Inspection report on compliance with HTA licensing standards
Inspection date: **22 May 2024**

Russells Hall Hospital
HTA licensing number 30009

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 Russells Hall Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
A&E		*Carried out*	

Summary of inspection findings

This was an unannounced inspection of the establishment with a scheduled routine inspection brought forward due to concerns. 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 Russells Hall Hospital ('the establishment') had met the majority of the HTA's standards, two minor shortfalls were found against standards for Consent, 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

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		
d) Competency is assessed and maintained	Whilst consent seekers receive an assessment of competency this is not documented.	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	The trays used to store bodies in the contingency storage unit are not compatible for use with the hydraulic trolleys. This poses the risk of accidental damage to a body during transfer, and staff sustaining musculoskeletal injury.	**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 and strengthen the process relating to the identification of risk of infection. Consideration should be given to the use of fridge magnets, or additional ID bands on the body.
2.	GQ6(c)	The DI is advised to expedite existing plans in place for a staffing review and recruitment.
3.	PFE1(d)	The DI is advised to continue with the existing plans in place for the installation of additional CCTV and swipe access points within the post mortem suite.
4.	PFE3(a)	The DI is advised to consider replacing the trolley used to store cleaning supplies in the post mortem suite which is showing signs of wear and tear and is starting to rust.
5.	PFE3(c)	The ventilation system within the mortuary is subject to regular testing and servicing. However, records are not kept within the mortuary and are only available upon request. The DI is advised to request copies of all maintenance, servicing and repair reports so that they are easily accessible to the Mortuary Manager for review and monitoring purposes.

Background

Russells Hall Hospital has been licensed by the HTA since 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in August 2022.
Since the previous inspection, there have been no significant changes to the licence arrangements.
A Regulatory Decision Making meeting was held 13/03/2024 where the Director of Regulation made the decision to bring a routine scheduled inspection forward, and not to announce it to the establishment.
This followed concerns relating to an increase in incidents relating to identification checking and accidental damage to a body, which could have an impact on the safety and dignity of the deceased.

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 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, audits, risk assessments, meeting minutes, reported incidents and training records for mortuary and non mortuary staff.

Visual inspection
The inspection included a visual assessment of the establishment including the post mortem suite, body storage areas and viewing rooms. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records
Audits were conducted onsite of two bodies in refrigerated storage and one body in long term frozen storage. The release of one body into the care of the Funeral Director was observed. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork in addition to information held electronically. No discrepancies were identified. Audits of traceability were conducted for three cases of histology samples. No discrepancies were identified.

Meetings with establishment staff
Staff carrying out processes under the license were interviewed including the DI, Mortuary Manager, APT, Trainee APT, Porter and Perinatal Consent Seeker.

Report sent to DI for factual accuracy: 05/06/2024

Report returned from DI: 21/06/2024

Final report issued: 24/06/2024

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 August 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 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.