying for its own HTA anatomy sector licence; if a new licence is granted, it will cease to be a satellite site under current licensing arrangements.

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

All 47 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

Policies and procedural documents relating to all licensed activities, including standard operating procedures and traceability systems were assessed. Documents detailing staff training, adverse events, incidents, governance meetings, agreements with the establishments providing embalmed bodies and prosections, and audits were also reviewed.

Visual inspection
The inspection included a visual inspection of the hub facility, covering the anatomy suite and associated areas where staff receive and store embalmed bodies, prosections, and other relevant material, as well as areas used for training, anatomical examination, and dissection. The satellite site inspection included areas where staff receive and store bodies and relevant material, and where specimens are used for surgical skills training.

Audit of records
At the hub site, an audit was undertaken of records and labelling for three embalmed bodies in the storage area, ten prosections (two stored in fluid and eight in refrigerated storage), two potted specimens, and two plastinated samples. Full traceability was demonstrated for all items audited. At the satellite site, an audit was conducted of records and labelling for five bodies in storage and six anatomical specimens. Traceability was not maintained for two of the specimens, as their recorded storage locations did not match their actual locations at the time of inspection (see *Minor shortfall, T1(c)*)

Meetings with establishment staff
The inspection included discussions with the Designated Individual (DI), Clinical Anatomy Lead, Technical Team Lead, Bequeathal Secretary, Professor of Anatomy Education, Head of Risk, Compliance and Governance, and two Persons Designated (PDs).

Report sent to DI for factual accuracy: 27 June 2025

Report returned from DI: 22 July 2025

Final report issued: 22 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.