Inspection report on compliance with HTA licensing standards
Inspection date: **31 October 2022**

East Surrey Hospital

HTA licensing number 12117

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 **East Surrey 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 East Surrey Hospital ('the establishment') had met the majority of the HTA's standards, two critical, 12 major, one cumulative major and seven minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and

Premises, facilities and equipment. Two of the shortfalls (two minors) relate to findings from the last inspection. The HTA is concerned that adequate steps were not taken to address these findings in the intervening period and to embed suitable practices at the establishment.

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

Critical Shortfalls

Standard	Inspection findings	Level of shortfall
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
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)	The portering staff entrance to the mortuary directly accesses the body store from the hospital corridor. There is no further internal door or security between the hospital corridor mortuary access and the body store, with porters using an internal pull-across curtain to screen the body store from view. The entrance doorway has a double (side-by-side) pair of swing access doors, one wider than the other. Both doors must be opened to allow a concealment trolley to be brought into the mortuary. The narrower door does not automatically close following use. There is a risk of the door not being properly secured after use, risking uncontrolled access to the body storage area of the mortuary, which would be a serious security breach. Furthermore, there is no alarm or hospital corridor CCTV covering the hospital corridor entrance to the mortuary and so no means of alerting mortuary or security staff if this door has not been properly closed. The entrance door to an external building housing temporary body storage units is accessed by swipe card. This door shows significant signs of wear and tear and is in need of repair. There is a risk that the door would be ineffective in preventing unauthorised access to the temporary units.	**Critical**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The temporary contingency storage units that are in use are located in a separate building. This building is also used by the estates department. There are no additional internal security measures in place to segregate and secure the temporary storage units and prevent access to them by estates staff accessing the building for their own purposes. There is no Trust policy or standard operating procedure (SOP) in place stating that the building must be kept secured, the external door must be kept locked, that only estate staff who have a legitimate right of access for work purposes should access this building and that estate staff must not enter it alone but must be in pairs. The Designated Individual (DI) has no means of controlling or monitoring access to this external building and the storage units it contains. This presents a risk that estates or other staff could be accessing the building without appropriate control, monitoring or supervision. *See findings against standard PFE1(d) for issue over the state of this external door.* All porters employed by the Trust are automatically given swipe cards that permit them to access to the mortuary even though they may not need this and may not be involved in licensed activities. The DI does not have effective control or oversight over who is given the means to access to the mortuary. Security personnel are responsible for conducting audits of staff using swipe cards to access the mortuary and the external temporary storage units for auditing CCTV. At the time of the inspection, no records of these audits were available to the DI or the inspection team. A disused temporary contingency refrigeration unit is located in the garage area. This prevents funeral directors (FD) and ambulance staff from reversing their vehicles fully into this area so that the shutter door, which would otherwise provide additional security and shielding from public view, cannot be closed whilst FDs are present for admission or release. The area where the FDs park is overlooked by laboratories and a cafeteria and is also used by Trust staff and contractors to move between buildings. There is a risk that passers-by could view movement of bodies in and out of the mortuary. During the inspection it was observed that the shutter to this garage area was in any case not working so leaving the garage area open.	**Critical**

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	At the time of the inspection the establishment do not have a Consent policy which governs consent for post mortem (PM) examination and the retention of tissue which reflects the requirement of the HT Act and the HTA's Codes of Practice.	**Major**
b) There is a documented standard operating procedure (SOP) detailing the consent process	There is no standard operating procedure (SOP) in place for detailing the consent process for perinatal/paediatric PM examinations. This was identified as a shortfall in the previous site visit inspection and has not yet been sufficiently addressed by the establishment. A draft SOP prepared in response to the finding at the previous inspection has not been finalised and issued to staff. *See advice item 1.*	**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	<u>*Perinatal/paediatric consent training*</u> At the time of the inspection the establishment could not provide training records for the bereavement midwife and clinicians involved in seeking consent for perinatal/paediatric PM examination. This was identified as a shortfall in the previous site visit inspection and has not yet been sufficiently addressed by the establishment. The training records on which assurances were provided following the previous inspection appear not to have been completed. *(as a result, standards C2(b), (c) and (d) cannot be met)* *See advice item 4.*	**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.	Some 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 of unidentified bodies; • viewing of deceased; • release of unidentified bodies; • return of tissue; and • HTA reportable incidents. This is not an exhaustive list of the amendments required to all the SOPs and, to fully address this shortfall, the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate, are cross referenced to the appropriate SOPs and contain sufficient detail of procedures.	**Major**
GQ2 There is a documented system of audit		

a) There is a documented schedule of audits	Although the establishment have undertaken audits, regular horizontal and vertical audits have not been undertaken of compliance with all licensed activities e.g., consent forms, traceability of bodies and equipment records.	**Cumulative Major**
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	Whilst the establishment has a checklist for audits, the checklists contain little detail or comment on what was looked at on the audit or have a written report to identify non-compliances and an action plan to complete follow-up actions.	
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, a number of discrepancies were identified by the inspection team when conducting the traceability audits for 2019. There is no assurance that tissue which should have been disposed of in-line with the families' wishes has been conducted for a number of cases in 2019. *Refer to shortfall against standard T2(a) for further detail.*	
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	The current system for porter training is for mortuary staff to train the portering supervisors who disseminate this training to porters. The inspection team found that the portering supervisors are not disseminating this training and new porters are trained by existing porters. This presents a risk of portering staff not following the establishment's procedures for key mortuary activities.	**Major**
c) Staff are assessed as competent for the tasks they perform	There is no system for assessing and recording competency of portering staff in the mortuary procedures they perform. Site managers who prepare deceased for viewing out of working hours have not been assessed by the establishment as competent to undertake this activity in accordance with the establishment's procedures.	**Major**

g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	Visiting staff do not receive training in mortuary policies and procedures. This includes visiting pathologists who undertake PM examinations at the establishment. This presents a risk of staff not following the establishment's procedures for key mortuary activities.	**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	The inspection team identified incidents reported on the Trust incident system since the previous inspection which have not been reported to the HTA. The HTA reportable incidents (HTARI) SOP does not indicate what areas are covered by licence or the specific personnel who should be able to identify those incidents that must be reported to the HTA. This presents an ongoing risk of staff undertaking licensed activities not reporting incidents.	**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	The establishment's documented risk assessments do not cover all licensed activities and the risks of incidents associated with these activities. For example, the following risks have not been assessed: • removal of tissue from a body without authorisation or consent; • viewing of the wrong body; • PM examination conducted not in line with consent; • tissue traceability; and • Incident leading to unplanned closure. This is not an exhaustive list of the risks not assessed and, to fully address this shortfall, the establishment should review all risk assessments relating to licensed activities to ensure that all risks have been identified. The route used by mortuary staff to transfer bodies to and from the body store to the temporary units which are located in a separate building is by the road outside the funeral director's entrance. This area is frequented by members of the estates team, contractors, pathology staff and could be viewed by members of the public through the windows of the cafeteria overlooking the route. This task is usually undertaken by a single member of staff; there is an increased risk of accidental damage to the body and lack of dignity for the deceased arising from having to transport the deceased on a trolley across this uneven surface on a public route. The external building housing the temporary units has two doors. The shutter door, which was intended to be the main access door for the movement of the deceased, is not working. Staff are therefore required to use the side door mentioned previously (PFE1(d) and (e)). This door is itself opposite a door to the hospital used by members of the public, contractors and Trust staff. Release of deceased is occasionally conducted from the temporary units. However, access to the building for staff and funeral directors for parking and transfer of the deceased is impeded by works and there is a risk of this procedure being observed. These risks to the dignity of the deceased are not addressed in the existing risk assessments. *Refer to shortfalls against standard PFE1 (d) and (e) 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	Staff make arrangements for viewing having only been provided with identity details of the deceased, for example name, verbally by those visiting. No further identification checks of the body are performed prior to the viewing. This practice poses a risk of viewing the wrong body. *See advice item 6*	**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 cannot provide assurance that tissue has been disposed of as soon as reasonably possible for a number of cases in 2019. During the inspection, seven cases in 2019 were identified where tissue slides from PM examination were transferred to another HTA licensed establishment for analysis. For some of these cases, the coroner's authority has been concluded but these slides have not been returned, despite regular follow-up by establishment staff. There is a risk that the tissue is being stored at the other establishment without appropriate consent under the HT Act as the family's wishes were for all tissue to be disposed of sensitively.	**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	The establishment have been unable to provide the service records for the ventilation system and staff are not aware if the ventilation system is operating to the required standard.	**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		
g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided	The perinatal/paediatric consent form does not give the option of disposal or repatriation of tissue or organs as options. The guidance notes also refers to the HTA Code of Practice 3. *See advice item 3.*	**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	Although the establishment has a range of SOPs covering licensable activities, a small number of SOPs have the same author and authoriser.	**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	Not all staff involved in licensed activities are invited to governance meetings or receive the minutes.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
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	There is no documented procedure in place for the transfer of organs to other establishments for analysis including a follow up period for any requested return of the organ by the family.	**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	The establishment does not have any freezer storage for bariatric bodies and only has a verbal agreement with other licensed establishments within the foundation Trust for the storage of these bodies, when required.	**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 mortuary staff do not manually challenge the body store alarms and the call out procedure on a regular basis. This does not provide assurance that the call out procedure will work as expected when temperatures deviate from the expected range.	**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 at the establishment are suffering from obvious signs of wear and tear making it difficult to adequately clean or decontaminate this area, posing a potential health and safety risk to mortuary staff and visitors for example: • the body hoists have large areas of rust; • the base of the rack in the PM examination room is rusty; and • the bin legs and feet in the PM examination room are rusty.	**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.	C1b	The adult consent seeking SOP states that medical records are to be kept for 25 years. The DI is advised to check the Trust record retention policy to ensure this timeframe is accurate. The flow chart in the adult consent seeking SOP refers to next of kin (NOK). The DI is advised to review the SOP and remove the reference to NOK and replace with person highest in the hierarchy of qualifying relationship. The DI is advised on the next review of the adult consent seeking SOP to refer to the use of a translator SOP.
2.	C1e	The DI is advised when seeking consent for adult PM examination to fully explain the options for research to ensure informed consent is obtained if this option is chosen by the family.
3.	C1g	The DI is advised to request an updated perinatal/paediatric consent form from the Stillborn and Neonatal Death Charity (SANDs).
4.	C2a	Two members of staff are currently booked onto forthcoming external consent training sessions. The DI is advised to ensure that at least one staff member that seeks adult consent for PM examination attends a suitable consent training session.
5.	GQ1e	The DI is advised to ensure staff are registered with the quality management system to increase the robustness of the current system of recording that staff have read and understood the latest version of documents.
6.	T1c	The DI may wish to strengthen the procedure for viewings by introducing a form to be completed by relatives when they attend. This can include relevant information to check the identification on the deceased before the viewing takes place. This may help to mitigate the risk of misidentification and relatives viewing a wrong body.
7.	T1d	The DI is advised to increase the robustness of the same/similar name process by highlighting in the electronic register variations of the same names.
8.	PFE2f	The DI is advised to formalise and record the weekly check of the temperatures of the fridges and freezers and to conduct a trend analysis of the temperatures as a preventative action to a potential failure of the fridge and freezer units.

Background

East Surrey Hospital (ESH) 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.

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

Since the previous inspection, the histopathology laboratory has been incorporated into Berkshire and Surrey pathology which now comprises of St Peters Hospital, East Surrey Hospital, Royal Berkshire Hospital and Frimley Park Hospital.

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 servicing of equipment, 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 and viewing room.

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 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. One discrepancy found that slides have not been returned from another establishment.

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, mortuary manager, portering staff, maternity staff, and adult consent seeker.

Report sent to DI for factual accuracy: 29 November 2022

Report returned from DI: 20 December 2022

Final report issued: 6 January 2023

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 March 2024

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.