Licence application assessment report on compliance with HTA licensing standards
Assessment dates: **14 August (remote) and 20 August (site visit) 2025**

Freeman Hospital

Proposed HTA licensing number 12809

Application for a licence under the Human Tissue Act 2004

Activities

Premises/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
Freeman Hospital Newcastle Surgical Training Centre	Application made	Application made	Application made	Application made

Summary of assessment findings

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

Although the HTA found that Freeman Hospital ('the establishment') had met the majority of the HTA's standards, two minor shortfalls were found against standards for governance and quality systems 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 site visit.

Compliance with HTA standards

Minor Shortfalls

Standard	Assessment findings	Level of shortfall
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 had documented risk assessments in place for its practices and processes. However, risk assessment did not reference the use of CCTV monitoring in the storage area, meaning that potential risks linked to the management and operation of CCTV in this area have not been formally considered, documented or monitored. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised*	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
d) There are documented contingency plans in place in case of failure in storage area.	The establishment does not currently have a documented contingency plan in place for use in the event of a failure in the storage area. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised*	**Minor**

Advice

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

Number	Standard	Advice
1.	C1(a)	The establishment will receive cadaveric material from external suppliers under agreements. The proposed DI is advised to ensure that documented agreements are in place which reflect the donor's recorded wishes regarding disposal, including by whom and how this will be carried out.
2.	GQ1(a)	The establishment will order and dispose of materials as part of its routine activities. The proposed DI is advised to ensure that a documented procedure is in place for ordering and disposal, and that all information relating to these activities is shared with the proposed DI to support their oversight and governance arrangements.
3.	PFE2(c)	The temperature ranges for fridges and freezers are documented in standard operating procedures. To improve awareness and monitoring in practice, the proposed DI is advised to consider displaying these temperature ranges on the fridges and freezers.

Background

The Newcastle Surgical Training Centre, based at Freeman Hospital is a facility that provides surgical training and education. The establishment will receive body parts under an agreement from Newcastle University, Science Care and National Repository Centre at Nottingham.

Description of activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during the desk-based assessment and site visit:

At the time of assessment, the establishment was storing relevant material as satellite site for Newcastle University, HTA licensing number 12148.

Standards assessed against during assessment

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 will 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 examination of the training suite, including the areas designated for the receipt of HTA relevant material by staff and the spaces allocated for the storage and use of relevant material for training purposes

Meetings with establishment staff

The inspection included discussions with the proposed DI, Directors, Head of Corporate Risk and Assurance, and two Persons Designated (PDs).

Report sent to proposed DI for factual accuracy: 28 August 2025

Report returned from proposed DI: 28 August 2025

Final report issued: 29 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, or;
   - 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 site visit.

   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, or;
- 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.