Inspection report on compliance with HTA licensing standards
Inspection date: **6 and 12 April 2023**

Manchester University NHS Foundation Trust- Central hospitals

HTA licensing number 12554

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 Manchester Royal Infirmary	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	-	*Carried out*
Satellite site Trafford General Hospital	Licensed	Licensed	Licensed
Mortuary (satellite site)	-	-	*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 Manchester University NHS Foundation Trust- Central Hospitals ('the establishment') had met the majority of the HTA's standards, four major and two 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
All applicable HTA standards have been assessed as fully met.

Major shortfalls

Standard	Inspection findings	Level of shortfall
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.	Some Standard Operating Procedures (SOPs) lack detail and are not reflective of staff practice. This includes the SOPs for: • Adult release out of hours- Hub and satellite sites • Viewing of a deceased adult • Out of hours viewing of a deceased adult at Trafford General Hospital • The Management of Adult PM Material, including Retention and Disposal Policy This is not an exhaustive list of the SOPs requiring amendment. To fully address this shortfall, the establishment should review all SOPs relating to mortuary activities where there is a requirement for checking the identity of bodies to ensure they are accurate and contain sufficient detail to reflect current practice.	**Major**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		

a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete	Whilst the establishment has introduced a system to ensure tissue is disposed of in line with family wishes, and additional staff have been provided to support this. There has been a delay in acting on these wishes leading to some tissue taken from adult PMs awaiting disposal for up to twelve months after receiving notification that Coroner's authority has ended.	**Major (cumulative)**
d) The method and date of disposal are recorded	The inspection team identified blocks and slides for two cases that had been removed for disposal in line with family wishes, however the date of disposal had not been updated on the system. Furthermore, the records do not always identify the method used for the disposal of adult tissue.	
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Staff access the mortuary using swipe cards and a coded alarm system is in operation. Whilst swipe card access lists are reviewed and updated regularly, these are not routinely cross checked against CCTV footage to ensure security arrangements protect against unauthorised access and ensure oversight of visitors and contractors who have a legitimate right of access in the adult mortuaries. The establishment provided evidence and assurance a security audit is planned, but this has not yet been undertaken.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	There is insufficient freezer storage capacity to meet establishment needs. Due to the limited freezer storage facilities, bodies were identified as being held in refrigerated storage for longer than the HTA's recommended 30 days.	**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	The establishment does not have a system in place for assessing staff as competent with the HTA requirements when seeking consent for Adult PMs. This includes those who have received consent training.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
c) Staff are assessed as competent for the tasks they perform	The inspection team are not assured all staff who carry out licensed activity receive regular competency assessments. No records were available for review relating to clinical coordinators and specialist bereavement staff being assessed as competent to undertake out of hours release of the deceased in the paediatric mortuary. This poses a risk of release of the wrong body.	**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.	GQ4(a)	New electronic record keeping systems are in place, however the establishment have chosen to continue with paper records also. This results in lots of duplication. The DI is advised to progress the move from a paper based to a paperless system to reduce the burden of paperwork on staff in the adult mortuaries and reduce the risk of duplication errors.
2.	PFE1(e)	The DI is advised to change the codes to the mortuary alarm system and keypad locks on a regular basis.
3.	PFE3(a)	The DI is advised to replace one worn dissection board in the adult mortuary PM room. Additionally, the DI is advised to monitor and address the slight damage to the paint on the hydraulic trolley in the hub site adult mortuary.
4.	N/A	The DI is advised to consider the revocation of the license for the making of PM examinations at the satellite site as the PM suite is decommissioned and PMs have not been carried out for over five years.

Background
Manchester University NHS Foundation Trust- Central Hospitals has been licensed by the HTA since 2007. This was the fourth inspection of the establishment; the most recent inspection took place in November 2019.
Since the previous inspection there have been no significant changes to licensed activity undertaken or personnel.

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 applicable HTA licensing standards were covered during the inspection (standards published 3 April 2017)

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, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and training records for both the mortuary staff, site staff, midwives and porters.

Visual inspection
The inspection included a visual assessment of both sites including, body storage areas in the mortuaries and in the maternity department, PM room, viewing rooms and tissue storage areas. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records
Hub Site
Whilst inspecting the adult mortuary, audits were conducted of five bodies from refrigerated storage, and one body in long term frozen storage. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork. No discrepancies were identified.

The release of one body into the care of a funeral director was observed. Identification details on the body were crosschecked against the information recorded in the register and associated paperwork brought by the Funeral Director. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides from four coronial cases. These included audits of the consent documentation for the retention of these tissues. The inspection team identified blocks and slides for two cases that had been removed for disposal in line with family wishes, but no slip had been inserted to indicate the removal. Furthermore, the date of

disposal had not been updated on the system. A slide for one case was found to be in the possession of the pathologist, however there was no slip to identify it was being analysed (refer to shortfall T2(d) above).

Whilst inspecting the paediatric mortuary, audits were conducted of two bodies from refrigerated storage. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides from three PM's. These included audits of the consent documentation for the retention of these tissues. No discrepancies were identified..

Satellite Site

Audits were conducted onsite of two bodies from refrigerated and one body from long term frozen storage. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork. No discrepancies were identified.

Meetings with establishment staff

Staff carrying out processes under the license were interviewed including the DI and Clinical Director for Pathology, mortuary manager, APT, pathologist, mortuary porter, and bereavement midwives.

Report sent to DI for factual accuracy: 24/04/2023

Report returned from DI: 28/04/2023

Final report issued: 02/05/2023

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: 9 August 2023

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.