Site visit inspection report on compliance with HTA licensing standards
Inspection date: **19 – 21 November 2019**

Manchester University NHS Foundation Trust – Central Hospitals

HTA licensing number 12554

Licensed under the Human Tissue Act 2004

Licensed activities

Hub and satellite site rows denote whether the site is licensed to carry out an activity; the rows below the hub and satellite rows denote whether or not the activity is currently carried out in that area.

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, Manchester Royal Children's Hospital and St Mary's Hospital**	Licensed	Licensed	Licensed
Manchester Royal Infirmary			
Adult mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology laboratory	-	-	*Carried out*

Manchester Royal Children's Hospital			
Paediatric mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology laboratory	-	-	*Carried out*
St Mary's Hospital			
Maternity department and Gynaecology ward	-	-	*Carried out*
Satellite site **Trafford General Hospital**	Licensed	Licensed	Licensed
Mortuary	-	-	*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, eight major and ten minor shortfalls were found against standards for Consent, Governance and Quality, 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
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) do not reflect current practice or do not contain sufficient details of procedures. • SOPs describing the procedures for identification of the deceased do not always make it clear that a minimum of three identifiers of the deceased should be checked, what the identifiers could be and what they should be checked against. This includes the SOPs for receipt of bodies into the adult mortuaries, release of bodies from the adult and paediatric mortuaries and viewings of bodies. • The introductory text for the SOPs for post-mortem (PM) examination and the policy for the retention and disposal of adult PM tissue refer to the 'Next of Kin' in relation to who can give consent for these activities. This is not in accordance with the requirements of the HT Act or the HTA's codes of practice. • The establishment's HTA reportable incident (HTARI) SOP does not include the requirement to report near miss HTARIs to the HTA. In addition, the HTARI classifications detailed in the SOP are not up to date.	**Major**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Many of the scheduled audits in the last two years have not been completed. Audits of tissue have not been regularly undertaken. Where traceability audits of bodies have occurred, these audits included only one body.	**Major**

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	Staff who conduct out-of-hours viewings at the satellite site are not aware of the SOP for viewings and have not been trained in the procedure.	**Major**
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	The inspection team identified a number of incidents, including some serious incidents and near miss incidents since 2017 in the establishment's incident log, which should have been reported to the HTA. The establishment has provided assurance to the HTA that these incidents were investigated internally.	**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	The establishment's procedures for identification of bodies for viewings do not ensure that a minimum of three identifiers of the deceased are checked. • Staff in the adult mortuaries do not follow the documented procedure for viewings. Visitors are only requested to provide the name of the deceased when they attend for viewings. Two identifiers may be checked if the deceased has a same and/or similar name to another body in the mortuary. • Three identifiers of the deceased may not always be checked with visitors when they attend the paediatric mortuary for a viewing.	**Major**

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The establishment's procedures for traceability of PM specimens are not robust. • The establishment do not receive confirmation from the laboratory where toxicology specimens are sent to provide assurance they have arrived. • PM tissue specimens transferred to the adult pathology laboratory are not always signed for by staff transferring the specimens or the staff receiving them in the laboratory. • The computer system in the adult pathology laboratory is not updated when the system automatically generates additional slides that are not required, or when slides are disposed of. The inspection team's traceability audits found issues with legibility and transcription errors in records. These were in relation to deceased's names, a date of birth, date of death and a PM specimen number.	**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	The establishment is storing PM tissue removed under the authority of the coroner from 2016. The establishment is not aware of the status or the instructions for this tissue. This means that the establishment may be storing tissue where the coroner's authority has ended and consent for continued retention has not been given. Where instructions to dispose of tissue have been received from the coroner's office for adult PM cases, this is not always acted on by the establishment in a timely manner.	**Major**
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	The establishment do not have a robust system to ensure they receive relative's instructions for tissue from the coroner's office following adult PM examinations.	

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	The establishment does not have sufficient freezer storage capacity for long-term storage of bodies and does not have robust contingency arrangements for freezer storage. The inspection team found that some bodies had not been transferred to freezer storage in line with the establishment's procedure for long-term storage of bodies.	**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		
g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided	Information about donating whole organs for medical education and research is given in section seven of the adult PM consent form. However, relatives are not able to choose either of these options because the form includes options for disposal only.	**Minor**
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
d) Competency is assessed and maintained	Pathologists and maternity department staff who are involved in seeking consent for PM examination are not competency assessed in this procedure.	**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	Some SOPs are authored and authorised by the same member of staff.	**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 inspection team's audits of tissue traceability found that tissue blocks and slides could not be located for one case. There is no record to state whether these samples were in use or had been disposed of.	**Minor**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
d) The method and date of disposal are recorded	The inspection team's audits of tissue traceability found that the date of disposal was not recorded for one case. The tissue blocks and slides were not present in the tissue store; however, there was no disposal tracer card to indicate that the samples had been disposed of.	**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	The mortuary at the satellite site is showing some signs of wear. There is a crack in the body store floor meaning staff may find it difficult to adequately clean and disinfect the area.	**Minor**
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)	The fridge used to store pregnancy remains in the gynaecology ward is not locked and is located in an area that is not secure.	**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	The upper alarm trigger points for freezers are not set at an appropriate temperature to ensure that the alarm will trigger if the storage temperature increases. The alarm trigger points for the paediatric mortuary fridges are not set at appropriate temperatures to ensure that alarms will trigger when storage temperatures deviate from the set range. The fridge in the maternity department is not connected to a remote alarm system. The local alarm may not be heard if storage temperatures deviate from the set range.	**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	There is a wooden stool and an instrument with a wooden handle in the PM room at the paediatric mortuary. These items cannot be adequately cleaned or disinfected.	**Minor**
d) Staff have access to necessary PPE	Staff are not face-fitted for the disposable FFP3 masks available for them to use in the adult mortuary PM room.	**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(g)	The DI is advised to consider separating the options on the consent form for tissue retained following hospital PM examinations (adult and paediatric/perinatal). This will allow relatives to make separate decisions about the options for tissue. The DI may wish to consider adopting the HTA's model PM consent form for adults and the Stillbirth and neonatal death charity (Sands) model consent forms for perinatal and paediatric cases.
2.	C1(g)	The DI is advised to review the first page of the adult PM consent form to reflect the current procedure for seeking consent. The form requires the consent seeker (the clinician) to sign to confirm that they have completed the relevant training, observed a PM examination and are aware of what tissue blocks and slides are. However, the establishment's procedure for seeking consent does not require the clinician to have completed this training, provided that they are supervised by an appropriately trained member of staff.
3.	GQ1(a)	The DI is advised to review documented procedures and policies to ensure that references to external documents are guidance are up to date. Some SOPs refer to the Health Building Note 20 document, which is no longer current.
4.	GQ1(a)	The DI is advised to review the procedure for release of bodies directly to parents from the paediatric mortuary during normal working hours. The procedure should include that the parents sign the mortuary register for the deceased transferred in to their care.
5.	GQ3(a)	The DI is advised to ensure the scheduled training for viewings is completed by the paediatric intensive care unit staff.
6.	GQ6(a)	The DI is advised to risk assess the use of the tissue cassette racks for more than one PM case in the paediatric mortuary and laboratory. This will help to assess if the process in place is sufficient to mitigate the risk of tissue mix-up between cases.
7.	T1(a)	The mortuary staff are advised to cease the practice of writing the identification details of bodies on the outside of body bags. Although this is not done in place of labelling the bodies, there is a potential risk that the identification details on the bag could be used to release a body.
8.	PFE1(d)	The DI is advised to ensure that the building alarm system keypad in the area adjacent to the fridge room at the satellite site is repaired. This will help ensure that staff consistently set the alarm when they leave the building.

Background

Manchester University NHS Foundation Trust has been licensed by the HTA since September 2009. This was the fourth site visit inspection of the establishment; the most recent previous inspection took place in November 2016.

The licence covers Manchester Royal Infirmary, Manchester Royal Children's Hospital and St Mary's Hospital, all located at the hub site, and Trafford General Hospital, the satellite site.

Since the previous inspection, the adult mortuary at Manchester Royal Infirmary has been refurbished.

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 included a review of the establishment's governance documentation covering the adult and paediatric mortuaries at the hub site and the satellite site. This included policies and procedural documents relating to licensed activities, cleaning records for the mortuaries and the PM rooms, contracts for servicing of equipment and records of servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training records.

Visual inspection

The inspection included a visual inspection of areas covered by the licence at the hub site and satellite site including the mortuary body stores, PM rooms, viewing rooms, both adult and paediatric pathology laboratories, the maternity department and the gynaecology ward at the hub site.

Audit of records

An audit of body identifiers, storage locations, mortuary register details, mortuary database details and associated documentation was carried out for seven bodies at the hub and satellite site (two adult community deaths and five adult hospital deaths), including two bodies in frozen storage. Four paediatric/perinatal hospital bodies were audited in the paediatric mortuary. Some discrepancies were found in relation to legibility and transcription errors (see shortfall against standard T1(g)).

Audits were conducted of tissue removed during PM examination for seven adult coroner's cases between 2017 and 2019 and four paediatric/perinatal cases between 2016 and 2019 (two coroner's cases and two hospital consented cases). The audits included details of tissue type, number of blocks and slides retained, and review of consent forms, other associated documentation and electronic database records. Discrepancies were found with four adult PM cases relating to the laboratory computer records, the location of tissue blocks and slides and the process for obtaining relatives' wishes for tissue from the coroner's office.

Meetings with establishment staff

The inspection included interviews with the DI and staff carrying out processes under the licence at both sites, including Anatomical Pathology Technologists, Biomedical Scientists, pathologists, pathology laboratory staff, porters, an obstetrics and gynaecology nurse and a bereavement midwife.

Materials held for the police

Under section 39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings stored in a designated area in the PM room were reviewed by the HTA during the inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

Report sent to DI for factual accuracy: 19 December 2019

Report returned from DI: 7 January 2020

Final report issued: 14 January 2020

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: 14 May 2020

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 site visit 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 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 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 site visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.