Site visit inspection report on compliance with HTA minimum standards

Royal Surrey County Hospital

HTA licensing number 12222

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**

29 November 2012

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 Royal Surrey County Hospital (the establishment) had met the majority of the HTA standards, shortfalls were found in relation to consent and governance and quality standards; in particular: the adult post mortem examination consent form; documented procedures for mortuary activities; the absence of a documented procedure for reporting serious untoward incidents to the HTA; and systems for disposal of blocks and slides from coronial cases where the relatives' wishes are unknown.

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 (DI) are set out in Paragraph 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

The establishment carries out post mortem (PM) examinations on deceased adults, including high risk and forensic cases. Approximately 500 PM examinations are performed each year, the majority of which are under the authority of HM Coroner for Surrey. A small number of adult hospital (consented) PM examinations may also be undertaken. Perinatal and paediatric cases are transferred to another HTA-licensed establishment for PM examination. Tissue removed at PM examination for non-forensic cases is processed into blocks and slides for histopathological analysis at the establishment. Toxicology samples and whole organs are sent to other HTA-licensed establishments for specialist analysis.

The establishment has been licensed by the HTA since July 2007. It received its first routine site visit inspection in January 2009. This report describes the second, routine, site visit inspection of the establishment in November 2012. The inspectors interviewed staff involved with licensable activities, visually inspected the mortuary and histopathology laboratory, and reviewed documentation. An audit of the identifiers and storage locations of three deceased persons revealed no anomalies. Records of the admission, PM examination and release of four other cases were audited. For two cases, which were forensic PM examinations, records showed that PM tissue was sent to another establishment for analysis. For the other two cases, which were non-forensic PM examinations, tissue was processed into blocks and slides at the establishment. No anomalies were found for one of the cases. For the other, the

deceased's name was spelt incorrectly in laboratory records. The Coroner's form (FIN178) also indicated that the family had requested disposal of the tissue when coronial authority ended. (The establishment confirmed on 3 December 2012 that the blocks and slides had been disposed of, in accordance with the family's wishes).

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

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 uses the 2003 Department of Health (DH) 'Consent to a post mortem examination on an adult' form. This form states that PM tissue blocks and slides are retained as part of the deceased's medical record. The HTA considers that blocks and slides stored as part of the medical record are being stored for potential use for a scheduled purpose. The obsolete DH form does not make it clear to the consent giver what blocks and slides may be used for or that they can only be retained with appropriate consent. Appropriate consent is required in accordance with Section 3 of the Human Tissue Act 2004 (the HT Act). *(Refer to advice item 1)*	**Minor**

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	Documented standard operating procedures (SOPs) do not give sufficient detail on mortuary practices and procedures, as described by staff during the inspection. In particular, the Clinical post mortems SOP does not: • state which identifiers will be checked to confirm a deceased person's identity prior to PM examination, and by whom; • detail the PM examination procedure, or; • state how to label PM tissue pots. There is no SOP explaining how porters should admit a deceased person to the mortuary out of working hours, what to do if a fridge or freezer alarm is ringing, or if a serious untoward incident (SUI) occurs. The SOP for admitting bodies from the community refers to checking the deceased's wrist band upon admission. This check is not currently made, as bodies from the community are admitted in body bags that are sealed at the scene of death. *(Refer to advice item 2)*	**Major**
GQ7There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	The Trust has an internal incident reporting and investigation procedure. There is, however, no documented procedure stating: • what serious untoward incidents are reportable to the HTA; • who may notify HTA of an SUI, and how to do so; • that a notification should be made within five working days of an SUI occurring. *(Refer to advice item 4)*	**Minor**

Disposal

Standard	Inspection findings	Level of shortfall
D1 There is a clear and sensitive policy for disposing of human organs and tissue.	SOP CPH58 does not specify a timeframe for the disposal of PM tissue blocks and slides. This SOP also states that blocks and slides will be retained for 30 years if no FIN178 is received, which is not in accordance with the HTA Code of Practice on Post mortem examination (see advice item 7). Any retained tissue must have appropriate consent for its retention.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised that a model consent form for adult hospital PM examination is available from the HTA website: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/modelconsentforms.cfm
2.	GQ1	Bodies of the deceased brought in from the community are in body bags sealed with a security tag at the scene of death. The Coroner requires that the body bag must remain sealed until a PM examination takes place, the body is viewed by relatives or released to a funeral director. Mortuary staff are therefore unable to confirm upon admission if a wrist tag for identification purposes was applied to the body at the scene, or to check for signs of accidental damage or decomposition. This poses a risk to the establishment, should an error be identified later. The DI is advised to seek further guidance from the Coroner on whether body bags may be opened upon admission of the body to the mortuary, and the body transfer SOP CPM06 should be updated to reflect practice. (Exceptions will be forensic cases.) The DI should also consider developing a system of follow up where notification of the end of coronial authority has not been received. This system should be documented in SOP CPH58. Funeral directors do not currently present any documentation when collecting the body of a deceased person from the mortuary. The establishment will only release bodies once they receive a copy of the Coronial release documentation; however this does not specify which funeral directors the family has chosen, and increases the risk that a body may be released to the wrong firm. The DI is advised to consider how procedures for release may be strengthened. Form FIN178 from the Coroner's Office contains the wishes of the family with regard to tissue retention/disposal options. However, it does not state the relationship of the person to the deceased. If the option of 'retention for use for research or other purposes' has been selected, the DI must ensure that the person is the most appropriate to give consent under the HT Act.
3.	C2	The DI is advised that a model information leaflet on adult hospital PM examinations for relatives is available from the HTA website:

		http://www.hta.gov.uk/_db/_documents/Post-mortem_examination_-_your_choices_about_organs_and_tissue_FINAL_v3_0_201201255642.pdf
4.	GQ7	The DI is advised that relevant staff, including hospital porters, should receive training on what an SUI is, the requirement to report SUIs to the HTA, and how to do so. Attendance at training, and when staff have read and understood the SUI reporting SOP, should be recorded.
5.	GQ8	The DI is advised that the risk of misidentification of deceased persons with the same or similar sounding names can be reduced by, for example, placing a coloured sticker on the wrist tag of such persons, or attaching a notice to the shroud, as visual cues to staff. Similar measures can also reduce the risk of releasing a body waiting for tissue or organs to be repatriated.
6.	PFE5	The DI is advised that body fridge and freezer alarms should be tested regularly to ensure these continue to function correctly, and that alarms are set to trigger at appropriate temperature level.
7.	D1	The DI is advised that SOP CPH58 should refer to the 2009 version of HTA Code of practice 5 on Disposal of human tissue. The DI is also advised to refer to paragraphs 64-69 of HTA Code of practice 3 on Post mortem examination for advice on handling outstanding cases where relatives' wishes for retained PM tissue blocks and slides have not been determined.
8.	-	The DI is advised to nominate a Person Designated (PD) in areas of the hospital where removal of relevant material from deceased infants in sudden unexpected death in infant cases may take place. The establishment explained that such removal of tissue would only take place under the authority of HM Coroner. The DI is advised to initiate regular meetings, or some other form of communication, with this PD to retain oversight of such activity.

Concluding comments

Despite the shortfalls, some strengths were identified. The mortuary has detailed risk assessments for mortuary activities, including assessments of risks which may lead to an SUI. In addition, the mortuary premises are clean and well maintained.

There are a number of areas of practice that require improvement, including one major and three minor shortfalls. The HTA has also given advice to the Designated Individual to further improve practices and documentation.

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: 20 December 2012

Report returned from DI: 21 December 2012

Final report issued: 31 December 2012

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: 3 March 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.

GQ6A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audittrail

- 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.

GQ7There 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 thatneed 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 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.