

**Site Inspection Report for
Southend University Hospital
Licence number: 11068**

Licensed for

The making of a post mortem examination,

The removal from the body of a deceased person (otherwise than in the course of carrying out an anatomical examination or making a post mortem) of relevant material, 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.

1 December 2009

Introduction

1. The Human Tissue Authority (HTA) was set up to regulate the removal, storage, use and disposal of human bodies, organs and tissue for a number of Scheduled Purposes such as research, transplantation, and education and training. The requirements of the HTA are set out in the Human Tissue Act 2004 (HT Act) and the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006. There are supplementary requirements for those establishments storing tissue for transplantation and they are summarised in HTA Directions 001/2006.
2. As part of the regulatory framework, the HTA licenses establishments and undertakes inspections to assess compliance with expected standards.
3. Under the HT Act, the HTA has a statutory responsibility to make judgements about the suitability of the Designated Individual, Licence Holder, premises and practices in relation to the licensed activities. These responsibilities are set out in Schedule 3 to the HT Act, which is the framework for the HTA's approach to licensing and inspection.
4. The HTA must satisfy itself that the Designated Individual (DI) is a suitable person to supervise the activity to be authorised by the licence and that they will undertake the following duties:
 - secure that other persons to whom the licence applies are suitable persons to participate in the licensed activities;
 - secure that suitable practices are used in the course of carrying on the activity; and
 - secure that the conditions of the licence are complied with.
5. The HTA must satisfy itself that the applicant for the licence is a suitable person/entity to be the holder of the licence.
6. The HTA must satisfy itself that the premises are suitable for the activity to be authorised by the licence.
7. To fulfill its statutory responsibilities, the HTA must be able to assess whether an establishment is suitable to carry out one or more of the activities regulated by the HTA. Suitability is assessed through a process of inspection. Inspections can be routine or risk based, announced or unannounced.

Inspection Process

8. HTA defines inspection as a process encompassing desk-based review, on-site assessment and analysis of relevant written, numerical, verbal and visual information to evaluate the establishment's compliance with expected standards. Desk-based reviews, described as phase one inspections, focus on the evaluation of the compliance report submitted by the Licence Applicant and Designated Individual, as well as any additional information provided by the establishment at the request of the HTA. On-site assessments, described as phase two inspections, focus on a review of the establishment's operational policies and procedures, inspection of its premises and scrutiny of its practices. Where the inspection process identifies that a standard is

not being met, additional conditions may be placed on an establishment's licence to ensure that appropriate action is taken to address the non-compliance/s.

9. Both desk-based review and on-site assessments may lead to advice and guidance for improving practice in one or more areas.

Judgements

10. To enable the HTA to make effective judgements about the suitability of the DI and the Licence Holder, the suitability of the premises and the suitability of the practices taking place on the premises under the supervision of the DI, the HTA standards were developed under four high-level headings:

- Consent
- Governance and Quality
- Premises, Facilities and Equipment
- Disposal

11. The evidence gathering during inspection focuses on these standards, with particular emphasis on any areas identified as requiring special attention in phase one of the inspection, as detailed above.

12. Throughout the inspection process, standards are assessed using the same four-point numerical scale used by the DI in the completion of the initial compliance report.

Numerical scale	Interpretation
1	Standard not met
2	Standard partially met
3	Standard almost met
4	Standard fully met or exceeded

13. The information gathered throughout the inspection process informs the HTA's licensing decisions within the regulatory framework. Where the HTA is not presented with evidence that the establishment meets the requirements of a standard/s, it works on the premise that a lack of evidence indicates non-compliance. There are varying degrees of non-compliance. The action an establishment will be required to make following the identification of a non-compliance is based on the HTA's assessment of risk to patient safety and/or tissue integrity and/or a breach of the HT Act or associated Directions.

The Inspection Report

14. The inspection report represents the findings from the evidence supplied during phase one and phase two of the inspection process, that is from the initial compliance report any additional documentation provided prior to the site-visit and the evidence obtained through interview and observation during the site-visit. Future inspections may identify other areas of non-compliance if new evidence is obtained. Where full compliance with a standard has been established, this is noted. Where standards have been found to be non or partially compliant, details are included of the evidence for this finding.

15. Once the factual accuracy of the report has been agreed with the establishment, it

may be published on the HTA website.

Inspection Report for Southend University Hospital

16. Southend University Hospital carries out around 650 post-mortem (PM) examinations each year. Almost all PM examinations are undertaken on behalf of the HM Coroner for Essex, Number 2 District [REDACTED]. The hospital carried out less than ten consented adult PM examinations last year. The hospital does not undertake high risk PM examinations and paediatric or perinatal PM examinations. However, consent for paediatric and perinatal PM examinations is taken at Southend University hospital prior to bodies being sent to the Royal London Hospital where the PM examinations take place.
17. PM examinations are carried out by four pathologists who are based at the hospital. An independent pathologist, [REDACTED], attends the mortuary and undertakes PM examinations as required. The mortuary has two Anatomical Pathology Technologists (APTs), one of whom is the mortuary supervisor, and one trainee APT.
18. The on-site inspection of Southend University Hospital was carried out on 1 December 2009.
19. The inspection team comprised:
 - [REDACTED], Regulation Manager - Lead Inspector
 - [REDACTED], Regulation Manager - Support Inspector
20. The timetable for the site visit was developed in consideration of the results of the phase one inspection process. Prior to the visit, the establishment was asked to provide a range of documentation, including policies and standard operating procedures (SOPs) which cover activities taking place under the licence, for review during the inspection.
21. As part of the inspection process, interviews were held with the DI (Consultant Histopathologist), the Associate Director for Service Reliability and Safety who represented the corporate licence holder contact, a Consultant Histopathologist, the Mortuary Supervisor, the senior APT, the Quality Manager, a Bereavement Support Midwife and a Coroner's Officer.
22. During the inspection, the labelling of two bodies in storage was checked to ensure it matched details held in the mortuary register. An audit trail was carried out of the documentation relating to two bodies from which tissues were removed during PM examinations. An audit trail was also carried out of the documentation relating to tissue samples removed by an independent pathologist during PM examinations at Medway Hospital and brought to Southend University Hospital for processing. The findings from the audit trail can be found under standard GQ6.

Compliance with standards, Codes of Practice and Directions

Consent

Standard	Assessment	Score
<p>C1 Consent is obtained in accordance with the requirements of the HT Act 2004 and as set out in the Code of Practice.</p>	<p>This standard is partially met.</p> <p>Consent is taken by a Consultant or Bereavement Support Midwife, as appropriate (see advice and guidance 1, section 32).</p> <p>The consent form is based on the NHS consent form which states that blocks and slides will be retained as part of the medical record. A condition is proposed (see proposed condition 1, section 31; see also advice and guidance 2, section 32).</p> <p>Consent for paediatric PM examinations is taken by a Bereavement Support Midwife using the consent form provided by Royal London Hospital.</p> <p>The mortuary is provided with consent documentation when tissues are removed for research.</p> <p>The Coroner's Officer has taken on the role of the 'nominated person' and an effective system of communication is in place between the hospital and the coroner. The system helps to ensure that tissues are not stored without consent after the Coroner's authority ends.</p>	2
<p>C2 Information about the consent process is provided and in a variety of formats.</p>	<p>This standard is almost met.</p> <p>Patient advocates and interpreters are available if required. See advice and guidance 3, section 32.</p>	3
<p>C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.</p>	<p>This standard is almost met.</p> <p>All new medical staff attend consent training as part of their induction. Core members of staff have recently undergone refresher consent training and records of attendance are kept (see advice and guidance 4, section 32).</p>	3

Governance and Quality

Standard	Assessment	Score
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<p>GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.</p>	<p>This standard is partially met.</p> <p>Pathology departmental meetings are held regularly and mortuary issues are included in the agenda.</p> <p>There are documented procedures for a range of activities carried out in the mortuary and the histopathology laboratories including receipt and release of bodies, PM examination, removal and tracking of tissues and disposal of tissues.</p> <p>Advice and guidance is offered against this standard (see advice and guidance 5, section 32).</p> <p>The hospital does not have an updated SOP which details the consent procedure for taking consent for hospital, perinatal and paediatric PM examinations. A condition is proposed against this standard (see proposed condition 2, section 31).</p> <p>Porters and site managers deliver bodies and arrange out of hours viewings. The procedures to be followed are included in an SOP (see advice and guidance 6, section 32). The hospital is planning to introduce a system where a member of the Bereavement Service attends all viewings which take place out of hours.</p> <p>The hospital pathology laboratory occasionally receives tissues from an external pathologist for processing into blocks and slides. However, there is no agreement in place between the pathologist and the establishment (see advice and guidance 7, section 32).</p>	<p>2</p>
<p>GQ2 There is a documented system of quality management and audit.</p>	<p>This standard is partially met.</p> <p>The hospital uses the Q-pulse system for document control, revisions and approval. Procedures are reviewed and updated every two years or whenever a procedure is changed.</p> <p>The mortuary does not have a comprehensive schedule of audits. Audits of records are not undertaken. Conditions are proposed against this standard and against standard GQ4 (see proposed condition 3 and condition 4, section 31).</p>	<p>2</p>

<p>GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.</p>	<p>This standard is almost met.</p> <p>The hospital provides health and safety training and induction training for new staff. Staff have regular appraisals. The hospital portering services department provides training to porters on mortuary procedures which cover out of hours delivery and release of bodies and viewings (see advice and guidance 8, section 32).</p>	<p>3</p>
<p>GQ4 There is a systematic and planned approach to the management of records.</p>	<p>This standard is partially met.</p> <p>Details of bodies received and PM examinations including tissues retained are kept in several records. Mortuary records include the mortuary register, a 'mini' mortuary register and Wintegrate which is a computer database used to record tissues removed for histology. Mortuary staff correct errors in paper records using correction fluid or by writing over the original entry. Advice and guidance is offered against this standard (see advice and guidance 9, section 32).</p> <p>Organs and tissue blocks taken during PM examination are recorded on the histology form. The pathology laboratory uses Winpath to track receipt and processing of tissues. The laboratory does not record the number of slides produced from tissue blocks, though the HTA was assured that records are kept if the number of slides exceeded the number of blocks (see advice and guidance 10 in section 32).</p> <p>Details of tissues brought in by external pathologists are not recorded in Winpath, which is the main pathology sample management system (see advice and guidance 11 in section 32).</p> <p>The mortuary documents the removal of tissues by tissue retrieval teams and the transfer of tissues to other establishments. Records are also kept of organs which are removed and sent to tissue banks or sent away for specialist examination (see advice and guidance 12 in section 32).</p> <p>Records relating to PM examinations carried out in the hospital are not audited. A condition is proposed (see proposed condition 4, section 31; see also compliance</p>	<p>2</p>

	under standard GQ 2).	
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.	This standard is not applicable. Mortuary staff are not involved in tissue retrieval for human application.	N/A
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	This standard is almost met. An audit trail demonstrated that there are systems in place to ensure traceability. The labelling of two bodies stored in the mortuary was checked against the mortuary register. No anomalies were found (see advice and guidance 13 in section 32). An audit trail was carried out of the documentation, computer records and blocks and slides relating to two cases where organs and/or tissues were removed during PM examination. In one case, the blocks and slides were traced and continued retention was in accordance with consent. In the second case, no consent had been given for the tissues to be kept but there were no records to confirm that the tissues had been disposed of. The family has asked for the blocks and slides to be returned with the body and since they were not stored in the laboratory, the staff concluded that they had returned to the body (see advice and guidance 14 in section 32). An audit trail of tissues relating to two PM examinations conducted at Medway Hospital was also carried out. The establishment recorded the name of the deceased and the number of blocks and slides released to the pathologist. The establishment did not record details of the tissues received from the pathologist (see advice and guidance 11, section 32).	3
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.	This standard is almost met. Adverse events are recorded on the Datix system and investigated. However it was not clear if all incidents which impact on bodies and tissues are formally reported and investigated (see advice and guidance 15, section 32).	3
GQ8 Risk assessments of the establishment's practices and	This standard is almost met. There is an established system of risk	3

processes are completed regularly and are recorded and monitored appropriately.	assessments with a focus on the health and safety of staff. Assessments of the risk to bodies held in the mortuary are not carried out (see advice and guidance 16 in section 32).	
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Premises, Facilities and Equipment

Standard	Assessment	Score
PFE1 The premises are fit for purpose.	This standard is fully met. The premises are clean and well maintained. There is sufficient space for all activities to be carried out efficiently.	4
PFE2 Environmental controls are in place to avoid potential contamination.	This standard is fully met. There is a regular cleaning schedule. Staff are provided with appropriate PPE. Clean and dirty areas are clearly demarcated.	4
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.	This standard is fully met. The mortuary has 91 storage spaces for bodies, which is sufficient for the level of post-mortem activity. All the fridges are linked to a central alarm system. Fridge temperatures are checked daily. Blocks and slides are stored securely on site. There is sufficient space for storage of consumables.	4
PFE4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to its destination.	This standard is fully met. The coroner is responsible for SLAs which cover transport of bodies and tissues.	4
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.	This standard is fully met. Fridges and freezers are regularly maintained and records are kept for all equipment.	4

Disposal

Standard	Assessment	Score
D1 There is a clear and sensitive	This standard is fully met.	4

policy for disposing of human organs and tissue.	The hospital has a disposal policy. Tissues from the deceased are packaged separately and disposed of in accordance with the HTA's code of practice on disposal.	
D2 The reasons for disposal and the methods used are carefully documented.	This standard is fully met. The coroner's officer sends the completed family wishes form to the hospital. The establishment is informed if tissues are to be returned to the body before it is released for burial or cremation. The date of disposal is recorded in paper records.	4

Conclusions

23. During the inspection process, the HTA made judgements about the suitability of the Designated Individual, the Licence Holder, the premises and the practices taking place on the premises under the supervision of the Designated Individual.

Suitability of DI and LH

24. [REDACTED] is a Consultant Histopathologist and is suitable to be the Designated Individual. Southend University NHS Foundation Trust is the Corporate Licence Holder. Following the inspection, the DI informed the HTA that the corporate licence holder contact has been changed. The new contact is [REDACTED] who is the Associate Director for Service Reliability.

Suitability of the Premises

25. Overall, the premises and facilities are suitable for the licensed activities taking place and provide a safe working environment for staff.

Suitability of Practices

26. The inspection team is satisfied that overall, the practices which take place at the establishment are generally suitable and comply with the HT Act. The HTA has concerns regarding the consent SOP, the consent form used by the establishment and the lack of a comprehensive system of audits. These concerns have been addressed by the additional conditions proposed in this report (see section 31). The DI is also advised to consider the advice and guidance on individual standards given in this report (see section 32) over the forthcoming months.

Summary comment

29. The HTA is satisfied that the establishment is suitable to be licensed for the purposes that it has set out.

Conditions (requirements) on the licence at the time of the phase one inspection.

30. There were no conditions on the licence at the time of the HTA phase two inspection.

Conditions (requirements) related to areas of non-compliance identified during the inspection process

31. The regulatory reference is noted so the DI can refer back to relevant standards in the Human Tissue Act 2004, the Compliance Report and Directions or Codes of Practice.

No	Regulatory reference	Conditions (including reasons for conditions)
1	C1	<p>Condition By 1 July 2010, the DI shall review and update the consent form used by the establishment to obtain consent for PM examinations and the associated patient information, in order to ensure that they are compliant with the Human Tissue Act 2004 and the HTA code of Practice on Consent (code 1).</p> <p>The DI should notify the Regulation Directorate in writing when the condition has been met, setting out details of compliance. This information should be sent to licensing.enquiries@hta.gov.uk or the HTA office marked 'Compliance'.</p> <p>Reason The current consent form and literature on PM examinations state that blocks and slides will be retained as part of the medical record, and may be used for medical training and audit. This means that blocks and slides are potentially being retained and used for medical training and audit, without appropriate consent under the HT Act.</p>
2	GQ1	<p>Condition By 1 July 2010, the DI shall put in place a standard operating procedure (SOP) which details the process for seeking consent, and documents the information which should be provided to families by members of staff who seek consent. The consent procedure should cover taking of consent for adult PM examinations and perinatal and paediatric PM examinations and should be in accordance with the Human Tissue Act 2004 and the HTA code of Practice on Consent (code 1).</p> <p>The DI should notify the Regulation Directorate in writing when the condition has been met, setting out details of compliance. This information should be sent to licensing.enquiries@hta.gov.uk or the HTA office marked 'Compliance'.</p> <p>Reason The establishment does not have an updated SOP which details the process for seeking consent and providing information to families. The formal documentation of the consent procedure will help the DI to ensure that consent for hospital PM examinations is taken in accordance with the requirements of the Human Tissue Act 2004 and the HTA code of Practice on Consent (code 1).</p>

3	GQ2	<p>Condition</p> <p>By 1 July 2010, the DI shall implement regular audits of procedures taking place in the mortuary such as receipt and release of bodies and PM examinations. The findings from the audits and all corrective actions taken by the establishment should be documented.</p> <p>The DI should notify the Regulation Directorate in writing when the condition has been met, setting out details of compliance. This information should be sent to licensing.enquiries@hta.gov.uk or the HTA office marked 'Compliance'.</p> <p>Reason</p> <p>The establishment does not undertake regular audits of procedures which take place in the mortuary. Regular audits of procedures will help the DI to ensure that staff in the mortuary follow SOPs and that porters who deliver bodies and arrange viewings out of hours follow mortuary procedures.</p>
4	GQ4	<p>By 1 July 2010, the DI shall implement regular audits of records relating to receipt and release of bodies, PM examinations, tissues removed during PM examinations and blocks and slides. Paper records and computer records should be checked for accuracy and completeness. The findings from the audits and all corrective actions taken by the establishment should be documented.</p> <p>The DI should notify the Regulation Directorate in writing when the condition has been met, setting out details of compliance. This information should be sent to licensing.enquiries@hta.gov.uk or the HTA office marked 'Compliance'.</p> <p>Reason</p> <p>The establishment does not audit records relating to PM examinations taking place in the hospital. Regular audits of records will help the DI to ensure that staff keep accurate records. During the inspection several shortfalls relating to record keeping were observed. Regular audits of records will help to ensure that pathologists and mortuary staff keep accurate records and that there is full traceability of bodies, organs and tissues.</p>

Advice and guidance

32. Below are matters which the HTA advises the DI to consider.

No	Regulatory reference	Advice
1	C1	Some establishments have found it useful for a member of staff from bereavement services who is trained in consent taking, to attend, when consent is sought for adult and paediatric PM examinations. This practice will help to support clinicians who take consent and will enable the DI to assure himself that appropriate and valid consent is in place for all consented PM examinations.
2	C1	The DI is advised to consider updating the hospital consent form to include a declaration by the person who takes consent which states that they have been trained to take consent. This declaration will help the DI to assure himself that all staff who take consent for hospital PM examinations have been trained to take consent.
3	C2	The DI is advised to consider providing consent information in other formats for example in electronic format or in other languages appropriate to the patient population. These steps will help to ensure that consent information is easily available and can be read and understood by most patients who use the hospital.
4	C3	The DI is advised to consider placing the consent training module on the intranet so that it can be accessed by staff who take consent. This will make it easier for the DI to provide information to staff on any changes to consent procedures and will help staff to be aware of the most recent guidance on consent. The DI is also advised to ensure that as part of their training, all staff, including midwives and bereavement services staff, who may be required to take consent, observe a PM examination so that they are able to respond fully to any questions asked by the person giving consent.
5	GQ1	The DI is advised to review the SOP for the PM procedure in order to reflect the procedures which are followed when more than one PM examination takes place in the mortuary at the same time. The steps followed by staff help to prevent mix-up of tissues when more than one PM examination takes place.
6	GQ1	The DI is advised to consider making a checklist available for porters and site managers to use when they deliver bodies and arrange viewings out of hours. The use of a checklist will help the DI to assure himself that porters and site managers follow mortuary procedures when they

		perform these duties.
7	GQ1	The DI is advised to put in place an SLA with external pathologists who bring tissues to the establishment for processing into blocks and slides. The SLA should cover the responsibilities of the pathologists and the establishment with regards to the receipt, processing, issuing, disposal and traceability of blocks and slides. Formalising these responsibilities will help the DI to ensure traceability of all material processed on behalf of external pathologists.
8	GQ3	The DI is advised to consider using senior mortuary staff to train porters and site managers in procedures such as delivering and releasing bodies and preparing bodies for viewing. This will help the DI to ensure that all porters are trained to follow mortuary procedures in accordance with SOPs used by the mortuary.
9	GQ4	The DI is advised to ensure that all corrections to incorrect written records are made by using a single line to cancel the incorrect record and writing the correct record next to it. The person correcting the record should sign and date the correction. Staff currently correct records using correction fluid and the member of staff who corrected the record cannot be identified.
10	GQ4	The DI is advised to document the number of slides produced from blocks processed by the laboratory. This can be included in the Winpath laboratory management system. The DI is also advised to consider including disposal records in the Winpath system. The use of one recording system will help to reduce potential errors which can arise when copying information into several records and help the DI to ensure traceability of tissues, blocks and slides.
11	GQ4	The DI is advised to consider recording details of the number and types of tissues submitted by external pathologists. The DI is also advised to document the number of blocks and slides produced from these tissues and released to external pathologists. It may be helpful to include this information in the Winpath system so that these blocks and slides can be tracked together with other blocks and slides processed in the laboratory. This practice will help to centralise all information relating to tissues, blocks and slides and will help the DI to ensure traceability.
12	GQ4	The DI is advised to set up a system to track the dispatch, return and disposal, as appropriate, of organs which are removed during PM examinations and sent away for specialist examination. The establishment has to ensure that organs sent away for specialist examination are

		traceable and returned to the body or disposed of in accordance with the wishes of the next of kin.
13	GQ6	The DI is advised to consider setting up a procedure for mortuary staff to check details of bodies delivered by porters out of hours. Staff should check records in the mortuary register and labelling of bodies. The mortuary does not have a system to check labelling of bodies delivered by porters until they are being prepared for a PM examination or just before they are to be released. A checking system will help to ensure that porters follow mortuary procedures when delivering bodies and recording information in the mortuary register. This system will ensure that staff identify any errors in labelling of bodies at an early stage and correct these errors in a timely manner.
14	GQ6	The DI is advised to implement monthly audits of blocks and slides processed in the laboratory to monitor the status of tissues so that they are not retained without consent after the coroner's authority ends. The blocks and slides must be disposed of in accordance with the wishes of the next of kin.
15	GQ7	The DI is advised to increase staff awareness of the types of incidents which would be regarded as adverse incidents for example, equipment failure, security incidents, release of a body without all tissue being returned in accordance with consent. Increasing staff awareness of the types of adverse incidents which could affected bodies and tissues will help to ensure that all such incidents are reported and investigated.
16	GQ8	The DI is advised to risk assess the risk to bodies and tissues for example, the risk to bodies brought in by porters, the risk that a body could be released without all tissue being returned in accordance with consent, the risk of the wrong body being released, the risk to the integrity of bodies caused by equipment failure. Once risk assessments have been completed, procedures should be reviewed in order to mitigate risks which have been identified, thereby reducing risks to bodies and tissues.

Report sent to DI for factual accuracy: 4 Jan 2010

Report returned from DI: 13 January 2010

Final report issued: 27 January 2010

