Licence application assessment visit report on compliance with HTA licensing standards
Site visit date: **16 and 18 March 2022**

University Hospitals Dorset

Proposed HTA licensing number 12723

Application for a licence under the Human Tissue Act 2004

Activities applied to be licensed

The table below shows the proposed activities this establishment is to be licensed for and the proposed activities to be 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 Bournemouth Hospital**	Not applied to be licensed	Not applied to be licensed	Applied to be licensed
Mortuary			*Applied to be carried out*
Satellite site **Poole Hospital**	Not applied to be licensed	Not applied to be licensed	Applied to be licensed
Mortuary (satellite site)			*Applied to be carried out*
Satellite site **Christchurch Hospital**	Not applied to be licensed	Not applied to be licensed	Applied to be licensed

Mortuary (satellite site)			*Applied to be carried out*

Summary of visit findings

The HTA found the proposed Designated Individual (DI) not to be suitable in accordance with the requirements of the legislation.

Although the HTA found that University Hospitals Dorset (the establishment) had met the majority of the HTA's standards, eight major and nine minor shortfalls were found against standards for Consent, Governance and Quality, 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 site visit.

Compliance with HTA standards

Major shortfalls

Standard	Visit 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 Standard Operating Procedure (SOP) in place detailing the consent process for perinatal/paediatric post-mortem (PM) examination.	**Major**
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.	SOPs lack sufficient detail. Key steps are included but these do not specify 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; • release of bodies; and • identification of deceased for viewing of bodies. 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**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The scope of the audit schedule for activities conducted under the licence is limited. The audit schedule does not include sufficient audits to check compliance with documented procedures, the completion of records, and traceability of bodies. *See advice item 4*.	**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	There is no formal training plan in place to train mortuary officers, bank staff or porters at either site.	**Major**
c) Staff are assessed as competent for the tasks they perform	Although staff have been initially 'signed off' on completion of training, there is no on-going competency assessments for mortuary officers or porters at either sites.	**Major**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		

c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	<u>Royal Bournemouth Hospital:</u> The number of staff employed at the establishment is not currently sufficient. This poses a risk that could lead to the unplanned closure of the establishment and impact its ability to deliver services. The proposed DI has other Trust responsibilities which means they may be unable to fulfil their primary legal responsibility under Section 18 of the Human Tissue Act 2004. This poses a risk to the establishment's ability to deliver post mortem services.	**Major**
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	Three identifiers are not obtained from those wishing to view the deceased or on release of a body. <u>Royal Bournemouth Hospital</u> • The procedure for conducting viewings does not include steps to check a minimum of three identifiers of the deceased provided by relatives against the identification on the body before a viewing takes place. • The form brought by funeral directors (FDs) for release of a body does not include a minimum of three identifiers that can be checked against the establishment's information. <u>Christchurch Hospital</u> • Although the establishment have paperwork that includes the minimum of three identifiers staff are releasing bodies verbally by name only. The use of less than three separate identifiers when identifying bodies, presents a risk of viewing or releasing the wrong body. *See advice item 6*.	**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	The fridge banks at both sites are not alarm tested to ensure that they trigger when temperatures go out of the set range and to ensure the call out procedure is working.	**Major**

Minor Shortfalls

Standard	**Visit 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		
g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided	The consent form for perinatal/paediatric PM examination does not adequately reflect the requirements of the HT Act. The form only gives the option for tissue taken at PM examination to be retained and relies on consent seekers to provide other options such as disposal of the material or repatriation. The consent form also refers to outdated HTA Codes of Practice.	**Minor**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		

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	Mortuary SOPs are not reviewed by someone other than the author.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
f) There is a documented induction and training programme for new mortuary staff	Royal Bournemouth Hospital: There is no formal induction or training plan in place for new mortuary staff.	**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	Royal Bournemouth Hospital: The inspection team noted that the mortuary register had blocked out corrections which means that the register cannot be audited satisfactorily.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
d) There is system for flagging up same or similar names of the deceased	Although a same/similar name system is in place it is not robust enough to reduce the risk of releasing the wrong body. *See advice item 7*.	**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	Some areas of the body store are showing signs of wear and require maintenance to ensure decontamination procedures are effective: <u>Royal Bournemouth Hospital:</u> • Large areas of rust was observed on the floor of one bank of fridges and on the fridge racking; and • There was exposed metalwork above the door to the body store. <u>Christchurch Hospital:</u> • The main entrance door has areas of exposed wood and rust; and • Areas of exposed wood on the viewing room door.	**Minor**
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)	<u>Christchurch Hospital</u>: The body store building is separate to the hospital. There is CCTV coverage of the gate into the courtyard area which is monitored by security.The gate to the body store building courtyard only has a latch in place. There is a risk that access to the body store building could be gained by opening the gate into the courtyard area. The viewing room is separated from the body store by a single door that cannot be locked from the body store side. Although viewings are rarely held there is a risk that families may be able to enter the body store via this door.The establishment has reduced this risk by a member of the portering staff being present in the body store when viewings are held.	**Minor**
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	Royal Bournemouth Hospital: The fridge seals on the oldest set of bank of fridges are deteriorating.	**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	Royal Bournemouth Hospital: The hydraulic and bariatric trolley have large areas of rust. This makes the equipment difficult to clean and decontaminate. Christchurch Hospital: The hydraulic trolley has areas of rust.	**Minor**

Proposed DI suitability

The proposed DI has the relevant experience to undertake the supervision of the licensed activity being applied to be carried out. However, their current workload of other Trust responsibilities means they are limited in time to ensure that activities are conducted properly, by people who are suitable to carry out those activities, and that all the necessary requirements are complied with. The HTA has identified risks in the proposed DI being able to deliver post mortem services and compliance with the HT Act 2004.

Advice

The HTA advises the proposed DI to consider the following to further improve practice:

Number	Standard	Advice
1.	C1(a)	The Trust consent policy refers to the old HTA Codes of Practice. The proposed DI is advised to review the Trust consent policy to update the references to the current Codes of Practice.

2.	C1(f)	The proposed DI is advised to add the minimum timeframe for families to change their minds to the consent seeker guidance notes.
3.	C2(a)	The consent seeking Powerpoint training slides refer to the old HTA Codes of Practice. The proposed DI is advised to review the training slides and update the references.
4.	GQ2(a)	The proposed DI is advised to develop an audit schedule to include horizontal and vertical audits of all licensable activities for example, receipt of a body, release of a body and consent forms. The proposed DI is advised to use these procedural audits as an opportunity to review SOPs to see if practice reflects what is written in the SOP for each activity.
5.	GQ5(a)	The proposed DI is advised to review the incident aide memoire in the body store to include an alternative contact and contact details.
6.	T1(c)	The proposed DI may wish to consider the introduction of a form to be completed by relatives when they attend for viewings. This form could include relevant identification information so that three identifiers can be checked by mortuary staff on the body before the viewing takes place. Guidance is also available on the HTA website: updated guidance for Traceability Standard T1c.
7.	T1(d)	The proposed DI may wish to consider using coloured wrist tags on bodies and/or a sign on the fridge door to strengthen the current procedure for flagging same and/or similar names.
8.	PFE2(a)	The proposed DI is advised to record any actions taken to ensure that the dignity of the deceased is preserved.
9.	PFE2(c)	Currently the establishment has no freezer storage. The proposed DI is advised to risk assess the need for freezer storage when the plans for the redevelopment of the body store are being done.

Background

University Hospitals Dorset is the amalgamation of Poole Hospital, Royal Bournemouth Hospital and Christchurch Hospital under one NHS Trust umbrella. The hub site would be Royal Bournemouth Hospital, with Poole Hospital and Christchurch Hospital being satellite sites.

Description of activities undertaken during visit

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during the visit:

Standards assessed against during visit

Standards GQ1(b), GQ2(c), T1(g), T2 (a-d), PFE3(c) and PFE3(e) were not assessed as they are not applicable to the activities undertaken. The remaining 63 HTA licensing standards (standards published 3 April 2017) were assessed.

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, records of equipment servicing, audits, risk assessments, meeting minutes, temperature monitoring records, staff training records and reported incidents.

Visual inspection

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

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, mortuary officer, portering staff and consent seeking maternity staff.

Report sent to proposed DI for factual accuracy: 11 May 2022

Report returned from proposed DI: 12 May 2022

Final report issued: 16 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: 13 April 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 site visit 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, and;
- 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, or;
   - 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 site visit.

   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 the 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 site visit inspection;
- a request for information that shows completion of actions;
- monitoring of the action plan completion;
- follow up at next routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.