Inspection report on compliance with HTA licensing standards
Inspection date: **26 July 2023**

Hull Royal Infirmary
HTA licensing number 12170

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 **Hull Royal Infirmary**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*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 Hull Royal Infirmary ('the establishment') had met the majority of the HTA's standards, one major and one minor shortfall were found against standards for Governance and quality systems. These related to errors at ward level impacting on admission of bodies to the mortuary and body condition checking procedures.

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 shortfalls

Standard	Inspection findings	Level of shortfall
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed	The inspection team identified a large number of repeat incidents relating to the incorrect completion of the electronic body transfer documentation at ward level. Actions identified at ward level, such as shared learning with staff, do not appear to have had the required impact in reducing the number of incidents reported. These errors have caused delays to the administrative process for admission of bodies to the mortuary and impacted on staff time due to staff having to report incidents of the same nature repeatedly.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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	Whilst regular condition checks of the deceased are undertaken to ensure bodies are stored at optimal temperatures and actions are taken to prevent deterioration, the procedure and process is not formally documented. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**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(a)	Whilst the information leaflet and the consent form in use for adult post mortem consent contains clear guidance on who should be contacted in the event consent is changed or withdrawn, the DI is advised to include the withdrawal of consent timeframes in the consent policy.
2.	C1(c)	The DI is advised to review the information leaflet for adult post mortem examination and remove references to the 'Next of Kin' (NOK) as the NOK may not be the most appropriate person to give consent under the HT Act.
3.	C1(e)	The DI is advised to liaise with the Coroner service and pathologists undertaking post mortem examination to ensure information provided to families on the retention of tissue at Coroner post mortem examination is fully reflective of the amount of tissue retained. Information provided informs that small blocks of tissue are taken, however, in practice pathologists may take large blocks or larger organ sections which are then trimmed down during tissue processing to create the small blocks for analysis.
4.	GQ1(a)	The DI may wish to consider amalgamating some SOPs related to the same task to reduce the number

		in operation. This may assist in ensuring staff are following tasks in a step wise order without having to refer to other documents and may assist the DI in reducing the number of documents requiring review.
5.	GQ3(c)	Whilst competency assessment of mortuary staff is completed regularly and competency assessments were up to date at the time of the inspection, the DI is advised to record the method used to assess competency for the observational assessments.
6.	GQ6(b)	Whilst risk assessments clearly document how mitigation of risks is achieved, the DI is advised to review risk assessments and include that staff are trained and assessed as competent in the procedure where this is relevant and not documented.

Background

Hull Royal Infirmary has been licensed by the HTA since May 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in March 2019.

Since the previous inspection, changes to the Persons Designated have occurred in 2019, 2020, 2021 and 2022. A change to the role of DI occurred in August 2019 and the current DI has been in post since March 2022.

The pathology department now sits under another HTA licensed establishment as a satellite site due to a recent merger of pathology services in the area. This change occurred just prior to this inspection.

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. Traceability audits, risk assessments, staff training and competency records, meeting minutes, cleaning logs and schedules, alarm testing records, incidents, consent seeking procedures, including information for relatives giving consent and the consent forms in use.

Visual inspection
The inspection team undertook a visual inspection of the premises which included the mortuary body storage areas, the PM room, and the viewing room. The area within the maternity department for the storage of bodies was also inspected.

Audit of records
The inspection team undertook audits of traceability for four bodies in storage. This included bodies with same / similar names, a body in frozen storage and a perinatal body. Traceability details were crosschecked between the identification band on the body, information on the mortuary whiteboard, and the electronic mortuary database. No discrepancies with traceability were identified.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence including members of mortuary staff, a member of the portering staff, staff involved in the consent seeking process for perinatal PM examination, staff on the maternity department responsible for monitoring storage of the deceased, a pathologist who undertakes PM examination, a member of the Emergency Department staff involved in the removal of tissue from the deceased and the DI.

Report sent to DI for factual accuracy: 11 August 2023

Report returned from DI: 21 August 2023

Final report issued: 04 September 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: 20 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.