Inspection report on compliance with HTA licensing standards
Inspection date: **09 10 April 2025**

Norfolk & Norwich University Hospital
HTA licensing number 11208

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 **Norfolk & Norwich University Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
A&E	-	*Carried out*	-
Satellite site **The Cotman Centre**	Not licensed	Not licensed	Licensed
Pathology lab	-	-	*Carried out*
Satellite site **The Norwich Biorepository**	Not licensed	Not licensed	Licensed

Research Tissue Bank (RTB)	-	-	*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 Norfolk & Norwich University Hospital ('the establishment') had met the majority of the HTA's standards, one cumulative major, six major and thirteen minor shortfalls were found against standards for Consent, 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

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	Insufficient body storage capacity and the continued use of temporary body storage units has been on the Trust's risk register since May 2020.	**Major (Cumulative)**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	The establishment has insufficient capacity for storage of bodies. Six temporary units are erected and in permanent use, including one in the post mortem (PM) room, which is blocking body store doors and a fire exit. To manage capacity mortuary staff transfer bodies from the main mortuary body store to the temporary and external body storage units on a daily basis. This increases the risk of: • Losing traceability and misidentification of bodies. • Accidental damage to bodies. • Musculoskeletal injuries to staff.	
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	Although the establishment have a comprehensive set of Standard Operating Procedures (SOPs), some of these lack sufficient detail for the processes they cover: SOP MORT 010 Generic Admission Procedure does not include what three identifiers require checking prior to the transfer of bodies into freezer or temporary storage. SOP MORT 035 Viewing procedures is not clear that the identifiers of the deceased should be provided by the relatives, not stated by mortuary staff when they greet relatives prior to a viewing. There is no detail of the process of how three identifiers of the deceased (and what these could be) are checked with the relatives or on the body prior to the viewing taking place (see shortfall against T1(c)). HIS.HTA.P.07 HTA Tissue release does not contain details of how tissue is recorded as being released or where to. SOP MORT BN 121 Organ transport to external hospitals refers to organising the correct disposal option for returned organs but does not provide details on how to carry this out, or reference another document containing this information. SOP MORT 031 PM specimen guidelines refers to sending a receipt with specimens sent off site and external pathologists signing for blocks and slides they take off site. However, there is no detail of the process to follow should a receipt for blocks and slides not be returned.	**Major**
GQ2 There is a documented system of audit		

c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	Audits of PM tissue in storage are not carried out in histopathology. The inspection team identified discrepancies with PM tissue blocks and slides in storage and the laboratory information management system (LIMS) during the tissue traceability audit. During the tissue audit, slides were found that should have been disposed of.	**Major**

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	Mortuary staff do not routinely check a minimum of three identifiers on the deceased with details provided by relatives before a viewing takes place. This poses a risk of viewing of a wrong body.	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		

a) The premises are clean and well maintained	The inspection team identified the following areas that require attention: • Patches of flaking paint and exposed plaster on the PM room walls. • The edge of the step between the PM room and the changing area is damaged exposing porous wood. The inspection team were informed the PM room was due to be refurbished in 2023 but this has been delayed until this year. The above areas requiring attention would be addressed as part of those works. However, should there be further delays, these areas need to be addressed to ensure they can be adequately cleaned and disinfected. The use of a temporary body storage unit in the PM room hinders the effective cleaning and disinfection of the room which is also used for high risk PM cases.	**Major**
d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	There is insufficient CCTV coverage to monitor access, both in and out of hours, at the mortuary access door from the service corridor and the relatives entrance to the viewing room.	**Major**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The establishment have temporary body storage units erected and in permanent use in the mortuary hearse bay (see shortfall against PFE2(b)). The temporary units prevent funeral director vehicles from being able to fully reverse into the area. The roller shutter door to the hearse bay cannot be closed when bodies are being admitted and released. This presents the following risks: • The hearse bay and the external body storage area is left insecure giving access to the external and temporary body storage units which are not kept locked. This area is not permanently staffed therefore there is a risk of unsupervised and unauthorised access. • The roller shutter door has to be manually activated to close by funeral directors when they leave. Should they forget to do this, mortuary staff would not necessarily be aware this area has been left insecure. • Mortuary activity in this area could be overseen by unauthorised persons, which compromises the dignity of the deceased. Visitors and non-mortuary staff are not required to sign in and out of the mortuary, therefore there is currently no system for recording who has been in the mortuary (who do not have swipe access), the nature of their business and when they arrived and left. The door between the viewing room and the body store is secured by a thumb lock. However, this has been fitted the wrong way round meaning relatives could unlock the door and access the body store during viewings.	**Major**

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 HTA's codes of practice		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice	The Trust's consent policy has a brief section on consent for PM examination including a link to further information which does not work. There is no information on who can seek consent for paediatric/perinatal or adult PM examinations and who to contact should a PM examination be required.	**Minor**
b) There is a documented standard operating procedure (SOP) detailing the consent process	Although the SOP states consent seekers need to complete the necessary training, it does not include who should complete the training and how often.	**Minor**

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	Although clinicians and other staff have completed training for seeking consent for paediatric/perinatal post mortem (PM) examinations, refresher training has not been regularly undertaken. Although mortuary staff have received training for seeking consent for PM examination, training records for all these staff were not provided. *See Advice item 4.*	**Minor**

d) Competency is assessed and maintained	Review of the PM consent forms completed by clinicians and staff for paediatric/perinatal cases serves as an assessment of competence. However, there is no documented record to demonstrate competency is maintained. Competency records for mortuary staff involved in seeking consent for adult PM examinations are not maintained. *See Advice item 4.*	**Minor**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	The following documents are out of review date: CP.SH.P.1004 Incident reporting policy. HIS.HTA.P.01 Handling of block sized samples taken at PM. HIS.HTA.P.02 Handling of large pieces of tissue and organs taken at coroner's PM. HIS.HTA.P.07 HTA Tissue release.	**Minor**
e) There is a system for recording that staff have read and understood the latest versions of these documents	Pathologists are not included in the distributions lists for relevant SOPs on the electronic quality management system. This means they do not read and acknowledge SOPs relevant to the activities they undertake.	**Minor**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Formal mortuary staff meetings have not been regularly undertaken. Although the staff in the Research Tissue Bank (RTB) have weekly meetings, these are not documented. Although the DI has contact with Persons Designated, there are no formal documented meetings.	**Minor**
GQ2 There is a documented system of audit		

a) There is a documented schedule of audits	The current audit schedule runs over two years. Although audits of key activities are included in the audit schedule, the number of cases included in audits do not reflect representative numbers to provide sufficient assurance of an activity. For example, the 'Adult PM and associated tissue transfer to histopathology' audit only includes one case which may only be carried out once in two years. *See Advice item 8.*	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	Some porters are overdue refresher training for mortuary activities. *See Advice item 9.*	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	Although the mortuary keeps records of the total number of tissue blocks retained at PM examination for histological examination, the types of tissue are not recorded. The number and type of tissue retained is also inconsistently recorded on the histology request card sent to the laboratory with the tissue. Therefore, laboratory staff are unable to confirm if the tissue they receive in the laboratory for processing is correct.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The two external body storage unit power switches are not secured to prevent power to the unit being turned off, potentially compromising the condition of any bodies being stored in there.	**Minor**

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	Fridge alarm trigger points are not set at appropriate temperatures to alert staff to any failures in a timely manner, potentially compromising the condition of the deceased.	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	The inspection team identified minor patches of rust on mortuary trolleys and electric autopsy saws.	**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.	C1(b)	The SOP 'Obtaining consent for post mortem HIS.HTA.P.09' includes the hierarchy of qualifying relationships but also references 'next of kin' which the DI is advised to change.
2.	C1(g)	The DI is advised to review the adult PM consent form wording to ensure it states 'with consent' rather than what will happen. For example, '…..small tissue samples and bodily fluids will be retained'.

3.	C2(a)	The DI is advised to implement the E-Learning For Health module for paediatric/perinatal PM consent seeking and ensure clinicians and other staff involved in these cases complete this training regularly and record evidence of completion. The Research Tissue Bank (RTB) Manager is advised to ensure consent seekers undertake the Medical Research Council training for consent in addition to existing consent training.
4.	C2(b) C2(d)	Staff involved in seeking consent for PM examination on adults completed training two years ago. The DI is advised to ensure staff involved in this activity undertake regular refresher training and are re-competency assessed, especially as this activity occurs infrequently.
5.	GQ1(a)	The DI is advised to update: • the Incident Reporting policy CP.SH.P.1022 to reflect the updated HTARI classification definitions. • the portering services mortuary procedures NNUH-POT-PRO007 to include what action to take should an incident occur in the mortuary. The Mortuary Manager is advised to update the SOP for the release of bodies to include recording a final condition check when bodies are released. The RTB Manager is advised to update SOPs with references to the most recent version of the HTA's Codes of Practice.
6.	GQ1(d)	The DI is advised to ensure the frequency of document review dates is consistent.
7.	GQ1(g)	The RTB Manager is advised to continue with the plans to submit an application for a HTA Research sector licence. This will help ensure there is appropriate oversight of the RTB as the size and activity of the bank has increased since it first opened.
8.	GQ2(a)	The standard template used for audits does not appear to lend itself well for audits of mortuary activities. A number of fields are marked as 'not applicable'. The DI is advised to consider if the template is fit for purpose.

9.	GQ3(a) GQ3(c)	The Mortuary Manager is advised to ensure that training and competency records for mortuary and portering staff are fully completed to demonstrate up to date records. The RTB Manager is advised to ensure that competency assessments for staff are documented.
10.	PFE1(e)	The Trust's security team maintain and review the signing in and out log of the mortuary swipe card used by the portering team out of hours. For assurance, the DI is advised to ensure that review of this log is included in existing mortuary security audits.

Background

Norfolk & Norwich University Hospital has been licensed by the HTA since May 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in April 2022.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence. Since the inspection in 2022 the Research Tissue Bank (RTB) have been planning to apply for a separate HTA Research licence due to expansion of the facility (see Advice item 7).

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 reviewed policies and procedural documents relating to licensed activities for the mortuary, histology and the RTB. This included SOPs, risk assessments, audits, incidents, meeting minutes, training records and competency assessment documents. Consent seeking procedures and information for families giving consent for adult and perinatal PM examinations and servicing and maintenance records for mortuary and RTB equipment were also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the premises which included the mortuary access points, body storage areas, including the external but adjacent body storage units and the temporary units located in this area, the hearse bay and PM room (see shortfall against PFE2(b)), the viewing room and PM room. A visual inspection of the storage areas for tissue in the histopathology laboratory and RTB were also undertaken. The inspection team also observed the process for release of bodies from the mortuary.

Audit of records

The inspection team undertook audits of traceability for three bodies in storage. This included a perinatal case and a body with same/similar name. A body in long term storage was not included as none were being stored at the time of the inspection. Traceability details were crosschecked between the identification bands on the bodies, information in mortuary paperwork and the mortuary electronic record. No discrepancies were identified.

Audits were conducted of stored tissue taken at PM examination for four cases. Information was crosschecked between the mortuary documentation, coroner's paperwork, relatives wishes forms and tissue being stored. Discrepancies were identified with the number of blocks and slides in storage in one case and the number of blocks in another when compared with the LIMS. Tissue slides for another case not included in the audit were also identified as they had been misfiled and should have been disposed of (see shortfall against GQ2(c)).

The inspection team undertook traceability audits of the research material held for six cases in the RTB. Traceability details were crosschecked between the identifiers on the material, the electronic system and paper records through to consent documentation. No discrepancies were identified.

Meetings with establishment staff

The assessment team met with staff carrying out activities under the licence, including mortuary staff, histopathology staff, a portering staff member, a pathologist, staff involved in the consent seeking processes for PM examinations, staff responsible for the removal of relevant material in the Emergency Department, RTB staff and the DI.

Report sent to DI for factual accuracy: 2 June 2025

Report returned from DI: 12 June 2025

Final report issued: 20 June 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.