Inspection report on compliance with HTA licensing standards
Inspection date: **12th and 14th of April 2022**

Southampton General Hospital
HTA licensing number 12214
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
Southampton General Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Neonatal Intensive Care Unit	-	*Carried out*	-
A&E	-	*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 Southampton General Hospital ('the establishment') had met the majority of the HTA's standards, four minor shortfalls were found against standards for Consent, Governance and quality systems, and Traceability. 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
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training.	Records demonstrate up-to-date staff training for those who seek consent for paediatric post mortems. This training addresses the requirements of the HT Act and the HTA's Codes of Practice. However, although those who seek consent for adult post mortems have received comparable training as part of their induction, records do not demonstrate that training for these individuals has been updated in recent years.	**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.	There are instances where Standard Operating Procedures (SOPs) lack clarity and/or sufficient detail. In particular, it is not always clear which specific identifiers are used to check the identify of the deceased and what documentation this is cross-referenced against. These include, but are not limited to, SOPs detailing the procedure for: • Release of Adult Patients to Designated Persons; and • Procedure for Viewing the Deceased by an Authorised Person;	**Minor**

(g)) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework.	Although instances are rare, tissue is removed from the deceased in both the Accident and Emergency Department and the Neonatal Intensive Care Unit. The establishment has adopted the RC Path Guidelines for sudden unexpected death in infancy and childhood, and no governance concerns were identified by the inspection team. However, there is no HTA Persons Designated within the Accident and Emergency Department or the Neonatal Intensive Care Unit. This increases the risk that removal of tissue could occur outside of the DI's oversight.	**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	For viewings of the deceased who are under the Coroner's jurisdiction, the mortuary technicians check three identifiers on the deceased when preparing a body for viewing. The mortuary technicians also carry out a final check using a minimum of three points of identification of the deceased provided by the visitors prior to them entering the viewing room. However, viewings of the deceased who are not under coronial jurisdiction, are arranged and accompanied by the bereavement team. For these viewings, although the mortuary technicians will check three identifiers on the deceased when preparing a body for viewing, the inspection team was not assured that the bereavement team carry out a final check using a minimum of three points of identification of the deceased provided by the visitors prior to them entering the viewing 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.	GQ1(a)	The DI is advised to review all SOPs to ensure they contain up-to-date references and also accurately reflect staff practices. For example, the Post Mortem Consent & Human Tissue Disposal Policy refers to the HTA's old Code of Practice 5.
2.	GQ2(a)	The establishment carries out an annual audit against HTA Code B Standards and Guidance, which encompasses a security audit. The DI is advised to consider a standalone audit of mortuary access on a regular basis to include a cross check of legitimate rights of access to the mortuary against frequency, duration and patterns of attendance to ensure access is in line with the purpose for which it was granted.
3.	GQ3(c)	The inspection team reviewed records of staff training and competencies. Competencies are regularly reassessed using reflection and verbal assessment methods. The DI may wish to consider incorporating some practical assessments/observations into this competency framework.

Background

The establishment has been licensed by the HTA since June 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in April 2017.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence.

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 establishment's 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 procedure 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, freezer room, PM rooms and viewing room.

Audit of records

The inspection team undertook audits of traceability for three bodies in storage. This included a body in long term storage and a paediatric body. Traceability details were crosschecked between the identification band on the body, and information in the mortuary register. No discrepancies were identified. Audits were conducted of tissue taken at PM examination for four cases. Information was crosschecked between the mortuary documentation, pathology department system, Coroner's paperwork, family wishes forms and tissue being stored. Full traceability of tissues was demonstrated for both cases.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including mortuary staff, a pathologist, a porter, maternity and bereavement staff as well as the DI.

Report sent to DI for factual accuracy: 13th May 2022

Report returned from DI: 17th May 2022

Final report issued: 31st May 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: 5 January 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.