Inspection report on compliance with HTA licensing standards
Inspection date: **18-19 May 2022**

Royal Berkshire Hospital NHS Foundation Trust

HTA licensing number 12232

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 Berkshire Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Maternity			*Carried out*
Satellite site **Harborne House**	Not licensed	Not licensed	Licensed
Pathology Lab			*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 Berkshire Hospital NHS Foundation Trust ('the establishment') had met the majority of the HTA's standards, nine major and nine 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**
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training	*Perinatal/paediatric post mortem examination* The establishment could not provide assurance that records of training for clinicians seeking consent for perinatal post mortem (PM) examinations are in place.	**Major**
d) Competency is assessed and maintained	The establishment could not provide assurance that competency assessments are in place for clinicians seeking consent for perinatal PM examinations. *See advice item 3.*	**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**
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 current procedure for auditing PM tissue only covers reviewing those tissues with instruction for disposal. Full audits of tissue retained at PM examination through to the laboratory are not undertaken. *See advice item 5*	**Major**
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	Not all procedures relating to licensed activities have been risk assessed.	**Major**
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	Although storage capacity of bodies has been incorporated into the Trust risk register, the permanent use of two temporary fridge units has been in place for an extended period of time. This could risk the establishment's ability to deliver post mortem services as one of the temporary units is situated in the PM room. *Refer to shortfalls against standards PFE2(b) and PFE2(c) for further detail*	**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	Although bodies are identified with three identifiers via the mortuary register and on the identification band, non-coronial bodies are released to funeral directors on one identifier only. Funeral directors only bring the green form with them which does not state the required three identifiers. Bodies are viewed when staff are only provided with verbal communication of the name of the deceased by those visiting the mortuary. No further identification check of the body is performed prior to the viewing. These practices pose a risk of releasing or viewing of the wrong body. *See advice item 6*	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	The establishment is permanently using a temporary fridge unit to store bodies in the PM room. There is also a second temporary fridge unit that has been in use for over six months which is situated in the body store. This has required the establishment to move the lone standing perinatal fridge into the viewing room; this is moved back into the body store area when viewings are conducted. This movement of the fridge increases the risk of accidental damage to bodies stored. Temporary storage units should not be used for extended periods of time.	**Major**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The mortuary does not have sufficient freezer storage capacity to meet the need for long-term storage of bodies. There is insufficient refrigerated storage for bariatric bodies. At the time of the inspection all freezer storage was in use and a temporary fridge unit was being used on a permanent basis to store bariatric bodies.	**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 Consent for Hospital Post Mortem for Adults policy does not include detail about refresher training or re-competency assessment or the contact details for the Trust interpreter service. The policy refers to the previous HTA codes of practice and standards.	**Minor**
f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds	The Stillbirth and Neonatal Death Society (SANDs) consent form does not include the timeframe for families to change their minds. *See advice item 2*.	**Minor**
g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided	The consent form used to seek consent for adult PM examinations does not include the option to return organs or tissue to the body.	**Minor**
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) relating to mortuary activities are not reflective of current practice. These include, but are not limited to, SOPs detailing the process for: • Admission and release of bodies; • Post mortem examination; • Lone Working; and • Contingency arrangements.	**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 found during the body audit that errors in the mortuary register had been blocked out. This does not allow for full auditability of any changes to a record.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The establishment do not receive confirmation of receipt of samples sent off site for analysis.	**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 mortuary premises are showing signs of wear and require maintenance to ensure decontamination procedures are effective: • The drain on the floor of the body store had an area of rust surrounding it. • There were small areas of exposed plaster on the walls of the PM room.	**Minor**
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 unit on the maternity ward has an external alarm to the pathology department, however, this is not tested to ensure that the alarm triggers when temperatures go out of the upper or lower set range and that the call out procedure works. *See advice item 7*	**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	Hydraulic trolleys are showing signs of rust and require maintenance to ensure decontamination procedures are effective. Trolley in the PM room holding equipment for use in the PM examination has areas of rust on the legs and around the feet.	**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.	C1(a)	The DI is advised to ensure that they hold records of staff involved in the consent seeking process and that this is accurately reflected in the policy. The DI is also advised to ensure that all the links to the HTA website are updated.
2.	C1(f)	There are currently two maternity consent forms in circulation for seeking consent for perinatal/paediatric PM examinations. The DI is advised to consider removing one of the consent forms from circulation to ensure that trained staff are seeking consent using one agreed and ratified consent form.
3.	C2(d)	The DI is advised to ensure that staff who would have attended the refresher training which was postponed due to the COVID-19 pandemic, attend at the earliest convenience.

4.	GQ2(a)	The DI is advised to develop an audit schedule to include horizontal audits of all licensable activities for example, receipt of a body, release of a body and consent forms. The DI is advised to use these procedural audits as an opportunity to review SOPs to check that practice reflects what is written in the SOP for each activity.
5.	GQ2(c)	If the family's wishes are that the tissue is retained for research, but no research is ongoing at the establishment, the DI is advised to consider communicating with research tissue banks to see if the tissue could be utilised for research via this avenue.
6.	T1(c)	The DI may wish to consider the introduction of a form, which can be used by funeral directors for the release of non-coronial bodies. This form could include relevant identification information so that three identifiers can be checked against the mortuary register and identification band on the body before being released.
7.	PFE2(e)	The DI is advised to add the procedure and regularity for testing the alarms in the body store to the contingency SOP.

Background

Royal Berkshire Hospital NHS Foundation Trust (RBH) 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.

RBH has been licensed by the HTA since 2007. This was the third inspection of the establishment; the most recent previous inspection took place in May 2017.

Since the previous inspection, the establishment has added Harborne House as a satellite site due to the movement of the histology laboratory off site.

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 and post-mortem room, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents and staff training records.

Visual inspection

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

Audit of records

Audits were conducted for three bodies in refrigerated storage and one in long term storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and electronic database. No discrepancies were found.

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. No discrepancies were found.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, mortuary manager, histology staff, portering staff, maternity staff, and an adult PM consent seeker.

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 has been shared with the Home Office, but these do not appear in the report as they are outside the scope of the HT Act.

Report sent to DI for factual accuracy: 17 June 2022

Report returned from DI: 20 June 2022

Final report issued: 11 July 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: 28 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.