Site visit inspection report on compliance with HTA minimum standards

King's College Hospital

HTA licensing number 12377

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.**

16 and 17 July 2013

Summary of inspection findings

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

Although King's College Hospital was found to have met most of the HTA standards, minor shortfalls were found in respect of consent, governance and quality, and disposal standards. In particular, these related to the use of an outdated consent form used for post mortem examinations undertaken at other HTA licensed establishments, the procedure for taking consent for the removal and use of liver biopsies from the deceased, aspects of audit and disposal of post-mortem tissue samples.

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

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 are set down in Paragraph 18 of the Human Tissue Act 2004 (HT Act). 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 licenses 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 and description of inspection activities undertaken

King's College Hospital (the establishment) is licensed to carry out post-mortem (PM) examinations and the removal and storage of PM tissue for use for scheduled purposes under the HT Act. For HTA licensing purposes, King's College Hospital is the 'hub', with a satellite site located at the Valmar Trading Estate, where a quantity of blocks and slides containing tissues from the deceased are stored. King's College Hospital NHS Foundation Trust is the corporate licence holder; the corporate licence holder contact is the Associate Director of Governance and Assurance.

A site visit inspection of King's College Hospital was undertaken on 16 and 17 July 2013. This was the third HTA inspection of the establishment and was scheduled to include a review of improvements made to address shortfalls observed during the previous inspection in July 2012.

The HTA team interviewed the Service Delivery Manager,Tissue Services (the DI), as well as a Consultant Histopathologist, a Consultant Neuropathlogist, the Neuropathology Laboratory Manager, the Mortuary Manager (PD), Bereavement Officers, a Trainee Anatomical Pathology Technologist and a Coroner's Officer. The inspection included a visit to the satellite site where blocks and slides are stored and the Institute of Liver Studies, where liver biopsies

removed from deceased individuals under the authority of the Coroner or with consent from relatives are stored.

Kings College Hospital undertakes around 250 PM examinations each year, the majority of which are undertaken on behalf of the Inner South London Coroner. The mortuary has storage capacity for 66 bodies, including a bariatric storage area and four freezer spaces. There are contingency arrangements in place with funeral directors for additional storage of bodies if required. The main PM room has four tables and is sometimes used to train medical students. High risk PM examinations are undertaken in a separate PM room.

The mortuary is staffed by an experienced Anatomical Pathology Technologist (APT) who is the mortuary manager, two trainee APTs and an adminstrative officer. PM examinations are undertaken by designated histopathologists and neuropathologists based at the hospital. Hospital porters, who have been trained by mortuary staff, transfer bodies from hospital wards to the mortuary. APTs check and record the details of each body in the mortuary register. Very occasionally, bodies are brought in from the community by funeral directors. The coroner's officer faxes the coroner's authorisation for a PM examination to the mortuary and obtains the wishes of the next of kin regarding disposal of any tissues removed during a PM examination.

Tissues removed during PM examinations, other than central nervous system (CNS) tissues, are processed at the Pathology Unit, which is part of a joint venture between King's Path, GSTS Pathology and Serco. CNS tissues removed during PM examinations are processed and stored at the Neuropathology Laboratory at the Department of Clinical Neuropathology. During the inspection it was noted that liver biopsies from the deceased are occasionally removed in the Liver Intensive Care Unit and processed at the Institute of Liver Studies. Although this Department is on the same premises covered by the HTA licence, the HTA was not aware that the licensable activity of removal of tissue from the deceased is taking place in this area. Immediately following the inspection, the establishment notified the HTA formally of these arrangements.

The Histopathology and Neuropathology laboratories track slides issued to pathologists. Once the pathologists have returned the slides, all blocks and slides which are to be disposed of are sent to the mortuary, where arrangements are made for disposal in accordance with the wishes of the next of kin.

The establishment put several corrective and preventative actions in place following the HTA inspection in 2012. Consent procedures were improved so that consent for adult hospital PM examinations is taken by Bereavement Services staff, who have been trained to seek consent. The establishment issued SOPs which cover the management of tissues removed during PM examinations and their disposal. In addition, the mortuary assumed responsibility for ensuring that appropriate consent was in place for long term storage of blocks and slides containing PM tissue following processing at the Histopathology Laboratory at the Pathology Unit. The establishment also provided training on the HT Act and HTA licensing requirements to all staff who work in the Histopathology Laboratory, to ensure they are aware of their responsibilities when handling tissues from the deceased.

A document review was carried out. The documents reviewed included: standard operating procedures (SOPs) relating to PM examinations; policies; paper and computer records of bodies booked into the mortuary, tissues removed during PM examinations and disposal records; temperature monitoring records; equipment maintenance records; incident reports; audit reports; cleaning records; and training records. The inspection did not review records relating to receipt and transportation of tissues for specialist examination.

An audit trail was undertaken of two bodies stored in the mortuary. Details in the mortuary register, storage location and identity tags were checked. There were no discrepancies. Records relating to tissues removed during three Coroner's PM examinations and one hospital PM examination were traced from the mortuary register to the paper and computer records in the Histopathology Laboratory, or the Neuropathology Laboratory, as appropriate. Paper and computer records were reviewed, including: the Coroner's authorisation form; disposal/retention of tissue forms; and, disposal records in the computer database used to track tissue samples and organs removed during PM examinations. There were no discrepancies and tissues were retained in accordance with the wishes of the next of kin. Two completed consent forms for hospital PM examinations were also reviewed.

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
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.	Bereavement midwives use a version of the Department of Health consent form, which predates the HT Act and includes the statement 'Blocks and slides will be kept as part of the medical record'. Although midwives inform parents that their consent is required for blocks and slides to be kept, there is no record of this on the consent form.	**Minor**
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process	Clinical staff remove liver biopsies from the deceased with appropriate consent from the relatives or under the authorisation of the coroner. The establishment does not have a documented procedure which governs this activity and covers taking consent, documenting consent and communicating to the deceased's relatives the options for continued retention of the samples for use for scheduled purposes, or their disposal.	**Minor**
GQ2 There is a documented system of quality management and audit.	Audits relating to mortuary activities and tissue traceability do not fully capture compliance with operational procedures. Audit findings are recorded, but corrective actions are not documented.	**Minor**

Disposal

Standard	Inspection findings	Level of shortfall
D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes.	Liver biopsies are occasionally removed from deceased patients in the Liver Intensive Care Unit.There is no system in place to ensure that these samples are disposed of following their analysis at the Institute of Liver Studies.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1, C2,	Consent for baby and child PM examinations, which take place at another HTA licensed establishment, is usually taken by Bereavement midwives. The establishment intends to start using the forms and guidance provided by the Still Birth and Neonatal Death charity (SANDS). The DI is advised to ensure that these forms are implemented as soon as possible, so that parents are provided with up to date information regarding consent for retention of tissues. The DI is also advised to ensure that the paediatric clinicians in the special care baby unit who take consent for PM examinations are always supported by staff who have been trained to take consent. The DI is further advised to ensure that clinicians who remove tissues such as liver biopsies are made aware of and act upon relatives' wishes in respect of continued retention or disposal of these tissues.
2.	GQ1	The establishment is planning to become part of a multicentre research project, which involves using CNS tissue from deceased organ donors. The DI is advised to inform the HTA and ensure that the relevant SOPs and training are in place before this activity commences. The DI is also advised to identify a person designated under the licence to oversee these arrangments.
3.	GQ2	The DI is advised to provide training to staff who undertake audits and to implement a system whereby staff conduct audits in an area other than their own. This will help to ensure that audits are independent and objective. During a review of three audit reports, it was noted that non conformances are not always noted in the summary section of the reports even though non-conformances are noted in the observations attached to the reports. The DI should consider amending the format of audit reports, to give greater prominence to identified non-conformances. The establishment has implemented a tracking system, using a sample tracking form which accompanies all tissues transferred between the mortuary and the Histopathology Laboratory at the Pathology Unit. The DI is advised to continue to audit the use of this form by staff in the Histopathology Laboratory in order to ensure the accuracy of records.

4.	GQ4	The improvements in working practices which were made following the previous HTA inspection resulted in some duplication of record keeping. The DI is advised to review record keeping in the mortuary and Histopathology Laboratories with a view to identifying gaps, reducing duplication of records and simplifying record keeping relating to tissues removed during PM examinations.
5.	GQ8	As part of a programme of risk assessmsent, the DI is advised to assess the risks to bodies and tissues in the care of the mortuary; for example, the risk of a body being released without all tissue being returned in accordance with the family's wishes, or the risk of the wrong body being released. This will ensure that all practices relating to licensable activities have been risk assessed and the risk of a serious incident occurring is minimised
6.	D1	The DI is advised to update the disposal SOP so that it provides more detailed information about disposal practice. The disposal SOP states that tissues and organs are disposed of in accordance with the wishes of the next of kin, but does not outline how these tissues should be handled, packaged or disposed of.

Concluding comments

The HTA recognises the considerable effort put in by staff to address the shortfalls identified during the previous HTA inspection particularly in relation to obtaining consent for adult PM examinations and management of tissues removed during PM examinations.

The DI, pathologists, Bereavement Services staff, Mortuary Manager, APTs and Administrative Officer based at the mortuary work well together as a team. The Trust's Post Mortem booklet produced by Bereavement Services, provides detailed and appropriate information on PM examinations for relatives and could be distributed more widely, as the booklet covers Coroner's PM examinations as well as hospital PM examinations.

The DI has transferred the management of PM tissues from the Histopathology Laboratory at the Pathology Unit, to the mortuary and has regular meetings with mortuary staff to ensure a consistent approach to managing tissues removed during PM examinations. The mortuary audits all PM examinations undertaken to identify cases where the wishes of the next of kin have not yet been provided to the mortuary, and uses this information to prompt the Coroner's Officers. The Mortuary Manager has set up an effective tracking system to ensure that tissues are retained only in accordance with the wishes of the next of kin. The Neuropathology laboratory, which is independent of the Histopathology Laboratory, has robust systems of traceability.

The HTA has identified a small number of minor shortfalls and has provided advice relating to obtaining consent for retention of blocks and slides following PM examination of babies, improving audits and records management, embedding the process for ensuring that relatives are provided with information on the options for disposal of liver tissue and extending the range of risk assessments relating to licensable activities.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan 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.

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

Report sent to DI for factual accuracy: 8 August 2013

Report returned from DI: 3 September 2013.

Final report issued: 13 September 2013

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: 09 December 2013

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

- 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 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.