Inspection report on compliance with HTA licensing standards
Inspection date: **29 and 31 March 2022**

Royal Lancaster Infirmary

HTA licensing number 12356

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 Lancaster Infirmary	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Satellite site Furness General Hospital	Licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*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 Lancaster Infirmary ('the establishment') had met the majority of the HTA's standards, 2 major and 3 minor shortfalls were found against standards for Governance and quality systems, Traceability 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

Major shortfalls

Standard	Inspection findings	Level of shortfall
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
c) Disposal is in line with the wishes of the deceased's family	During the traceability audit of PM tissue (archived blocks and slides), the HTA found two discrepancies whereby consent is not in place for continued retention. • Blocks were found from one case in storage from 2018 where the families wishes was for the material to be disposed of. • Blocks were found from one case in storage from 2018 where the consent form was blank.	**Major**
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	The use of keys and key code locks does not provide the establishment with oversight of those accessing the mortuary. Furthermore, there is no system in place to formally review access records to ensure that it is limited to those with legitimate right of access. The use of keys and key code locks has not been risk assessed. The key codes which allow access to the mortuary are not regularly changed.	**Major**

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	The establishment do not conduct audits of PM tissue being stored in the block and slide archive.	**Minor**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	The SOP for the reporting of HTARIs is overdue review and does not provide enough detail to ensure that staff are fully aware of what needs to be reported to the HTA. During the inspection one incident was identified that may be a near-miss HTARI and has not been reported.	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		

a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	Not all procedures related to licensed activities have been risk assessed.	**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 the *Consent for Hospital Post Mortems (CORP/PROC/014)* SOP as it is overdue the review date.
2.	C1(e)	The establishment gives the option to families for retention of PM material for research. Currently the establishment does not conduct research. The DI is advised to consider providing this information to families to set expectations and ensure that informed consent is obtained.
3.	GQ1(e)	The establishment only redistribute SOPs after changes have been made. The DI is advised to redistribute SOPs after review even when there are no changes made as part of refresher training.
4.	GQ1(h)	Due to the COVID pandemic the HTA governance meeting schedule has been disrupted. The DI is advised to reinstate the regular meetings and is also advised to provide a template for minute taking to formalise and standardise the process.
5.	PFE2(a)	Although condition checks are carried out routinely for all bodies, the DI is advised to formalise the checks and document the findings.
6.	PFE2(e)	Whilst fridge alarm tests are undertaken as part of an internal monitoring system, the DI is advised to implement regular unannounced fridge alarm tests from within the mortuary. This will provide a robust challenge procedure to ensure the call out procedures work as expected in the event of a unit failure.

7.	PFE3(a)	Paint from one of the trolleys within the body store at Royal Lancaster Infirmary has begun to flake away, exposing metal which is likely to rust. The DI is advised to have the trolleys serviced to preserve their integrity.
8.	PFE3(f)	Although the key items of equipment including the fridges, freezers and trolleys are subject to maintenance when required the DI is advised to include these on servicing contracts as a preventative measure (as opposed to a responsive measure).

Background

Royal Lancaster Infirmary has been licensed by the HTA since September 2007. This was the fourth inspection of the establishment; the most recent inspection took place in December 2016.

Since the previous inspection, there has been some significant changes to the licence arrangements including the removal of a satellite licence at Westmorland General Hospital in 2022, a change of Designated Individual (DI) in 2016 and a change to the Corporate Licence Holder contact (CLHc) in 2021.

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 Manager in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. This included standard operating procedures, risk assessments, audits, incidents, ventilation reports, training and competency assessment documents. Consent seeking procedures and information for relatives giving consent for adult and perinatal post mortems were also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the hub and satellite premises which included the mortuary body storage areas, the PM suites 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 at the hub site. This included community and hospital cases, adults and a perinatal case. Traceability details were crosschecked between the identification band on the body and information in the mortuary register. No discrepancies were identified.

Audits were conducted of stored tissue taken at PM examination for eight cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, the mortuary electronic database, and tissue being stored. Two discrepancies were identified. Blocks were found from one case in storage from 2018 where the families wishes was for the material to be disposed of. Blocks were found from one case in storage from 2018 where the consent form was blank.

The inspection team undertook audits of traceability for two bodies in storage at the satellite site. This included an adult community case and an adult hospital case. Traceability details were crosschecked between the identification band on the body and information on the mortuary register. No discrepancies were identified.

Meetings with establishment staff
The assessment team met with staff carrying out activities under the licence, including mortuary staff, a pathologist who conducts PM examinations, a portering staff member, cell pathology manager, staff involved in consent seeking processes and the DI.

Report sent to DI for factual accuracy: Friday 22 April 2022

Report returned from DI: No response

Final report issued: 10 May 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: 25 October 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.