Inspection report on compliance with HTA licensing standards
Inspection date: **25 & 31 May 2023**

Harrogate District Hospital

HTA licensing number 12118

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 **Harrogate District Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	*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 Harrogate District Hospital ('the establishment') had met the majority of the HTA's standards, four minor shortfalls were found against standards for audits and the viewing facilities.

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 standard operating procedure (SOP) detailing the consent process	Whilst there is a documented process in place for taking consent, this is within the SOP 'Death Certification, Cremation Forms and PM Examinations' which is not available to all consent takers within the Trust. Furthermore this document does not include the hierarchy of qualifying relationships as outlined in the Human Tissue Act 2004 or the HTA's codes of practice.	**Minor**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	Condition of the bodies are routinely checked and appropriate remedial actions taken as required. However there is no procedure for recording the condition of the bodies to evidence that this has been completed.	**Minor**

GQ2 There is a documented system of audit		
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	Tissue is audited to ensure sufficient disposal, however this does not include archived tissue where the coroner's jurisdiction has finished. One single slide of tissue, from 2021, was identified as being retained without consent following disposal of the remaining 23 slides in the set. Audits of archived tissue would mitigate against this type of incident where slides are misplaced or misfiled.	**Minor**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
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)	Visitors to the deceased takes place in a designated family area. Access to restricted areas of the mortuary is via a door with a manual lock. Whilst accompanied at all times, there is a risk that visitors may access the body store as the lock is visitor side facing.	**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(b)	The DI is advised to review all documentation regarding the consent taking process so information is centralised, and easily accessed by all trained consent takers.

2.	GQ1(e)	The DI is advised to implement a process of following up those that have not acknowledged documents within a set timeframe.
3.	GQ3(a)	The DI is advised to progress the plans for training and competency assessments of laboratory staff in mortuary regulated activities, in order to strengthen their staffing contingency plans.
4.	PFE1(a)	The DI and mortuary manager are advised to monitor slightly perished seals to the floor within the PM room to ensure it does not deteriorate further as this could result in a shortfall of HTA standard PFE1(a).
5.	PFE2(c)	The DI is advised to monitor and progress the already agreed business case to provide bariatric sized spaces.
6.	PFE2(e)	Whilst the temporary fridge unit is not currently constructed, the DI and mortuary manager are advised to explore remote alarm monitoring systems in preparation for its use.
7.	PFE3(a)	The DI and mortuary manager are advised to monitor minor rust to the mortuary trolleys to ensure it does not deteriorate further as this could result in a shortfall of HTA standard PFE3(a).
8.	PFE3(c)	Air changes within the post mortem are currently at 11.29 per hour. Whilst this meets the HTA standard of 10 air changes per hour, the DI is advised to monitor and assess the efficiency of the ventilation system to ensure it is not failing and meeting the guidance set out by NHS England.

Background

Harrogate District Hospital has been licensed by the HTA since August 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in September 2018.

Since the previous inspection, there has been a change to both the Designated Individual in March 2022, and corporate licence holder contact in April 2022.

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 27 September 2022).

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, cleaning records for the mortuary, records of servicing of equipment, audits, risk assessments, meeting minutes, reported incidents and training records for staff.

Visual inspection

The inspection included a visual assessment of mortuary fridge room, post mortem room, tissue storage areas and the viewing facilities. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records

Audits were conducted for three bodies from refrigerated storage and one from frozen storage. Identification details on bodies were crosschecked against the information recorded in the mortuary register and associated paperwork. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides from six Coroners consented cases. These included audits of the consent documentation for the retention or disposal of these tissues. One discrepancy was identified where a single slide had been missed following disposal of the rest of the case's blocks and slides. *See shortfall GQ2(c)*

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, Mortuary Manager, APT, Mortuary Porter, and Bereavement Midwife.

Report sent to DI for factual accuracy: 20 June 2023

Report returned from DI: 02 July 2023

Final report issued: 04 July 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: 28 November 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.