Inspection report on compliance with HTA licensing standards
Inspection date: **07/08/2025**

Wythenshawe Hospital

HTA licensing number 12203

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
Wythenshawe Hospital	Not licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	-	*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 Wythenshawe Hospital ('the establishment') had met the majority of the HTA's standards, six major and ten minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment.

One of the identified shortfalls (PFE1 a) pertains to findings from the previous inspection conducted in 2022. This was acknowledged by the establishment and progress will be monitored through an agreed corrective action plan.

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
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 document *PM policy Adult or child is an overarching MFT policy and* does not stipulate that those obtaining consent must be trained and competency assessed or provide information on the training required. Furthermore, the policy does not reflect current practice, for example states consent must only be taken by a named consultant clinician, however consent is also obtained by medical examiner officers and the DI.	**Cumulative Major**
b) There is a documented standard operating procedure (SOP) detailing the consent process	A standard operating procedure outlining the consent process was not provided during the inspection. The absence of such documentation may lead to inconsistencies in how consent is obtained and recorded.	
c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice	Information provided to those giving consent is not specific to the establishment undertaking the post mortem. Relatives are directed to the HTA website. This approach does not ensure that organisation-specific details regarding the post-mortem or how tissue may be handled following the post mortem are provided.	

d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives	See shortfall against standard C1(c) above	

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.	Three separate documents were identified that contain guidance on condition and decomposition checks of the deceased. However, the timescales for conducting these checks vary across the documents, leading to potential inconsistencies in practice. The mortuary security SOP lacks sufficient detail and does not accurately reflect current practices regarding the use of panic alarms. The SOP lacks clear, written guidance on how security audits are undertaken as well as the end day mortuary closing procedure.	**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 flooring within the body store was observed to be uneven, with cracked and damaged tiling exposing porous surfaces. These conditions prevent effective cleaning and decontamination, posing a risk to infection control and hygiene standards. Additionally, the surface becomes slippery when wet, increasing the risk of slips and falls. The uneven flooring also creates operational difficulties, particularly when using the electric hoist when moving bodies. This shortfall was identified during the previous inspection.	**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)	While access to the mortuary is restricted, additional physical security measures to prevent unauthorised access to the body store and post-mortem room are not in place. These areas remain accessible once inside the mortuary. A separate storage unit for perinatal and paediatric cases is located within the post-mortem room. This unit is not covered by CCTV and access to this area it is not restricted. Access to the condenser unit controls at the rear entrance is not protected, meaning the condenser could be inadvertently or deliberately switched off, resulting in fridge failure.	**Major** **Cumulative**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The methodology employed when undertaking monthly security audits does not provide adequate oversight of activities within the mortuary. The inspection team is not assured that the audits incorporate a sufficiently representative sample size or range of activities to ensure those entering are authorised to and do so for a legitimate purpose. Furthermore, the visitors' log is not currently included in the scope of the audit The inspection team identified an unsecured door providing direct access from the relatives' room into the staff area allowing unrestricted movement into all other areas of the mortuary should relatives enter undetected.	

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The inspection team identified two bodies during the audit where as part of last offices sheets had been taped tightly across the head area of the body, which could cause disfigurement. The inspection team were advised that this is an ongoing problem that mortuary staff had been unable to resolve with ward colleagues. A further body was found to be purging with a soiled sheet. The establishment took action to address this prior to completion of the inspection. The inspection team observed that the entrance used by funeral directors is directly overlooked by a ward balcony. Although it was reported that this balcony is designated for staff use only, its positioning allows visibility of the delivery and collection of deceased individuals.	**Major** **Cumulative**

b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	The establishment has a documented procedure permitting the use of trays placed on the floor of the fridges to increase storage capacity when required. However, the body trolley in use does not lower to the level of these floor trays. As a result, deceased individuals stored in this manner are subject to additional manual handling during placement into and removal from the refrigerated storage. This practice poses an increased risk of accidental damage to the deceased. Additionally, this process has not been risk assessed. SOP *Management of the deceased* states that bodies may not be moved to long-term storage due to insufficient freezer capacity. This presents a risk that bodies may not be transferred to long-term storage after 30 days, potentially leading to deterioration.	
d) Fridge and freezer units are in good working condition and well maintained	During the inspection, it was noted that 15 refrigerated units located in the lobby area were out of use. The inspection team was advised that these units have been non-operational for an extended period and are awaiting repair. The lack of operational storage significantly impacts the mortuary's overall capacity and may compromise the ability to store bodies appropriately. The power switch on the condenser units located in the external compound was found to be damaged and inoperable.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
d) Competency is assessed and maintained	There were no documents available for review assessing staff as competent with the HTA requirements when seeking consent for perinatal PM's	**Minor**

GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity	The audit schedule does not include audits related to deviations from document practices.	**Minor**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Matters relating to Human Tissue Authority (HTA) licensed activities are discussed at HTA committee meetings. However, these meetings do not include staff who work directly under the license, nor do they involve Persons Designated (PDs) operating in other relevant areas, such as maternity services. This limits the opportunity for effective communication, shared learning, and oversight across all areas where licensable activities occur.	**Minor**

GQ2 There is a documented system of audit

a) There is a documented schedule of audits	Although there is a generic documented schedule of audits for the establishments within the Manchester University NHS Foundation Trust (MFT) this does not include sufficient vertical and horizontal audits relating to mortuary procedures undertaken at this establishment. The absence of targeted audits limits the ability to monitor compliance and identify risks.	**Minor**
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	Evidence to demonstrate that audits of stored tissue are routinely undertaken was not provided.	**Minor**

GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	Whilst staff know how to identify and report incidents, the inspection team identified a recent incident related to equipment failure which met the threshold for reporting to the HTA which had not been reported	**Minor**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	Risk assessments are in place across the establishment; however, some do not accurately reflect current operational practices. For example, the *Lone Working Risk Assessment – MORHS34* does not align with the lone working procedures described by staff during the inspection. Additionally, the *Security Risk Assessment* contains generic mitigation measures applicable to the wider Trust but lacks specificity to the mortuary department. It does not reflect current practices, such as the use of an intruder alarm system, which is in operation but not documented. Bodies are occasionally stored on trays placed at the base of the fridges to increase capacity. This practice poses a significant risk of accidental damage to the deceased and presents manual handling risks to staff required to place or retrieve bodies from this location. This activity has not been formally assessed.	**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).	The tissue audit conducted during the inspection identified a discrepancy in one case, where the number of slides stored did not match the number recorded. (See advice item 3)	**Minor**

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	Areas of the mortuary premises are showing signs of wear and require maintenance to ensure decontamination procedures are effective. These include but are not limited to: • Damage was noted to a number of wooden doors and door frames within the Mortuary exposing irregular and porous surfaces these included the body store and pm room doors. • Flooring within the main corridor was heavily soiled with areas of splitting present. • An area of the corridor wall was damaged exposing underlying plaster • The drain cover in the body store is heavily rusted • Areas of flaking paint and rusting were visible on the radiator in the body store.	**Minor**
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	Generic cleaning and decontamination procedures are documented for establishments within the Manchester Foundation Trust (MFT) group. However, records reviewed during the inspection indicated that the body store at Wythenshawe has not been cleaned since 2022.	**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	The DI and mortuary manager are advised to ensure that the details of both porters admitting the deceased are recorded on the transfer form along with any observers/ staff accompanying them.
2.	C1(e)	DI advised to liaise with the Coroner's service to ensure that options for the retention and use of tissue reflect those available and that retention for purposes of medical record should not automatically imply retention for all other scheduled purposes.
3.	T1 (g)	The DI is advised to undertake an audit of tissue held to ensure this is held in accordance with relatives wishes and the correct number of blocks and slides are recorded.
4.	PFE1(d)	Whilst there is CCTV that covers the body store this does not extend to provide coverage of the refrigerated units in the rear lobby area. The DI is advised to consider extending the CCTV to ensure coverage of the rear lobby and the storage unit within the PM room.
5.	PFE2 (e)	DI is advised to include the lower temperature alarm testing for body stores in the mortuary and Maternity unit.

Background

Wythenshawe Hospital has been licensed by the HTA since December 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in November 2022.

Since the previous inspection, there have been no significant changes to the licence arrangements, or the activities carried out under the licence

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

69 out of the 72 licensing standards were covered during the inspection (standards published 22 September 2022). The remaining standards of T1(g), PFE3(c) & (e) were not applicable as '*making of a postmortem* examination' is not a licensed activity on the license.

Review of governance documentation

The inspection included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records for the mortuary, records of servicing of equipment, audits, risk assessments, meeting minutes, reported incidents and training and competency records for both the mortuary staff and porters.

Visual inspection

The inspection included a visual assessment of the mortuary body storage areas, PM room (not in use), viewing room and tissue storage areas in the pathology laboratory.

Audit of records

Audits were conducted for four bodies from refrigerated storage. Identification details on bodies were crosschecked against the information recorded in electronic register and associated paperwork. No discrepancies were identified in relation to identification, however two bodies with same names did not have the notification wristbands in place demonstrating a deviation from the documented practice. Audits of traceability were conducted for tissue blocks and slides from five coroners consented cases. These included audits of the consent documentation for the retention of these tissues. In one case, six additional slides were identified in storage that were not recorded in the documentation.

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, mortuary manager, APT, mortuary porter, adult consent taker and a bereavement midwife.

Report sent to DI for factual accuracy: 03/09/2025

Report returned from DI: 16/9/2025

Final report issued: 18/09/2025

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.