Inspection report on compliance with HTA licensing standards
Inspection date: **22 and 25 May 2023**

Royal Devon and Exeter Hospital

HTA licensing number 12370

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 **Royal Devon and Exeter Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*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 Royal Devon and Exeter Hospital ('the establishment') had met the majority of the HTA's standards one major shortfall was found against standards for 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

Major Shortfall

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The door to the mortuary opens onto an open courtyard where hospital waste is stored and collected. Refuse vehicles come and go throughout the day and there is oversight of mortuary activities. This congestion is affecting mortuary services and delaying collection of the deceased. This poses the risk of reputational damage to the establishment as this area is where families will be greeted by mortuary staff prior to viewing of deceased.	**Major**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfall 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 (d)	The DI is advised to review the consent policy to ensure it is clear and distinguishes the requirements for seeking consent regarding living and deceased tissue.
2.	GQ1 (a)	The DI may wish to review standard operating procedures (SOPs) to see where these SOPs can be amalgamated. In addition, the establishment is advised to include a formal sign off by staff once identification details are checked on bodies prior to commencing a PM examination.
3.	GQ1 (h)	The DI may wish to consider inviting the Portering Manager to the relevant meetings.
4.	GQ6 (a)	The DI is advised to have an overarching risk assessment which covers the HTARI categories. The establishment is also advised to risk assess current staffing levels to see if it is sufficient to meet the needs of service.
5.	PFE1 (d)	The DI may wish to consider changing the alarm code and reflect this in the relevant policies and procedures.
6.	PFE3 (a)	The DI is advised to continue with her plans to upgrade the existing air cooling unit in the high risk forensic suite to ensure that staff have a more comfortable working environment.
7.	General	The establishment may wish to review the options given regarding consent for retention and disposal of tissues taken from PM examination to ensure that informed consent is given. If the establishment is retaining tissue for research but eventually disposing of the tissue if there is no research available, then the timeframe for disposal of the tissue should be explicitly stated on the consent forms.

Background

The Establishment has been licensed by the HTA since 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in October 2018.

Since the previous inspection, there has been a change in DI and four new Persons Designated added 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 assessment 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 for the mortuary were reviewed. Traceability audits, risk assessments, meeting minutes, incidents, consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection

The inspection included a visual inspection of the mortuary body store, contingency storage, viewing room and PM room and high risk forensic room.

Audit of records
Audits were conducted for three bodies in refrigerated storage and one body in freezer storage. Body location and identification details on bodies were crosschecked against the information recorded on the electronic system and relevant documentation. No discrepancies were found.

Forward and reverse audits of traceability were conducted for tissue blocks and slides from coronial and hospital consented PM cases, including audits of the consent documentation for the retention and disposal of these tissues. Perinatal consent forms were also reviewed. No discrepancies were found.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence, including the DI, Anatomical Pathology Technologists, a porter, and consent seekers for PM examinations.

Report sent to DI for factual accuracy: 22 June 2023

Report returned from DI: 14 July 2023

Final report issued: 18 July 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.