Inspection report on compliance with HTA licensing standards
Inspection date: **31 August 2022 – 02 September 2022**

Royal Derby Hospital

HTA licensing number 12537

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 Derby Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	-	*Carried out*
A&E	-	*Carried out*	-
Satellite site Queen's Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*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 Derby Hospital ('the establishment') had met the majority of the HTA's standards, 6 major and 12 minor shortfalls were found against standards for Consent, 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.

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		
a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice	Doctors responsible for taking paediatric consent, at both the hub and satellite site, have not received training in the HTA requirements of taking consent.	**Major (Cumulative)**

b) Records demonstrate up-to-date staff training	Records do not demonstrate up to date training in HTA requirements when seeking consent. Adult consent training records were last completed in 2010. No records were available for doctors taking pediatric consent.	**Major (Cumulative)**
c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual	The inspection team were not assured that individuals trained in HTA requirements were always present when consent was sought for pediatric post mortems.	**Major (Cumulative)**
d) Competency is assessed and maintained	The establishment does not have a formalised system in place for assessing staff as competent on the HTA requirements when seeking consent. This includes those who have received the initial training.	**Major (Cumulative)**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	Standard Operating Procedures (SOPs) at Queen's Hospital site lack sufficient detail. Key steps are included but these do not specify the individual actions that need to be undertaken to accomplish each step. At the time of inspection, procedures observed by the inspection team were not consistent with that of the SOPs. These include, but are not limited to, SOPs detailing the process for: admission of bodies; post-mortem examination; release; and retention, disposal, and transfer of PM samples. This is not an exhaustive list of the SOPs requiring amendment. To fully address this shortfall the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate and contain sufficient detail to reflect current practice.	**Major** **(Cumulative)**

c) Procedures on body storage prevent practices that disregard the dignity of the deceased	Whilst condition checks are taking place at Royal Derby hospital, these are only on admission and release. Condition checks between this time are ad hoc, and there is no formal documented procedure to ensure any additional checks take place. On conducting the body audit, the inspection team identified a body in soiled sheets and with excessive fluid leakage (please see shortfall at PFE2a below). Initial checking on admission recorded no concerns with condition, this indicates that no checks or subsequent actions were taken to prevent deterioration. The DI was requested to report this as a reportable incident and the establishment have since commenced an internal investigation. At Queen's Hospital regular condition checks take place, however these are ad hoc and not documented.	**Major (Cumulative)**
d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	Policies and SOPs at Queen's Hospital are not regularly reviewed, ratified or version controlled. SOPs on mortuary practises were issued in 2004. These have been reviewed and changed twice since and are still assigned as the first version.	**Major (Cumulative)**
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	There are no Persons Designate for areas other than the mortuary. The inspection team is therefore not assured that the DI has oversight of regulated activities within the laboratory or on maternity wards.	**Major (Cumulative)**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Matters relating to HTA-licensed activities are not discussed at regular, formalised governance meetings involving the Designated Individual (DI) and establishment staff.	**Major (Cumulative)**
GQ2 There is a documented system of audit		

a) There is a documented schedule of audits	There is no documented schedule of audits at Queen's Hospital.	**Major (Cumulative)**
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	As per GQ1(a) audit findings at Queen's hospital are not documented.	**Major (Cumulative)**
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 inspection team were not assured that staff are fully aware of what tissue is being held and why. Royal Derby Hospital does not have a robust system for tracking or auditing tissue being stored. The inspection team identified tissue that had been retained without consent since 2018. Whilst tissue at Queen's Hospital was disposed of in a timely manner following instruction from the coroner, mortuary staff do not have oversight of family wishes and are therefore unaware of the reasons for storing tissue.	**Major (Cumulative)**
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	A single use key is used for porters, at Queen's Hospital, to access the mortuary and is not signed in and out. This means the mortuary team do not have oversight of who has entered the mortuary. The establishment are in the process of introducing swipe card access, and immediate actions were taken during the inspection process to ensure that access to the mortuary is fully traceable during this interim period.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

a) Storage arrangements ensure the dignity of the deceased	Whilst completing the body audit at the Royal Derby Hospital, the inspection team found one patient wrapped in soiled shrouding and another patient was wrapped in shrouding which contained leakage.	**Major**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	A ventilation report was unavailable for Queen's hospital. The inspection team were not therefore assured that the ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually.	**Major**

Minor Shortfalls

Standard	**Inspection findings**	**Level of shortfall**
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice	There is no documented policy which governs consent for post-mortem examination and the retention of tissue which reflects the HT Act and the HTA's Codes of practice.	**Minor**
b) There is a documented standard operating procedure (SOP) detailing the consent process	Whilst staff follow guidelines, there is no formal standard operating procedure detailing the consent process.	**Minor**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	Whilst the establishment provide a verbal housekeeping induction to visiting pathologists, this does not include written evidence of sign off against the establishment's documented policies and procedures.	**Minor**
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	The inspection team identified white stickers used to redact information in the mortuary register. This was not in line with hospital procedure and means that some records are not fully auditable.	**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	Risk assessments were last completed in 2016 and were therefore not reviewed on a regular basis.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	The establishment's procedure for release and viewing of bodies does not make clear that information provided by funeral directors and/or visiting families must include a minimum of three identifiers of the deceased. At Queen's hospital, three identifiers were not routinely provided by funeral staff when collecting bodies.	**Minor**

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	Following completion of the tissue audit, the whereabouts of one set of slides was unknown. The establishment had made the HTA aware of this prior to the inspection process and the establishment has already put steps in place to mitigate incidents of a similar nature.	**Minor**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete	Tissue was not disposed of in a timely manner. Tissue was found to have been awaiting disposal since 2018.	**Minor**
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	Responsibility for reviewing material retained following Coroners post-mortem examination currently sits with individual pathologists without full oversight of the Designated Individual. There is no documented procedure in place for following up with third parties to determine when Coroner's authority has ended. Current arrangements do not ensure that tissue is not kept longer than necessary.	**Minor**
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	Walls to the fridge room at Royal Derby have large areas of exposed plaster. This means they cannot be cleaned or decontaminated effectively.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	Due to the limited freezer storage facilities at the hub site, bodies and foetal remains were found to be held in refrigerated storage in the mortuary for more than 30 days, which is not in accordance with the HTAs recommended guidance for long term storage of bodies.	**Minor**
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	The inspection team identified two single unit fridges within the mortuary and maternity ward used for storing relevant material. Whilst there was temperature monitoring in place, these were not connected to any alarm systems.	**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.	GQ1(a)	The establishment has recently merged with another trust and is currently in the process of upgrading the quality management software system. The DI is advised to continue to roll-out this system to strengthen record management.
2.	GQ3(a)	Whilst porters had received competency re-assessments at Royal Derby Hospital, the DI is advised to

		reinstate the routine formal training schedule which had been disrupted during the COVID pandemic.
3.	PFE1(a)	The DI is advised to monitor very minor rust to the flooring and racking at Queen's Hospital to ensure it does not deteriorate further as this could result in a shortfall of HTA standard PFE1(a).
4.	PFE1(c)	Whilst the inspection team were assured that the establishments are clean, and cleaning rotas were documented. The DI is advised to ensure that these cover all areas of the fridge rooms in Royal Derby Hospital.

Background

Royal Derby Hospital has been licensed by the HTA since 2009. This was the third inspection of the establishment; the most recent previous inspection took place in September 2017.

Since the previous inspection, Queen's hospital was added to the licence as a satellite site in 2018. Queen's hospital is licensed to undertake the same licensed activities as Royal Derby Hospital. There has also been a change to the corporate licence holder and Designated Individual.

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 included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records for the mortuary, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and training records for mortuary staff, maternity staff, consultant clinicians, pathologists and porters.

Visual inspection
The inspection included a visit to both the hub and satellite site. A visual inspection of the mortuary body store, PM room, viewing room, and tissue storage areas was completed at both locations. A visual inspection of storage within the maternity wards was completed in Derby. The inspection team reviewed the processes for admission, release and viewing of bodies within the mortuaries.

Audit of records – Hub Site
Audits were conducted for four bodies in refrigerated storage and one body in frozen storage. Identification details on bodies were crosschecked against the information recorded in the mortuary register and associated paperwork. Whilst one minor discrepancy was found regarding spelling of a surname, this was not sufficient to amount to a shortfall and oral advice was given to the establishment at the time of the inspection.

Audits of traceability were conducted for tissue blocks and slides from five coroners consented cases. These included audits of the consent documentation for the retention of these tissues. Three discrepancies were found. Two were regarding the timely disposal of tissue, see shortfall GQ2(c). One was regarding the unknown location of slides, see shortfall T1(g).

Audit of records – Satellite Site
Audits were conducted for four bodies in refrigerated storage. Identification details on bodies were crosschecked against the information recorded in the mortuary register and associated paperwork. No discrepancies were identified.

The inspection team were unable to complete an audit on traceability of blocks and slides at the satellite site due to the unavailability of consent documentation, see shortfall T2(b)

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, mortuary managers, Anatomical Pathology Technologists, pathologists, mortuary porters, bereavement midwifes and a bereavement officer.

Report sent to DI for factual accuracy: 30 September 2022

Report returned from DI: 21 October 2022

Final report issued: 07 November 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: 22 June 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.