Inspection report on compliance with HTA licensing standards
Inspection date: **23 and 24 November 2021**

Sheffield Children's Hospital

HTA licensing number 12001

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 **Sheffield Children's Hospital**	Licensed/Not licensed	Licensed/Not licensed	Licensed/Not licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Histology laboratory	-	-	*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 Sheffield Children's Hospital ('the establishment') had met the majority of the HTA's standards, seven minor shortfalls were found. These related to consent documentation, standard operating procedures (SOPs), the viewing process, security arrangements, fridge alarm testing and ventilation records.

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

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		
b) There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination)	The SOP for conducting PM consent (350.2.009) does not detail the procedure in place for the withdrawal of consent. The inspection team determined that although it is not detailed within the SOP, consentees are given the opportunity to withdraw in line with the HT Act and the HTA's Code of Practice.	**Minor**

c) There is written information for those giving consent (provided to those giving consent), which reflects the requirements of the HT Act and the HTA's Code of Practice	The documents 'Guide to Coroners Post Mortem procedure' (350.1.034) and 'A guide to hospital post mortem examination on a baby or child' (HPM 1.7) both refer to the next of kin (NOK) deciding on what happens to material retained at PM. The inspection team determined that although the guidance states NOK, all consent has been taken from the appropriate person as detailed in the hierarchy of qualifying relationships.	**Minor**
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	Standard Operating Procedures (SOPs) do not always reflect current practice. These include but are not limited to: • Post-Mortem SOPs (350.1.095, 350.2.002, 360.1.019, 350.4.001a) – do not include sufficient detail of identification checks performed relating to traceability of bodies, organs, and tissues - the inspection team noted that the staff carried out sufficiently detailed checks to identify the deceased against information provided, however this is not reflected in the SOPs. • 350.1.095 The Coroners Post-Mortem SOP – has not been updated to detail the freezer capacity at Sheffield Children's Hospital. • 350.2.002 Infant Autopsies SOP – does not detail who carries out the external examination on the body.	**Minor**
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 procedure for viewing of the deceased does not include a final check using a minimum of three points of identification of the deceased prior to visitors entering the viewing room.	**Minor**
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	The establishment do not have a system in place to review records of swipe card access to the mortuary to ensure that it is limited to those with legitimate right of access. There is also no formalised process for changing the mortuaries alarm code.	**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	Although serviced and calibrated annually, there is no formal testing of the fridge and freezer temperature alarms to ensure call-out procedures work and are followed.	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The ventilation system is serviced annually, however reports are not reviewed to ensure that there are the necessary ten air changes per hour. In 2020 the service report showed a failure to meet the standard however no actions were taken.	**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.

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

Number	Standard	Advice
1.	C1(g)	The DI is advised to check the document control on the 'Hospital Post Mortem Consent Form' (350.1.032) as some pages state version 6 and some version 7.
2.	GQ1(a)	SOPs are redistributed to staff after changes are made. The DI is advised to redistribute SOPs to staff after review even when no changes are made as part of refresher training.
3.	GQ1(a)	There are some duplications of SOPs detailing key mortuary processes. The DI is advised to review these and amalgamate ones which overlap.
4.	GQ2(a)	Some of the establishments 2020 audits have been carried out against the HTA's old standards. Following substantial stakeholder engagement, revised standards came into effect in 2017, and the DI is advised to make sure these are referenced in all relevant future audit activities.
5.	GQ6(a)	There are some duplications of risk assessments relating to licensable activity. The DI is advised to review these and amalgamate ones which overlap.
6.	GQ6(b)	The establishment has a comprehensive suite of risk assessments however the DI is advised to refer to relevant SOPs and include staff training and competency assessments within the mitigating factors.

Background

Sheffield Children's Hospital has been licensed by the HTA since June 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in October 2016.

Since the previous inspection, there has been some significant changes to the licence arrangements including a refurbishment of the mortuary in 2020 and a change of Corporate Licence Holder contact in June 2018.

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 team reviewed the establishments self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. This included standard operating procedures, records of servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training records. Consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the premises which included the mortuary, body storage area, PM room, viewing rooms and storage arrangements for relevant material held within the histology department.

Audit of records

The inspection team undertook audits of traceability for three bodies in storage. Traceability details were crosschecked between the identification band on the body, information on the door of the storage unit, the mortuary register and paperwork. No discrepancies were identified.

Audits were conducted of tissue taken at PM examination for four cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, laboratory database, and tissue blocks being stored. Full traceability of tissues was demonstrated for all four cases.

Meetings with establishment staff
The assessment team met with staff carrying out processes under the licence, including mortuary staff, a pathologist who conducts PM examinations, a portering staff member, staff involved in the consent seeking process, the quality team and the DI.

Report sent to DI for factual accuracy: 20 December 2021

Report returned from DI: No response

Final report issued: 07 January 2022

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: 8 April 2022

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.