Inspection report on compliance with HTA licensing standards
Inspection date: **7th (virtual assessment) and 8th (site visit) July 2025**

Wrightington Hospital
HTA licensing number 12487

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
Wrightington Hospital	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 Wrightington Hospital ('the establishment') had met the majority of the HTA's standards, one major and four minor shortfalls were found against standards for Governance and quality systems, Traceability and Premises, facilities and equipment.

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

Standard	Inspection findings	Level of shortfall
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.	There is no documented procedure which describes the process for ordering and receiving cadaveric material.	**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.	There is no process in place to manage actions arising from audits.	**Minor**

GQ5 There are systems to ensure that all adverse events are investigated promptly.		
a) Staff are instructed in how to use incident reporting systems.	The establishment does not have documented procedure for managing adverse events.	**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.	There was no assessment of risk for receiving material without appropriate consent or transporting cadaveric material to the radiology department for scanning purposes.	**Minor**

PFE1 The premises are secure and fit for purpose.		
b) Arrangements are in place to ensure that the premises are secure, and confidentiality is maintained.	Although the establishment is secure, staff enter using fob access, for which there is no means of checking electronic records of access in or out of the facility.	**Major**

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.	GQ2(b)	The establishment undertakes internal and external traceability audits on a regular basis. During the inspection, completed audits were reviewed and it was noted that they lacked sufficient detail about the scope of the audit. The DI should consider reviewing the approach to documenting audits to ensure all findings are recorded clearly.
2.	GQ3(b)	Porters support the Upper Limb Education Courses Administrator (Persons Designated) or Laboratory Technician by checking identifiers of the cadaveric material both on receipt and prior to disposal. At present there is no formal training for Porters involved in supporting laboratory staff in these activities. To improve governance further, the DI should consider introducing formal Porter training.

3.	GQ3(b)	The DI should consider formal competency assessment of staff who are trained to support activities in the Bioskills Laboratory. This will help to ensure there are appropriate records available for all staff which demonstrate competencies, before staff undertake licensable activities.
4.	GQ4(a)	Establishment staff should carry out a regular review of data entered into the inventory spreadsheet, as some minor discrepancies were noted during the traceability audit. This will help to ensure that the information recorded remains accurate and up to date.
5.	PFE2(d)	There is a business continuity plan which documents the arrangement for material to be transferred to another HTA-licence (on the same premises); however this does not provide sufficient detail about the procedure for moving cadaveric material to the other department in the event of an emergency. The DI should consider implementing a documented procedure which describes the process for moving material in an emergency.
6.	T1(c)	A log is kept documenting the freezing and thawing cycles of the cadaveric material as well as the courses the material was used for. Staff do not consistently document when cadaveric material is placed in the freezer on arrival to the Bioskills Facility. To strengthen the governance, the DI should ensure that staff record this information. This will help to ensure there is a full audit trail of material, including receipt, freezing, thawing, use and disposal.

Background

The establishment has been licensed by the HTA since 2007. This was the 2nd inspection of the establishment; the most recent previous inspection took place in December 2016.

Since the previous inspection, the establishment have moved their facility but this remains on the same premises. The establishment purchases cadaveric material from outside the UK. The material is used in Dental, Ear, Nose and Throat, and Anaesthetics courses

which are attended by surgical skills trainees. The material has appropriate consent from the deceased or from a family member and once the material is used in courses, it is disposed of appropriately by the establishment.

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

Review of governance documentation
During the inspection the following were reviewed: Policies and procedural documents relating to licensed activities, cleaning records for the storage areas and Bioskills Facility, contracts for servicing of equipment and records of servicing, audits, meeting minutes, risk assessments, temperature logs for the storage units, reported incidents, and staff training records.

Visual inspection
The visual inspection comprised a review of the Bioskills Laboratory including point of receipt, storage and areas where disposal would be arranged.

Audit of records

An audit of records and cadaveric material in storage was undertaken.

<u>Material used in Scanning</u>

An audit of records of two cadaveric specimens received in 2023 was undertaken by identifying them from the cadaveric register. The records showed a full audit trail of when the material was received, defrosted and used in scanning. Appropriate consent was in place

and no discrepancies were identified. At the time of the audit, the material was no longer in storage and had been disposed of. The disposal records were reviewed and there were no discrepancies identified.

Material in Storage

An audit of three cadaveric specimens from records to their storage locations was undertaken. Two of the three specimens had been used in the Bioskills laboratory and there was a full audit trail of when the material was received, defrosted and used. One minor discrepancy was identified; the shipment date of one specimen was incorrectly recorded on the register (*Advice and Guidance item, 5*). The remaining specimen had not been used. No other discrepancies were noted.

A further audit of two cadaveric specimens from storage location to records was undertaken. Appropriate consent was in place and no discrepancies were identified.

Meetings with establishment staff

The inspection involved meeting with staff carrying out processes under the licence, including the DI, PD and the Directorate Manager.

Report sent to DI for factual accuracy: 29 July 2025

Report returned from DI: 11 August 2025 (no comments)

Final report issued: 13 August 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.