Inspection report on compliance with HTA licensing standards
Inspection date: **9 and 11 November 2021**

Derriford Hospital

HTA licensing number 12034

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 **Derriford Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab			*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 Derriford Hospital ('the establishment') had met the majority of the HTA's standards, seven major and eight 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.

Compliance with HTA standards

Major 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		
b) There is a documented standard operating procedure (SOP) detailing the consent process	There is no documented SOP in place detailing the consent process for seeking adult and perinatal/paediatric post mortem (PM) examinations.	**Major**
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	Staff involved in the consent seeking process for adult and perinatal/paediatric PM examination have not received training which addresses the requirements of the HT Act and the HTA's codes of practice.	**Major (cumulative)**
b) Records demonstrate up-to-date staff training	No consent training records were available to demonstrate staff have up-to-date training. No accessible records are held for staff to determine who is appropriately trained to seek consent.	

d) Competency is assessed and maintained	Staff competency in seeking consent for adult perinatal/paediatric PM examination is not assessed.	
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) lack sufficient detail such that whilst the key steps are included these do not specify all the individual actions that need to be undertaken to accomplish each step. These include, but are not limited to, SOPs detailing the process for: • admitting bodies to the mortuary; • release of bodies to funeral directors; • identification of deceased for viewing of bodies; and • long stay storage of bodies. This is not an exhaustive list of the SOPs requiring amendments, and 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**
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	The establishment does not have a procedure in place for checking and documenting the condition of bodies following receipt into the mortuary. The inspection team's body traceability audit identified a body in freezer storage where the identity tag was unreadable. The establishment does not check the condition of bodies during the length of stay in the mortuary	**Major**
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	While an audit schedule is in place and these audits have been completed, discrepancies were identified by the inspection team when conducting the traceability audits. The discrepancies found had not been identified as part of the establishment's own routine audits:
	• the inspection team found that the consent forms in two cases were not completed correctly;
	  ○ one case stated that the patient leafet on PM examination was not available for the family to read at the time of consent being taken. No further information on any discussion held was documented; and
	  ○ one case the clinician taking consent for PM examination had not signed the consent form.
	• the inspection found one case where extra slides had been produced from tissue taken at PM examination that was not recorded either on the electronic tissue spreadsheet or in the laboratory management system.
		Major

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	There is no assurance that all staff undertaking licensable activities know how to identify and report HTA Reportable Incidents (HTARIs).	**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	The premises are showing sign of wear and tear: • There are cracks in the tiles of the floor of the body store and PM suite. • Areas of the floor at the base of the dissection benches and legs are rusted in the PM suite. • Tissue and debris was found in the drain of the PM suite. • There are large areas of exposed plaster on the walls of the body store. • Drain covers at the base of the PM tables are not flush with the floor. This means that the floor and wall surface is difficult to clean and disinfect adequately.	**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	The Trust Policy does not include the training required to seek consent for perinatal/paediatric PM examinations. (*see advice item 1 and 2*).	**Minor**
d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives	The perinatal/paediatric consent form does not include the option for disposal of tissue.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The scope of the audit schedules for licensed activities conducted under the licence is limited. The audit schedules do not include sufficient horizontal audits to check compliance with documented procedures, the completion of records and traceability of tissues.	**Minor**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
d) Information about incidents is shared with all staff to avoid repeat errors	There is no mechanism or practice of sharing information about incidents with the SUDIC and maternity teams.	**Minor**

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)	Due to the separate electronic recording and paper systems, there is no system in place to track each body around the body store.	**Minor**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The procedures for traceability of PM samples do not provide a full audit trail of transfer of the samples off-site. • The establishment does not receive confirmation that PM specimens are received at the toxicology laboratory. • There is no official sign-off of tissue taken at PM exam at histology specimen reception for check and receipt.	**Minor**
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	Although the establishment has a schedule of cleaning, the inspection team found that cleaning of the body store had not been documented.	**Minor**
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 items of equipment are suffering from obvious signs of wear and tear and are otherwise not fit for purpose, for example: • the trolleys have areas of rust and peeling paint. • the racking trays inside the fridges had small areas of rust.	**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.	C1a	The DI is advised to include a link to Code of Practice A: guiding principles and the fundamental principle of consent in the Consent to examination Trust policy.
2.	C1a	The DI is advised to include the reporting of HTA reportable incidents in the Consent to examination Trust policy.
3.	GQ2b	The DI is advised to ensure that repetitive non-conformances are adequately investigated and to ensure that effective corrective actions are put in place.
4.	GQ6a	The DI is advised to review the risk assessments for references to old HTA codes of practice.
5.	PFE1d	The DI is advised to add a security audit to the schedule to ensure that only those who are authorised have access to the establishment out of hours.

Background
Derriford Hospital is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

Derriford Hospital has been licensed by the HTA since 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in August 2016.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence.

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, records of equipment servicing, audits, risk assessments and reported incidents.

Visual inspection

The inspection included a visual inspection of the mortuary body store, PM room and viewing room.

Audit of records

Audits were conducted for six bodies in refrigerated storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and relevant documentation.

Audits of traceability were conducted for tissue blocks and slides from four PM cases, including audits of the consent documentation for the retention of these tissues. Discrepancies were found in three cases relating to completeness of consent forms and number of slides retained.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, Anatomical Pathology Technologists, a pathologist, portering staff, maternity staff, A&E department staff and organ retention staff.

Materials held for the police

Under section 39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. Any information provided by the establishment in relation to police holdings have been shared with the Home Office, but do not appear in the report as they are outside the scope of the HT Act.

Report sent to DI for factual accuracy: 3 December 2021

Report returned from DI: 3 January 2022

Final report issued: 7 January 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.