Inspection report on compliance with HTA licensing standards
Inspection date: **30 November – 01 December 2021**

Royal Surrey County Hospital
HTA licensing number 12222

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
Royal Surrey County 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 Royal Surrey County Hospital ('the establishment') had met the majority of the HTA's standards, ten major and eight minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities, and equipment. These related to consent seeking procedures, standard operating procedures and risk assessments, staff training and competency assessment, traceability of bodies, tissues and organs, maintenance of the premises and body storage capacity and procedures.

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		
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 perinatal consent policy does not include detail of how consent is obtained prior to the removal of relevant material from the deceased for microbiological analysis.	**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 involved in the release and viewing of bodies out-of-hours have not been trained or competency assessed in these procedures.	**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	During the inspection, the following issues were identified relating to traceability of bodies: • Bodies may enter the mortuary with less than three identifiers of the deceased detailed on the identification band. • A unique reference number is assigned and attached to the body following admission. However, this number does not allow easy tracking to a third identifier of the deceased, as the mortuary register, and the electronic recording system do not include three robust identifiers of the deceased. • As witnessed by the inspection team, funeral directors may arrive with less than three identifiers of the deceased which can be cross matched against the identification bands on the body prior to release. • The procedure for viewing of the deceased does not include a final check using a minimum of three points of identification of the deceased prior to visitors entering the viewing room.	**Major**
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	The establishment is storing tissue for which there is no consent for continued retention following Coroner authority ending. Cases date from 2013 onwards.	**Major**
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	The inspection team identified a number of instances where tissue is being retained longer than necessary due to the lack of sufficient communication with the Coroner. In addition, staff have been unable to prioritise communication with the Coroner to ensure the timely disposal of tissue.	**Major**
c) Disposal is in line with the wishes of the deceased's family	During the tissue traceability audit the inspection team identified one case where tissue blocks and slides were still in storage despite having been recorded as disposed of in line with the wishes of the family.	**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 were clean at the time of inspection. However, some areas of the body store and post mortem (PM) room are showing signs of wear and require maintenance: • The seal between the flooring and the walls requires replacement in some areas. • There are several areas of damage to walls and flaking paint exposing porous plaster in the body store and viewing room corridor, meaning that the walls cannot be sufficiently cleaned or disinfected. • The floors in both the body store and PM room are cracked in several places. Furthermore, the body store floor has some areas of rusting underneath refrigerated units. In addition, the door frame in the PM room is constructed from wood. This is damaged leaving it difficult to clean and disinfect adequately.	**Major**
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	Following PM examination, bodies are transferred on a trolley from the PM room into the body storage area to be returned to the refrigeration unit. This poses a risk of cross-contamination as the body store is also accessed by funeral directors and porters who do not routinely wear foot coverings. The floor of the body store is only cleaned routinely once per month which does not address the risk of cross-contamination sufficiently.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

a) Storage arrangements ensure the dignity of the deceased	The establishment use the base of the refrigerated units to increase capacity for body storage. Whilst the procedure has been risk assessed, the body trolley does not lower to the level of the storage trays used. This means that bodies stored in this location are subject to additional manual handling when being placed into and removed from the body storage units. This practice poses an increased risk of accidental damage to the deceased.	**Major**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The establishment does not have sufficient frozen storage capacity for bodies requiring long term storage.	**Major**

Minor 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	Competency is not assessed or maintained for staff seeking consent for perinatal PM examination.	**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) do not include sufficient detail of identification checks performed relating to traceability of bodies. These include but are not limited to: • MORT-RSCH-SOP-6 Receipt, Release and Transfer of Deceased – this SOP does not detail the type and number of identifiers funeral directors should arrive with or detail how this information is crossmatched against the identification on the body. • MORT-RSCH-SOP-7 Viewings Policy & Procedure – this SOP does not include detail that three identifiers of the deceased are provided by visitors and crosschecked against the body prior to entry of visitors to the viewing room. To fully address this shortfall the establishment should review all SOPs relating to traceability of bodies to ensure they contain sufficient details of identification checks performed.	**Minor**
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	Whilst staff know how to identify and report incidents internally, an incident falling within the HTA reportable incident (HTARI) categories had not been reported to the HTA as the establishment had determined the incident to be a near miss. *The establishment reported the incident to the HTA following the inspection for review.*	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		

b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed	Risk assessments do not sufficiently detail how identified risks are mitigated. Furthermore, not all risk assessments have been reviewed against the HTARI categories to ensure there is mitigation for identified risks.	**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)	The mortuary register and the electronic mortuary database are not routinely updated to reflect when a body has changed storage location.	**Minor**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The establishment does not have a procedure in place to confirm receipt of organs or tissues sent off-site. Furthermore, the mortuary does not routinely record the number and types of tissues taken at PM examination. This means the establishment have no assurance the pathology laboratory is signing for the correct number and types of tissue taken at PM examination.	**Minor**

h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements	The procedure for sending bodies to a referral centre for perinatal PM examination does not include confirmation of receipt of the body.	**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	The inspection team observed an excessive ice build-up on the components of the frozen storage unit which requires maintenance.	**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(b)	The DI is advised to ensure that consent seeking SOPs and policies accurately reflect the withdrawal of consent procedure the establishment has in place.
2.	C1(d)	The DI is advised to liaise with the Coroner regarding the family wishes form that is currently in use. The form does not provide clear information on options available for how tissue may be handled following PM examination, including the options available for storage of relevant material for future use.

		It is further advisable for the form to include information on what steps will be taken should relatives not make a decision.
3.	GQ1(c)	The DI is advised to review the 'Guidance on body storage' recently published by the HTA and align the recently introduced body condition checking procedure to the guidance provided.
4.	GQ1(d)	The DI is advised to update documents held on the electronic records management system to reflect the date documents were reviewed (as captured by the system) as some documents printed and displayed in the mortuary appear to be beyond the review date.
5.	GQ2(a)	The DI is advised to increase the frequency of body traceability audits to assist in identifying discrepancies in traceability as observed during the inspection. Increasing the frequency will allow for effective management of discrepancies and provide an additional control measure for risks associated with traceability of bodies.
6.	GQ2(c)	The DI is advised to review the effectiveness of the tissue traceability audit currently in place. The audit should capture discrepancies in the system as observed during the inspection.
7.	PFE1(a)	The DI is advised to routinely lock clinical waste bins stored in the funeral director garage area.
8.	PFE1(c)	The DI is advised to increase the frequency of floor cleaning in the body store and add information on the cleaning of floors throughout the mortuary to the cleaning schedules.
9.	PFE1(d)	Whilst the mortuary is secure, the DI is advised to review the following security arrangements: • The funeral director garage area has a door which is routinely left unlocked overnight for out-of-hours admittance of bodies to the mortuary. • A check should be made of the panic alarm system within the viewing area to ensure it is in working order and is tested regularly. • Consideration of additional screening of the window between the viewing room and body storage area to prevent the risk of oversight to the body store by visitors.

10.	PFE1(e)	The doors between the body storage area and the viewing rooms are secured using a manual key lock. The DI may wish to consider steps to mitigate the risk of unauthorised access to the body store should the manual key lock not be deployed.

Background

Royal Surrey County Hospital has been licensed by the HTA since July 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 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. This included cleaning records for the mortuary and post-mortem room, records of servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training records. Consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the premises which included the mortuary body storage area, PM room and viewing room as well as the area for storage of relevant material held within the pathology department.

Audit of records

The inspection team undertook audits of traceability for four bodies in storage. This included bodies with same / similar name and a body in long term storage. Traceability details were crosschecked between the identification band on the body, information on the door of the storage unit, the mortuary register and paperwork. Three bodies were in storage spaces differing from the location information in the mortuary register and the electronic mortuary database. The surname of one body was misspelled on the nameplate of the storage unit and one body did not have the name written on the nameplate of the storage unit. Whilst the identification of all bodies was fully traceable to paper records, the mortuary register and the electronic mortuary database do not contain sufficient robust identifiers of the deceased to trace bodies effectively to these records.

Audits were conducted of tissue taken at PM examination for four cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, laboratory database, and tissue blocks and slides being stored. The mortuary does not routinely record the number and types of tissue taken within the records held in the mortuary department. Recording is based on the number of 'pots' of tissue sent to the laboratory meaning the audit was unable to determine the correct number and types of tissue had been received into the laboratory. However, the records demonstrated that the 'pots' had been received in all four cases. Two cases demonstrated disposal of tissue had been completed in line with the wishes of the family. One case demonstrated that tissue was being stored with appropriate consent. The family wishes form for the fourth case indicated that the tissue was to be disposed of, however, whilst residual wet tissue had been disposed of, the blocks and slides were still in storage.

Meetings with establishment staff

The assessment team met with staff carrying out processes under the licence, including mortuary staff, laboratory staff, a portering staff member, staff involved in the consent seeking process, staff responsible for the removal of relevant material in the Emergency Department and the DI.

Report sent to DI for factual accuracy: 04 January 2022

Report returned from DI: 05 January 2022

Final report issued: 18 January 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: 23 June 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.