Licence application assessment visit report on compliance with HTA licensing standards
Site visit date: **02 October 2024**

Sandwell General Hospital
Satellite Application Midland Metropolitan University Hospital
Proposed HTA licensing number 12131

Application for a licence under the Human Tissue Act 2004

Activities applied to be licensed
The table below shows the proposed activities this establishment is to be licensed for and the proposed activities to be 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
Satellite site **Midland Metropolitan University Hospital**	Not applied to be licensed	Applied to be licensed	Applied to be licensed
Mortuary (satellite site)		*Applied to be carried out*	*Applied to be carried out*
A&E		*Applied to be carried out*	

Background

Sandwell General Hospital has been licensed by the HTA since 2007. The most recent previous routine announced inspection was carried out in November 2023.

Midland Metropolitan University Hospital is a newly built facility, the assessment visit took place in response to the application for the addition of a satellite site to the existing licence. The hospital is not yet operational, and no bodies were in storage at the time of the visit.

Plans are in place for the revocation of the licence of the existing satellite unit at City Hospital when the Midland Metropolitan Hospital is fully operational.

Summary of visit findings

The HTA found the proposed Designated Individual (DI) and the proposed Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Midland Metropolitan University Hospital which is a satellite site of Sandwell General Hospital (the establishment), was found to have met all HTA standards.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

The HTA advises the proposed DI to consider the following to further improve practice:

Number	Standard	Advice
1.	GQ1(a)(f)	The DI is advised to ensure Standard Operating Procedures (SOPs) are updated and acknowledged by staff as working practices change.

2.	PFE1(d)	The DI is advised to expedite the installation of the privacy screen obtained to prevent oversight of activity being undertaken in the body store from the internal staff entrance to the mortuary. Furthermore, consideration should be given to a permanent solution to the risk of oversight of mortuary activity by staff passing by.
3.	PFE2(a)	The DI is advised to undertake a fridge temperature trend analysis, and undertake a test of the out of hours fridge alerting procedures shortly after the mortuary becomes operational and begins to admit bodies. Furthermore, the DI is advised to consider the use of magnets to alert porters which fridge bank to use for the admission of bodies out of hours. This will mitigate the risk of an Accidental damage to a body incident due to bodies being stored at an incorrect temperature.

Description of activities undertaken during visit

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during the visit:

Standards assessed against during visit

26 out of the HTA's 72 standards were covered during the licence application assessment visit (LAAV). The assessment visit was limited to the proposed satellite ste at the Midland Metropolitan Hospital.

The satellite site will not undertake any post mortem examinations, store, dispose of or repatriate tissue blocks and slides. There were no bodies in storage at the time of the inspection and the hospital was not operational and treating patients.

The remaining applicable standards will be assessed during the next routine inspection.

Standards covered at this inspection are listed in Appendix 3.

Review of governance documentation

A review of governance documents submitted as part of the licence application was undertaken as part of this inspection, this included a selection of key policy and procedural documents, risk assessments, action plans, meeting minutes, maintenance

records and fridge temperature checks. A full review of governance documentation will be undertaken at the next routine inspection.

Visual inspection
The inspection included a visual assessment of the establishment including the body storage area, body preparation suite and viewing room.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence at the hub and satellite sites. This included the DI, Mortuary Manager and Divisional lead.

Report sent to proposed DI for factual accuracy: 10/10/2024

Report returned from proposed DI: 20/10/2024

Final report issued: 21/10/2024

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, and;
- 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, or;
   - 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.

Appendix 3: Standards Assessed

Governance and Quality systems
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. These include: i. post-mortem examination, including the responsibilities of Anatomical Pathology Technologists (APTs) and Pathologists and the management of cases where there is increased risk; ii. practices relating to the storage of bodies, including long term storage and when bodies should be moved into frozen storage; iii. practices relating to evisceration and reconstruction of bodies; iv. systems of traceability of bodies and tissue samples; v. record keeping; vi. receipt and release of bodies, which reflect out of hours arrangements; vii. lone working in the mortuary; viii. viewing of bodies, including those in long-term storage, by family members and others such as the police; ix. transfer of bodies internally, for example, for MRI scanning; x. transfer of bodies and tissue (including blocks and slides) off site or to other establishments; xi. movement of multiple bodies from the mortuary to other premises, for example, in the event that capacity is reached; xii. disposal of tissue (including blocks and slides), which ensures disposal in line with the wishes of the deceased person's family; xiii. access to the mortuary by non-mortuary staff, contractors and visitors; xiv. contingency storage arrangements.
c) Procedures on body storage prevent practices that disregard the dignity of the deceased.

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.
e) There is a system for recording that staff have read and understood the latest versions of these documents.
f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits.
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.
c) Staff are assessed as competent for the tasks they perform.
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.
b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible

for each action, deadlines for completing actions and confirmation that actions have been completed.
Premises,facilities and equipment
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.
b) There is demarcation of clean, dirty, and transitional areas of the mortuary, which is observed by staff and visitors.
c) There are documented cleaning and decontamination procedures and a schedule of cleaning.
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).
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.
PFE2 There are appropriate facilities for the storage of bodies and human tissue
a) Storage arrangements ensure the dignity of the deceased.
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity.

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.
d) Fridge and freezer units are in good working condition and well maintained.
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.
f) Temperatures of fridges and freezers are monitored on a regular basis.
h) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.
i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods.
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored
a) Items of equipment in the mortuary are in a good condition and appropriate for use: i. fridges / freezers ii. hydraulic trolleys iii. post-mortem tables iv.hoists v. saws (manual and/or oscillating)
b) Equipment is appropriate for the management of bariatric bodies.
d) Staff have access to necessary PPE.