Site visit inspection report on compliance with HTA minimum standards

Southampton General Hospital

HTA licensing number 12214

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**

4 February 2014

Summary of inspection findings

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.

Although the HTA found that Southampton General Hospital (the establishment) had met the majority of the HTA standards, one minor shortfall was found in relation to the documented procedure for reporting serious incidents to the HTA. This shortfall was addressed by the establishment to the HTA's satisfaction before the final report was issued.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

Following an agreement between the Home Office and the HTA, this inspection also covered police holdings stored at the establishment.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual (DI) are set out 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.

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. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, 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 given to the DI.

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

Approximately 900 adult, perinatal and paediatric post mortem (PM) examinations are carried out each year in the mortuary at Southampton General Hospital (the establishment). This total figure includes high risk (up to Category 3) and forensic paediatric cases. Most adult PM examinations are performed under the authority of HM Coroner for Hampshire with, typically, only a small number of adult hospital (consented) cases each year. The establishment is a referral centre for perinatal and paediatric PM examination cases. These are mostly consented cases with a small number being performed under coronial authority. Consent forms for paediatric and adult PM examination are adaptations of the HTA's model adult consent form, and hence fully compliant with the Act's consent provisions. The establishment is a referral centre for neuropathology.

The Princess Anne Hospital, located adjacent to the establishment, has a fridge for storage of fetal specimens and neonatal bodies prior to transfer to the histology laboratory or the mortuary respectively, depending on gestational age. The fridge temperature is recorded by staff twice each day. The transfer of neonatal bodies into and out of this fridge is recorded in a dedicated register.

The establishment has been licensed by the HTA since June 2007. Previous routine site visit inspections took place in July 2007 and July 2011. This report describes the third routine site visit inspection in February 2014. The inspectors interviewed staff involved with licensable activities and reviewed documentation. The visual inspection encompassed the mortuary, pathology laboratory and the temporary storage fridge at Princess Anne Hospital. An audit of identifiers and storage locations for two adult bodies in the mortuary found no anomalies. In addition, records relating to a further three bodies which had been subject to a PM examination (one consented and one coronial adult case and one consented paediatric case), where tissues or organs were retained for analysis, were audited. The audit included records from admission of the body to the mortuary through to the wishes of the family and storage of tissue following PM examination. No anomalies were found.

Tissue samples and organs removed during forensic paediatric PM examinations are stored at this establishment for police purposes, for a number of local forces. Under s39 of the Human Tissue Act 2004 ('the Act'), relevant material held for criminal justice purposes is outside of the scope of the Act and is not subject to its licensing requirements for storage.

In response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers (ACPO) audit of tissue held under police authority, that "...police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, with a mechanism for reporting back to the police and the Home Office", this establishment was chosen for a pilot exercise in which police holdings were reviewed by HTA at its site visit inspection. The HTA inspectors were accompanied by observers from the Home Office. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report.

The establishment holds HTA licences under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (licensing numbers 22567 and 22563). Activities taking place under those licenses were not reviewed at this inspection.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	Staff are aware of the requirement to report HTA Reportable Incidents (HTARIs) to the HTA. The establishment's standard operating procedure (SOP) for incident reporting to the HTA has not been updated to include: • the change in terminology for such incidents from 'Serious Untoward Incident (SUI)' to 'HTARI', and the online reporting method for HTARIs, which came into effect from April 2013; • the complete list of HTARI reporting categories. *The establishment submitted an updated HTARI reporting SOP which incorporates the HTA's HTARI guidance document, to address this shortfall, prior to the issue of the final report. The establishment has also provided evidence verifying this updated SOP has been circulated to staff. The HTA has assessed this information as satisfactory to address the shortfall.*	**Minor**

Advice

The HTA advises the DI to consider the following to further improve practices:

No.	Standard	Advice
1.	GQ1	The SOP "Storage, retention and disposal of all post mortem samples" (HTP 100 006), which is in draft form, uses the term 'next of kin' to refer the family of the deceased, including in relation to consent for retention of relevant material for a scheduled purpose. The DI is advised to clarify in this document that storage of relevant material from a deceased person for use for a scheduled purpose requires the consent of: • the person concerned (if they made a decision before they died), or; • their nominated representative, or; • in the absence of either of the above, a person in a qualifying relationship with the deceased when they died, which follows this

		descending order: o spouse or partner (including civil or same sex partner) o parent or child o brother or sister o grandparent or grandchild o niece or nephew o stepfather or stepmother o half-brother or half-sister o friend of long standing This clarification will then bring the SOP in line with the consent policy.
2.	GQ2	Neuropathology samples are audited regularly although, in a recent audit, some samples were overlooked as the auditor was unaware of all locations where samples were stored. The DI is advised that staff performing neuropathology sample audits should be adequately briefed, or provided with a checklist, so they are aware of all locations within the laboratory where specimens to be audited are being stored.
3.	GQ8	The DI is advised to expand the range of mortuary risk assessments to include how potential risks which may lead to a reportable HTARI are being mitigated.

Concluding comments

Many examples of strength were observed. The DI is supported in this role by knowledgeable and enthusiastic Persons Designated (PDs). Mortuary staff are diligent and hard working; outside normal working hours they are on-call to admit bodies from the community and to conduct viewings. Quality management is to a good standard, with detailed SOPs and there is a wide-ranging programme of procedural and documentation audits. Following the previous HTA inspection, the establishment introduced a detailed spreadsheet to record information on PM tissue entering the laboratory for analysis, including the family's wishes for the retention or disposal of such tissue. There is a comprehensive assessment of potential risks associated with eviscerating a body prior to arrival of the pathologist in the mortuary. The mortuary premises are well maintained and to a good standard.

Example of good practice included:

- an 'errors and omissions' checklist, which is completed if a hospital PM examination consent form from within the hospital or from one of the referral centres is not filled in correctly. This checklist is sent to the person who completed the consent form, so they are aware of the issue;
- a comprehensive training presentation on consent, given by a consultant histopathologist to staff at hospitals referring perinatal and paediatric PM examination cases to the establishment;
- a well-structured training programme for new mortuary staff.

Before the inspection report was finalised, the establishment submitted an updated HTARI reporting SOP that incorporated information from the HTA's guidance document on HTARIs. This SOP was assessed by the HTA as satisfactory to meet the shortfall. Consequently there is no longer a need to address this shortfall through a corrective and preventive action plan.

The HTA has given advice to the Designated Individual with respect to further improving governance and quality systems.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 21 February 2014

Report returned from DI: 06 March 2014

Final report issued: 06 March 2014

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

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 and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- 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.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person's

family.

- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

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 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.

   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 or site visit.

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. 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.