Site visit inspection report on performance against HTA quality standards
Worthing Hospital
HTA licensing number 12286

Licensed under the Human Tissue Act 2004 for the

- **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; and**
- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

20 and 21 September 2011

Executive Summary

A site visit inspection of Worthing hospital (the establishment) was carried out by the HTA on 20 and 21 September 2011.

The establishment was found to meet the majority of the HTA standards across the four areas of: consent; governance and quality; premises, facilities and equipment; and disposal. Some shortfalls were found, particularly in relation to the consent standards. Any particular examples of strengths or good practice are included in the concluding comments section of the report.

The HTA found the Designated Individual, the Licence Holder, the premises and the practices to be suitable in accordance with the requirements of the legislation.

All reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

Worthing Hospital (the hub) has a mortuary where both coronial and hospital (consented) post mortem (PM) examinations are carried out, including known high risk cases such as HIV and TB. Paediatric PM examinations are not performed there routinely and are transferred to other licensed premises, apart from on rare occasions when forensic paediatric PM examinations may take place.

The establishment has satellite premises at Southlands Hospital. PM examinations are not conducted there 'Storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose' is the only licensable activity taking place at the satellite premises, which house the archive store of blocks and slides and were visited as part of the inspection.

This was the second site-visit inspection of the establishment and was a routine inspection to assess whether the establishment is continuing to meet the HTA's standards. The timetable for the site visit was developed in consideration of the establishment's recent self assessment compliance information and audit of stored material, as well as pre-inspection discussions with the DI. During the visit, a visual inspection of the premises, review of documentation and interviews with establishment staff were undertaken.

An audit of two bodies in the body store was undertaken. Identification details contained on body tags were checked against details in the mortuary register and on the mortuary fridge doors; no anomalies were found.

Details of five post mortem examinations were taken representing a mix of consented (hospital) PM examinations and coronial PM examinations. Tissue had been taken in all cases. Blocks, slides and, where applicable, wet tissue were located as detailed in the establishment's electronic records and no anomalies were found. Included in the audit were two cases where blocks and slides are being stored in the archive at the satellite premises.

The establishment has recently changed practice and is recording the mortuary serial number along with the histopathology laboratory number on pots containing wet tissue. However, these numbers are in the same format with no indicator to differentiate between them; advice on making the numbers easier to distinguish has been given below (see advice section).

For the three cases where tissue is stored at the hub site, hospital consent forms or coronial family's wishes forms were reviewed and no anomalies were found.

Included in the visual inspection of the premises was an area of the Accident and Emergency Department at the hub site where tissue may be removed from the bodies of the deceased for the purpose of determining the cause death. A suitable area for the removal to take place has been identified and the DI has appointed a person designated who oversees tissue removal. The person designated helps the DI to maintain oversight of the licensable activity.

Meeting the HTA's licensing standards

The HTA developed its licensing standards with input from its stakeholders, in order to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA expects licensed establishments to meet these standards.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a licensing standard is not met, the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor' (see Appendix 3: Classification of the level of shortfall).

Unless otherwise advised, the establishment is required to inform the HTA within 14 days of the receipt of the final report of the corrective and preventative actions that will be taken to ensure that the improvements are addressed. A template for this purpose is provided as a separate Word document.

HTA standards not met

Consent

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 Code of Practice.	The establishment's consent training and supporting family information leaflets make it clear that tissue taken during PM examination can only be retained for use in scheduled purposes with appropriate and valid consent. However, the establishment uses the out of date Department of Health (DH) consent from which states that tissue taken during PM examination will automatically be retained in the deceased's medical record. The wording on the consent form should reflect the requirement of the Human Tissue Act 2004 (HT Act) that tissue may only be retained for use in scheduled purposes with appropriate and valid consent. *The establishment took action to address this shortfall as soon as it was identified. Suitable changes to the Hospital Post Mortem Consent form have been made to clarify that tissue will only be retained for future use with appropriate consent. Evidence of this change was supplied to the HTA on the 18 November 2011 and the revised document has been appended to the establishment's consent policy. Therefore, the shortfall was fully addressed prior to the issue of the final report.*	**Shortfall addressed prior to issue of final report**

Advice

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

No.	Standard	Advice
1.	C1	The establishment's consent policy and SOP refer to out of date DH information on PM examination to support the consent process. This information however is not being used by the establishment as updated information leaflets are now in use. In addition, although the hierarchy of qualifying relationships is detailed within the consent policy, it fails to include the two people ranked highest in the hierarchy; namely the deceased (prior to death) or a nominated representative. The DI is advised to update the consent policy to reflect the use of NHS direct information to support the consent seeking process. In addition the DI is advised to amend the consent policy and SOP to fully reflect the appropriate people who can give consent.
2.	GQ6	The establishment has recently updated its traceability systems to include the serial number when transferring tissue to the histopathology laboratory for processing. This number however is of the same format (incremental number followed by a year suffix) as the histopathology laboratory identification number, and there is the risk of staff referring to the wrong number when they are accessing tissue samples. The DI is advised to investigate the use of a prefix or other means to differentiate between these two numbers being used for tissue traceability. In addition the DI is advised to ensure that the serial number is captured within the histopathology laboratory's electronic records so that the audit trail from PM suite to histopathology laboratory is maintained and is searchable.
3.	GQ8	The establishment's risk assessments mainly focus on the health and safety risks involved in the various activities taking place. Recently the establishment has expanded risk assessments for some activities to include the risks to the tissues and bodies themselves, for example the risk of loss of traceability. The DI is advised to continue with the expansion of the scope of risk assessments to include the risks to the tissues and bodies themselves for all activities taking place under the licence. This could be done in tandem with the document reviews taking place as documented procedures are moved to the electronic document control system (Q-Pulse).
4.	PFE1	The establishment has had issues with wear in the PM suite floor and non-functioning height adjustable tables. During the inspection it was noted that there is remedial work planned for later in September 2011 to address these issues. Currently the floor in the body store area is not worn to the same extent; however, since the floor covering is the same as in the PM suite, the DI is advised to keep the condition of the floor under review to ensure early detection of any deterioration in the surface. Additionally the DI is advised to risk asses the area in the former theatres at the satellite premises, which is used for the storage of blocks and slides. Although the blocks and slides were traceable and stored in appropriate conditions, the lack of space presents a risk to the safety of material while staff are searching for particular samples.
5.	D1	Disposal of post mortem tissue is tracked well in the histopathology laboratory's electronic records. However, the SOP for disposal does not specify that tissue from the deceased must be disposed of separately from other miscellaneous

		laboratory waste. The DI is advised to amend the disposal SOP to fully reflect the requirements of the code of practice on Disposal.

Concluding comments

Areas of good practice were observed during the inspection, some examples of which have been included below.

The establishment hired the Trust's solicitors to deliver a PowerPoint training session to key staff involved in the seeking of consent. The training covered not only the consent process, but information about the HT Act and its implications. The training was of a high standard and has left the establishment with a valuable resource which can be used in conjunction with trained staff to train new staff as they join.

A series of comprehensive audits, both horizontal and vertical, was reviewed during the inspection. The establishment has well established systems of audit with pre-determined audit plans extending well into the future.

Report sent to DI for factual accuracy: 13 October 2011

Report returned from DI: 26 October 2011

Final report issued: 23 November 2011

Appendix 1: HTA inspection process

The Human Tissue Authority regulates the removal, storage, and use of human bodies, body parts, organs and tissue for activities such as research, transplantation, and education and training. The legal requirements for establishments which carry out such activities are set out in the Human Tissue Act 2004 and The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

We license establishments in England, Wales and Northern Ireland that carry out these activities, and inspect them to make sure legal requirements are met.

Inspections

We use the term 'inspection' to describe when we:

- visit an establishment to meet with staff, view premises and facilities, and review policies and procedures (a site-visit inspection); or
- assess written information we have requested from an establishment (a desk-based assessment / inspection).

We carry out inspections to assess if the Designated Individual (DI) is suitable to supervise the activity covered by the licence, as it is their responsibility to ensure that:

- other staff working under the licence are suitable;
- suitable practices are used when carrying out the activity; and
- the conditions of the licence are met.

We also need to be satisfied that the licence applicant or holder, the establishment's premises, and the practices relating to licensed activities, are suitable.

To help us reach our decisions, we have developed standards under four headings: Consent; Governance and Quality; Premises, Facilities and Equipment; and Disposal.

After every site visit inspection, we write a report documenting our findings. Where we find a particular standard is not fully met, we will describe the level of the shortfall as 'Critical', 'Major' or 'Minor'. In most cases, it will be the responsibility of the DI to seek the HTA's agreement on how they will address the identified shortfalls. More information about the classification of shortfalls can be found in Appendix 3.

The majority of our site-visit inspections are announced. If we have concerns about an establishment, we can also undertake an unannounced site visit inspection.

You can find reports for site visit inspections which took place after 1 November 2010 on our website.

Appendix 2: HTA standards

Standards which are not applicable to this establishment have been highlighted.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. • There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination). • There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. • Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). • Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. • Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent. • Refresher training is available (e.g. annually). • Attendance at consent training is documented. • If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
    - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
    - record keeping
    - receipt and release of bodies, which reflect out of hours arrangements
    - lone working in the mortuary
    - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
    - ensuring that tissue is handled in line with documented wishes of the relatives
    - disposal of tissue (including blocks and slides)

  (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.

- There is a documented training programme for new mortuary staff (e.g. competency checklist).

GQ4 There is a systematic and planned approach to the management of records

- There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.
- There are documented SOPs for record management.

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded:
    - material sent for analysis on or off-site, including confirmation of arrival
    - receipt upon return to the laboratory or mortuary
    - number of blocks and slides made
    - repatriation with a body
    - return for burial or cremation
    - disposal or retention for future use.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.
- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- 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.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
- There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).

  (Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
  - fridges / Freezers
  - hydraulic trolleys
  - post mortem tables
  - hoists
  - saws (manual and/or oscillating)
  - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- There are documented procedures for disposal of human tissue, including blocks and slides.

D2 The reason for disposal and the methods used are carefully documented

- There are systems in place that ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal records include the date, method and reason for disposal.
- Tissue is disposed of in a timely fashion.

  (Note: this means that tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner's or police authority ends or consented post-mortem examination is complete.)

Appendix 3: 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 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 Human Tissue Act 2004 (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:

(1) A notice of proposal being issued to revoke the licence

(2) 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.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) 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 CoPs, 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.

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 or site visit.

Follow up actions

A template corrective and preventative action plan is available as a separate Word document. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

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

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