Inspection report on compliance with HTA licensing standards
Inspection date: **26-27 March 2025**

University Hospital of North Durham
HTA licensing number 12461

Licensed under the Human Tissue Act 2004

Licensed activities

The table below shows the activities this establishment is licensed for and the activities currently undertaken at the establishment.

Area	Making of a post-mortem 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 the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose
Hub site **University Hospital of North Durham**	Licensed	Licensed	Licensed
Mortuary	*Not carried out*	*Carried out*	*Carried out*
Pathology laboratory	-	-	*Carried out*
Maternity department	-	*Carried out*	*Carried out*
Accident and Emergency	-	*Carried out*	-

(A&E) department			
Satellite site **Darlington Memorial Hospital**	Licensed	Licensed	Licensed
Mortuary	*Not carried out*	*Carried out*	*Carried out*
Maternity department	-	*Carried out*	*Carried out*
A&E department	-	*Carried out*	-

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 the University Hospital of North Durham ('the establishment') had met the majority of the HTA's standards, four major and two minor shortfalls were found against standards for Consent, 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

Major shortfalls

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training. d) Competency is assessed and maintained.	**Hub and satellite site** Records for training of consent seekers for perinatal consent were incomplete. The inspection team were informed by establishment staff that there is no formalised process for training and competency for perinatal consent seekers.	**Major (cumulative)**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post -mortem number, name, date of birth/death), including at least one unique identifier.	**Hub and satellite site** The procedure for viewings states that if visitors attend to view a body and they cannot provide three identifiers, then two identifiers will be accepted to match against the wristband of the deceased. The establishment will accept a third identifier that can be matched visually on the deceased (e.g. distinguishable scars). This practice does not provide assurance that a minimum of three identifiers on the body are checked against information from the family and relatives when attending viewings. This poses a risk to viewing of the wrong body.	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue		
a) Storage arrangements ensure the dignity of the deceased.	**Satellite site** Long term storage arrangements do not ensure the dignity of the deceased. For example: • the access route from the mortuary to the unit is through a basement and included within a large waste compound which can be overlooked by waste collectors; • a privacy screen is used during busy periods, however, this was not in use during the inspection; and • restricted space makes it difficult for staff to thoroughly decontaminate the units. The restricted space also increases the risk of accidental damage to bodies. ***See advice, item 3***	**Major**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in a good condition and appropriate for use	**Satellite site** The post mortem (PM) room floor has some minor cracks. Although the establishment do not use this room for PM examinations, the room is occasionally used for removal of relevant material from deceased for research.	**Major**

Minor shortfalls

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually.	**Satellite site** The ventilation system meets the requirements, however the annual servicing for the PM room is slightly overdue. The most recent servicing of the ventilation system was completed in February 2024. Although PM examinations are no longer offered at the establishment, the PM room is occasionally used for removal of relevant material from deceased for research purposes. *The establishment provided evidence of servicing records prior to the publication of the final report.*	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue		
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range.	**Satellite site** The lower trigger points for the fridge alarms are not tested.	**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 practice:

Number	Standard	Advice
1.	GQ1(a)	Whilst direct release from the maternity unit is not within the HTA's remit, good practice relating to traceability of bodies should be maintained to avoid the risk of misidentification of deceased. The establishment is advised to consider including good practice procedures to ensure maintenance of traceability to avoid the risk of release of the wrong body.
2.	GQ1 (g)	The DI is advised to include additional training for porters to include greater awareness of the types of incidents that are required to be reported to the HTA.
3.	PFE1 (e)	Establishment staff informed the inspection team that they plan to discontinue the use of the long-term storage units at the satellite site once the refurbishment at the hub site is complete. They could not confirm whether the units would be removed or kept for contingency storage in the event of capacity issues. The DI is advised to review these arrangements to ensure the dignity of the deceased is maintained.

4.	PFE2 (f)	Staff manually monitor and record the fridge temperatures in maternity on a daily basis The DI is advised to consider connecting the maternity fridge at the satellite site to an electronic monitoring system.
5.	General	The DI is advised to contact the HTA once the refurbishment of the mortuary at the hub site is operational. The HTA will conduct a follow up site visit to review the arrangements.

Background

The establishment has been licensed by the HTA since April 2007. This was the third inspection of the establishment; the most recent previous inspection took place in October 2019.

Since the previous inspection, the establishment no longer offers post mortem examinations as these cases are transferred to another licensed establishment. At the time of the inspection, the establishment was in the final stages of renovating the facilities at the hub site (see advice, item 5).

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

All 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

The inspection team undertook a review of policies and procedural documents relating to licensed activities, cleaning records for the mortuary and PM rooms, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, incident reports, staff training records and consent training information.

Visual inspection
The inspection team carried out a visual inspection of the body storage areas, PM rooms, viewing rooms, the maternity departments at both sites and the pathology laboratory at the hub site.

Audit of records

Audits were conducted for four bodies in refrigerated storage at the hub site and three bodies in refrigerated storage and two bodies in long term freezer storage at the satellite site. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and relevant documentation. No discrepancies were found.

Audits were also conducted of records and tissue taken at PM examination for three cases. Relevant documentation was cross referenced with location of tissue in the pathology department at the hub site. No discrepancies were found.

Meetings with establishment staff

Discussions with staff carrying out processes under the licence included the DI, Senior Anatomical Pathology Technologist, Quality Manager, Porters, a Bereavement Midwife, staff who seek consent for PM examinations, and staff involved in the Sudden Unexpected Death in Childhood (SUDIC) process.

Report sent to DI for factual accuracy: 28 April 2025

Report returned from DI: 12 May 2025

Final report issued: 13 May 2025

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 27 October 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 both the draft and 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.