Inspection report on compliance with HTA licensing standards
Inspection date: **28, 30 & 31 March 2023**

Heartlands Hospital
HTA licensing number 12366

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 Heartlands Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	-	*Carried out*
Satellite site Solihull Hospital	Not licensed	Not licensed	Licensed

Mortuary (satellite site)	-	-	*Carried out*
Satellite site **Good Hope Hospital**	Not licensed	Licensed	Licensed
Mortuary (satellite site)	-	-	*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 Heartlands Hospital 'the establishment' had met the majority of the HTA's standards, eight (8) major and two (2) minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment. These relate to competency assessment, staff training, systems to track bodies and tissue, equipment in the mortuary and viewing rooms.

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
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
d) Competency is assessed and maintained	There is currently no competency assessment in place for consent seeking.	**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	Site managers are not trained in out of hours procedures such as release and viewing of the deceased. This poses a risk of releasing or viewing of the wrong body.	**Major**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records)	Digital systems are in place to track bodies from admission to release. Written mortuary registers are also used. The inspection team noted that some bodies in storage at Solihull were included in the digital record but had not been added to the written record. This presents a risk when recording the release of bodies from this site.	**Major**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The system to transfer tissue from PM to histology does not include recording the number of blocks taken at PM in the mortuary which can then be checked and agreed upon receipt into histology to ensure the correct number of tissue blocks have arrived. This poses a risk of loss of tissue / tissue traceability.	**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	There are several areas which required maintenance in the body store at Heartlands Hospital: • Areas of damage to flooring which require sealing. • Damage to wooden doorframes throughout – exposed and unsealed wood. • Damage to walls exposing plaster. At Good Hope Hospital some fridge units have flooring constructed from concrete which is porous and is showing signs of damage which cannot be effectively decontaminated. (see PFE2d below)	**Major**
d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	At Good Hope Hospital, the external fridge condenser units for the body store and external controls for an additional storage unit are accessible. This leaves a risk of external controls being tampered with.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
d) Fridge and freezer units are in good working condition and well maintained	Two banks of fridge units at Good Hope have concrete floors which are porous and cannot be effectively decontaminated. One unit also has defective door handles which allow the fridge door to open due to increased air pressure when another door is closed. (See also PFE1(a) above)	**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	Some of the body hoists are manually operated (pump action). They do not fully extend to the height of the fridge spaces. This causes a risk to staff safety and risk to accidental damage to bodies.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ4 There is a systematic and planned approach to the management of records		
b) There are documented SOPs for record management which include how errors in written records should be corrected	Some entries in the written mortuary register at Solihull Hospital had been crossed out and were illegible.	**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 unauthorised access and ensure oversight of visitors and contractors who have a legitimate right of access	At Solihull and Good Hope Hospitals, the viewing room panic alarms are in areas which may make it difficult for staff to access in the event of an emergency.	**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.	PFE1a	Good Hope Hospital – some cardboard boxes were stored on the floor in the body store. The DI is advised to store these boxes off the floor to avoid the risk of contamination.
2.	PFE1d	Heartlands Hospital - The access door to the mortuary PM viewing gallery in the pathology corridor is not overseen by CCTV or on swipe card access. It is key code and key access. The DI is advised to consider either CCTV or swipe access so entry to this door can be monitored as part of security audits.
3.	PFE1e	The DI is advised to amend visitors logs on all sites to include time in and out of the mortuaries. This will strengthen security arrangements. The DI is advised to add regular audits of the CCTV against swipe card access to the audit schedule to strengthen security arrangements.

Background

Heartlands Hospital has been licensed by the HTA since 18 August 2008. This was the fourth inspection of the establishment; the most recent previous inspection took place in July 2017.

Since the previous inspection, there has been a change to the Designated Individual and a further satellite site at Solihull Hospital was added to the licence in 2023.

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 establishments self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. The team also undertook a review of records relating to equipment servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units and mortuary, reported incidents, and staff training. Consent seeking procedures and information for relatives giving consent 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, PM room and viewing rooms as well as the area for storage of relevant material held within the laboratory. Maternity departments were also visited.

Audit of records
The inspection team undertook audits of traceability for thirteen bodies in storage. Traceability details were crosschecked between the identification band on the body, information on the digital mortuary register and paperwork. No discrepancies were identified. Audits were conducted of tissue taken at PM examination for five cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, consent for PM examination forms (where relevant), the laboratory database, and tissue blocks and slides being stored. No discrepancies were identified.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence, including mortuary staff, staff involved in the consent seeking process, staff from the maternity departments and the DI.

Report sent to DI for factual accuracy: 24 April 2023

Report returned from DI: 9 May 2023

Final report issued: 10 May 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: 17 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.