Inspection report on compliance with HTA licensing standards
Inspection dates: **05-07 October and 01 December 2022**

Southmead Hospital Bristol

HTA licensing number 12413

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 **Southmead Hospital Bristol**	Licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*Carried out*
Pathology Laboratory	-	-	*Carried out*
Toxicology Laboratory	-	-	*Carried out*
Neuropathology Department	-	-	*Carried out*

Maternity Department	-	*Carried out*	-
A&E	-	*Carried out*	--
Satellite site **St Michael's Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*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 Southmead Hospital Bristol ('the establishment') had met the majority of the HTA's standards, five major and five minor shortfalls were found against standards for 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		

a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	Risk assessments have not been documented since 2018. The inspection team were therefore not assured that risk was assessed on a regular basis.	**Major (cumulative)**
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	Risk assessments do not include responsible persons, time frames or further actions to be taken to mitigate risk.	**Major (cumulative)**
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 viewing process at St Michael's Hospital does not include checking three points of identification when preparing bodies or meeting families. This increases the risk of the wrong body being prepared and viewed.	**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 preparation area at Southmead hospital has wooden doors and plaster walls. The contingency area also has areas of wooden flooring and walls, raised floor tiles and cracked concrete. This means that these areas cannot be maintained or decontaminated effectively.	**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)	The contingency area at Southmead Hospital is enclosed by wooden walls. These walls are not ceiling height. This is not secure, and accessible from outside of the hospital. Whilst CCTV covered these areas, the inspection team were not assured that adequate security was in place to prevent unauthorised access.	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	A single use key is used by porters at St Michael's hospital to enter the mortuary viewing facilities. Whilst there is a documented process for signing the key out at the main reception desk, the inspection team were not assured that the process was being adhered to. The inspection team identified occasions where the key had not been signed back in at reception. This does not therefore provide assurance that there is effective oversight and monitoring in place as to who had accessed the mortuary viewing facilities and for what purpose.	**Major**

Minor 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.	At the time of inspection, viewing procedures observed at Southmead hospital were not consistent with that of the Standard Operating Procedures (SOPs).	**Minor**

g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework.	There is a static historic collection of neurological tissue which has not been incorporated within the establishment's governance framework. Whilst these are all catalogued, these records have not been merged with newer records during the recent upgrade to the establishment's traceability system.	**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	The inspection team was not assured that all staff carrying out regulated activities, other than those working in the mortuary, are aware of incidents that must be reported to the HTA.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
d) There is a system for flagging up same or similar names of the deceased	Although there is a procedure in place for same or similar names, the inspection team were not satisfied that this was robust enough to reduce the risk of releasing the wrong body.	**Minor**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's Codes of Practice		
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	There is no procedure for following up with the Coroner to determine when the Coroner's authority has ended. This means that the establishment staff cannot assure themselves that tissue is not kept for longer than necessary. During the site visit to the Neuropathology Department the inspection team carried out an audit of brain tissue taken during PM. One of the cases selected for review had been stored for over a year since the PM despite the family having requested that the tissue should be disposed of once the coroner's process had ended. There was no documented evidence that this case had been followed up with the Coroner to establish whether tissue could be disposed of.	**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(c)	Whilst the condition of bodies is routinely checked on both sites, mortuary staff are advised to document condition on admission for all bodies. This will ensure full traceability of any actions or deterioration.
2.	GQ1(g)	The DI is advised to review the list of persons designate on the licence, to ensure all areas are covered where regulated activities take place.
3.	GQ1(g)	Within the Neuropathology department there is a collection of material for research projects stored under recognised Research Ethics Committee (REC) approvals. The approvals negate the need for the material to be stored under the authority of the HTA storage licence. The DI is advised to have oversight of the REC expiry dates to ensure that the specific project approval covers the samples in the future or, alternatively, the samples will need to be destroyed or stored under the HTA licence.
4.	GQ1(h)	Whilst matters relating to HTA-licensed activities are discussed at regular governance meetings, the DI is advised to formalise the process and distribute the minutes electronically.
5.	GQ2(a)	Whilst the audit schedule is up to date, these are all due towards the end of the year. The DI is advised to reinstate a routine audit schedule which has been disrupted during the COVID pandemic.
6.	PFE3(a)	The DI is advised to monitor very minor rust to the trolleys at Southmead Hospital to ensure it does not deteriorate further as this could result in a shortfall of HTA standard PFE3(a).

Background

Southmead Hospital Bristol has been licensed by the HTA since March 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in September 2017. St Michaels hospital has been licensed as a satellite site of Southmead Hospital since September 2016.

There is a collection of brain tissue stored within the Neuropathology Department which is stored for research purposes. The collection consists of wet tissue, and fixed blocks and slides. The consenting arrangements are carried out by the relevant Coroners Officers. The distribution and use of tissue to researchers is co-ordinated by a third party and released under material transfer agreements.

Since the previous inspection, two research tissue banks (RTBs) and a research collection that were stored under the licence at the last inspection are now covered under recognised REC approvals. The approvals negate the need for the material to be stored under the authority of the HTA storage licence.

The establishment receives toxicology samples from different establishments for testing. The consenting arrangements are carried out by the relevant Coroners Officers. Some material is stored by the establishment for the purposes of quality control, if there is adequate consent in place.

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)

Three out of the 72 standards, PFE1 (b), PFE3 (c)(e) were not applicable to Southmead hospital as they do not carry out post mortem examinations. Three out of the 72 standards, T2 (a)(c)(d) were not applicable to St Michael's Hospital as no PM tissue is retained on this site.

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 and porters.

Visual inspection
The inspection included a visual assessment of both establishments including, body storage areas, PM/preparation rooms, viewing rooms and tissue storage areas within the histology and neuropathology laboratories. The inspection teams observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records
Audits were conducted on both sites for three bodies from refrigerated storage and frozen 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 at Southmead Hospital for tissue blocks and slides from four coroners consented cases. These included audits of the consent documentation for the retention of these tissues. No discrepancies were identified.

Within the Neuropathology Department audits were conducted of neurological tissue taken at PM examination for ten cases. Information was crosschecked between the internal traceability systems, Coroner's paperwork, family wishes forms and tissue being stored. In one instance, the audit identified material in storage for which the family had requested disposal. The tissue had been stored for over one year subsequent to the request with no documented evidence of the following up of the case with the Coroner. See shortfall for T2(b).

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, mortuary manager, APT, pathologist, mortuary porter, professor of Neuropathology, Neuropathology staff and bereavement midwife.

Report sent to DI for factual accuracy: 04 January 2023

Report returned from DI: 08 February 2023

Final report issued: 10 February 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: 21 April 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.