Inspection report on compliance with HTA licensing standards
Inspection date: **4 August 2022**

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
Russells Hall Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Accident and Emergency Department	-	*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 Russells Hall Hospital ('the establishment') had met the majority of the HTA's standards two minor shortfalls were found against standards for Governance and quality systems and Premises, facilities and equipment relating to internal audits of post mortem (PM) material and security.

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
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	Every six months the establishment carries out an audit of tissue removed during PM examinations which have occurred during the preceding 6 months. However, the establishment's audit schedule does not include a regular audit encompassing the full catalogue of tissue retained by the establishment for future use (such as for education, training and research).	**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	CCTV and swipe card access records are only available on request in the event of an incident or concern arising. Records cannot be accessed by the Mortuary Supervisor for regular audit purposes which means checks cannot be made to ensure that access is limited to those with a legitimate right of access and for legitimate purposes. Furthermore, records of those with swipe-card access to the mortuary are only reviewed on an *ad hoc* basis.	**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(e)	The establishment gives the option to families for retention of PM material for future use including education, training and research. The establishment does not carry these out and has not done for many years. The DI is advised to consider providing this information to families to set expectations and to ensure that any consent given by families for tissue to be retained is suitably informed.
2.	GQ1(a)	The Trust is currently reviewing the Lone Working Policy and is implementing the use of personal 'man-down' alarms to provide additional protection for staff. Although lone working in the mortuary is very rare, the DI is advised to implement the use of this device to strengthen procedures and safe-guard staff.
3.	GQ1(h)	Due to the COVID pandemic the schedule for staff annual appraisals has been disrupted. The DI is advised to reinstate the routine carrying out of these as soon as possible.

4.	GQ3(a)	There is a HTA training presentation that is given to staff by the Mortuary Supervisor which covers HTA history and legislation. The DI is advised to update the references that are made to the HTA's old Codes of Practice 1-9 which were superseded by the Codes of Practice A-G in April 2017. The DI is also advised to formally ratify, schedule review and version control the presentation to ensure it is kept up to date and in line with the establishments policies and SOPs.
5.	GQ6(a)	There are some duplications of hazards in the establishment's risk assessments relating to licensable activity. The DI may wish to review these and amalgamate some which overlap. This will help to streamline documentation and also reduce the time taken for staff to review the documents.
6.	T1(g)	The establishment are planning to send all PM histology tissue off-site for processing and procedures related to this are currently being developed. The DI should ensure that material is fully traceable and that there is confirmation of arrival at the receiving laboratory.
7.	PFE3(f)	Key items of equipment (including fridges, freezers and the air handling units) are subject to regular maintenance however records are not kept within the mortuary and 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 Supervisor for review and monitoring purposes.

Background

Russells Hall Hospital has been licensed by the HTA since June 2007. This was the fourth inspection of the establishment; the most recent inspection took place in April 2018. Since the previous inspection, there have been some significant changes to the licence arrangements including the change of Designated Individual (DI) in June 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 3 April 2017).

Review of governance documentation
The inspection team reviewed the establishment's self-assessment document provided by the DI and Mortuary Supervisor in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. This included standard operating procedures, risk assessments, internal audits, incidents, ventilation reports, staff training records and competency assessment documents. Consent seeking procedures and information for relatives giving consent for adult and perinatal PMs were also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the premises which included the mortuary body storage areas, the PM suite as well as the storage arrangements for relevant material held within the facility.

Audit of records
The inspection team undertook audits of traceability for four bodies in storage. This included community and hospital cases stored in the main body store, freezer unit and overflow fridge area. Traceability details were crosschecked between the identification band on the body and information in the mortuary register and on the mortuary paperwork. No discrepancies were identified.

Audits were conducted of stored tissue taken at PM examination for three cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, the mortuary electronic spreadsheet, disposal records and the tissue being stored. No discrepancies were identified.

Meetings with establishment staff
The assessment team met with staff carrying out activities under the licence, including mortuary staff, a portering staff member, staff involved in consent seeking processes, the bereavement midwife and the DI.

Report sent to DI for factual accuracy: 19 August 2022

Report returned from DI: 02 September 2022

Final report issued: 02 September 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: 23 December 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.