Inspection report on compliance with HTA licensing standards
Inspection date: **5 and 6 July 2023**

Leeds General Infirmary
HTA licensing number 12231

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 **Leeds General Infirmary**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Maternity	-	-	*Carried out*
Satellite site **St James's University Hospital**	Licensed	Licensed	Licensed
Mortuary (satellite site)	*Carried out*	*Carried out*	*Carried out*

Pathology lab	-	-	*Carried out*
Maternity	-	-	*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 Leeds General Infirmary ('the establishment') had met the majority of the HTA's standards, six major and two minor shortfalls were found against standards for Governance and quality systems 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
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	The inspection team noted a body that had been in storage for 70 days that had not been placed into frozen storage despite being released by the coroner. This body showed signs of decomposition and had soiled shrouding. A second body had been in storage for 47 days, had also been the subject of a coroners release notification and had not been placed into frozen storage and showed signs of decomposition. The Establishment currently request permission from the coroner to place long stay bodies into frozen storage. This procedure is also being followed for bodies where the coroner has issued a release notification. The cases described demonstrate that the current practice risks accidental damage to bodies through decomposition. The inspection team noted a further body at the Leeds General infirmary site in soiled shrouding – this was addressed by staff whilst the inspection team were on site. At the St James's University Hospital site two bodies were noted to be in soiled shrouding. This was addressed by staff whilst the inspection team were on site.	**Major**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	Training records for mortuary staff are incomplete and do not provide sufficient evidence to meet this standard	**Major**

c) Staff are assessed as competent for the tasks they perform	Records of competency assessments for mortuary staff are incomplete and do not provide sufficient evidence to meet this standard	**Major**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
a) The premises are clean and well maintained	At Leeds General Infirmary, in the post mortem room the inspection team noted debris in lower level vents and some floor drains. There were some areas of damaged walling with exposed plaster in the post mortem room and body store that could not be fully decontaminated. Lower levels of dissection benches and docking posts for the post mortem tables had not been fully decontaminated.	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	Fridge units in the maternity departments at both sites are tested annually as part of a service contract. The current schedule presents a risk of undetected fridge failure. The alarm of the empty fridge unit at St James was tested by staff whilst the inspection team were on site and no audible alarm was heard. This presents a risk of accidental damage to bodies.	**Major**

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 trolley in use in the contingency store area at St James's University Hospital is not appropriate for use as it does not reach the lower levels of the fridge. Staff have to manually handle the body tray in order to get it to the correct level when placing or removing bodies from the fridge. This presents a risk of accidental damage to bodies and injury to staff.	**Major**

Minor Shortfalls

Standard	**Inspection findings**	**Level of shortfall**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	There was no cleaning schedule for the body store at Leeds General Infirmary	**Minor**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	At Leeds General Infirmary, the door from the visitors area to the staff office is not fitted with a lock. This allows potential access to the main mortuary. Whilst the current procedure is that staff remain with families, there is a risk of families being able to access the mortuary if staff were to leave for any reason. There is also a risk to staff who may need to retreat should they be the subject of confrontation.	**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.	GQ1a	The DI is advised to review the SOP relating to HTARI reporting. This contains a link to the HTA web site which is obsolete.
2.	GQ1c	The DI is advised to review communication with the coroner after release notification has been issued to reduce the risk of accidental damage to bodies through deterioration. See shortfall GQ1c above.
3.	GQ2a	Fridge Temperature monitoring is taking place on an ad hoc basis and is recorded when completed. The DI is advised to add this to the formal audit schedule.
4.	GQ5a	Whilst all staff including porters appear to be aware of HTARI categories The DI is advised to display the HTARI categories in the porter supervisors office as a reminder of those incidents that are required to be reported to the HTA
5.	PFE1d	The control units for condenser units of fridges at St James University Hospital are accessible. These are in an area that is not accessed by the public but could be inadvertently switched off or tampered with by maintenance or trust staff. The DI is advised to secure these controls.
6.	PFE3a	Two hose units in the post mortem room at St James University Hospital were leaking. Whilst this was being managed by staff by allowing leak to run away via sink or drain areas. The DI is advised to request maintenance for this equipment.

Background

Leeds General Infirmary has been licensed by the HTA since 12 March 2008. This was the fifth inspection of the establishment; the most recent inspection took place in February 2020.

Since the previous inspection, there has been a change to the Corporate License Holder contact (CLHc).

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. This included standard operating procedures, risk assessments, audits, incidents, equipment servicing reports, and training 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 hub and satellite premises which included the mortuary body storage areas, the PM suites, delivery suites, the storage arrangements for relevant material held at St James's University Hospital and the storage of relevant material stored as the Gerlis collection at Leeds General Infirmary.

Audit of records

The inspection team undertook audits of traceability for eleven bodies in storage. This included community and hospital cases. Traceability details were crosschecked between the identification band on the body and information in the mortuary register and electronic records. No discrepancies were identified. Two bodies in storage had not been placed into frozen storage after thirty days and showed signs of deterioration. See GQ1c above and advice and guidance 2.

Audits were conducted of stored tissue taken at PM examination for five cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, the mortuary electronic database, and tissue being stored. No discrepancies were identified. A collection of hearts known as the Gerlis collection was viewed by the inspection team at the Leeds

General Infirmary site. The samples were stored prior to implementation of the Human Tissue Act 2004 on 1 September 2006 and are therefore ‘existing holdings’. Storage arrangements were suitable. The establishment plans to transfer this collection to a research establishment during the latter months of 2023. Tissue viewed by the inspection team was labelled in accordance with current standards for research establishments.

Meetings with establishment staff

The assessment team met with staff carrying out activities under the licence, including the DI, the Mortuary Manager, an Anatomical Pathology Technologist (APT), a porter and staff involved in the consent seeking processes.

Report sent to DI for factual accuracy: 25 July 2023

Report returned from DI: 15 August 2023

Final report issued: 25 August 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: 18 December 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.