Site visit inspection report on compliance with HTA minimum standards

Royal Berkshire NHS Foundation Trust

HTA licensing number 12232

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**

11 December 2012

Summary of inspection findings

The Royal Berkshire NHS Foundation Trust (the establishment) was subject to a themed inspection focusing on consent, quality management and prevention of major equipment failures.

The HTA found that the establishment had met the majority of the HTA standards in these areas. However, two minor shortfalls were identified in relation to consent standards, particularly the need to use revised and updated consent documentation (C1) and the need to maintain an active list of individuals who have undertaken formal consent training (C3). Additionally, one shortfall outside the scope of the themes was identified in relation to premises, facilities and equipment (PFE1).

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

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. 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.

A themed inspection may be carried out at establishments which have been found previously to represent a lower risk of regulatory non-compliance. Themed inspections focus on standards against which the HTA has identified common shortfalls across the post mortem sector and areas of risk identified from analysis of serious untoward incidents reported to the HTA. The themes selected for 2012/13 business year are outlined in the table below.

Themes	**HTA Standards**
Appropriate consent is in place for post-mortem examinations not under the Coroner's jurisdiction and in the event that tissue is to be retained for future use. Where there is no consent for retention, tissue is disposed of.	
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.	C1
Information about the consent process is provided and in a variety of formats.	C2
Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	C3
Governance and quality systems promote robust traceability systems, reducing the risk of serious untoward incidents.	
All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process.	GQ1

There is a documented system of quality management and audit.	GQ2
A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	GQ6
There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	GQ7
Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	GQ8
Fridges and freezers safeguard the integrity of the deceased.	
There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.	PFE3

In addition to the standards listed above, the HTA will follow-up on any other issues that have arisen since the establishment's last inspection.

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 Royal Berkshire NHS Foundation Trust is a large district general hospital with a wide range of acute and specialised hospital services. The Pathology Service has five main departments. Mortuary facilities and post mortem activities are managed within the Department of Cellular Pathology.

The establishment undertakes approximately 600 post mortem (PM) examinations per annum, the majority of which are conducted at the request of HM Coroner (Berkshire). High-risk PM examinations are also conducted on site. Consent for paediatric cases is taken on-site however these cases are routinely sent to another licensed establishment for PM examination.

The DI is Clinical Service Unit Director (Pathology) and a Consultant Biochemist. The LH is the Royal Berkshire NHS Foundation Trust, with the Director of Corporate Affairs acting as the named contact. The mortuary has five full time Anatomical Pathology Technicians (APTs), including the Mortuary Manager and two trainee APTs.

The establishment was first inspected in November 2009. There were no conditions imposed on the establishment's licence at that time. This inspection was a routine themed inspection, which provided an opportunity for the HTA to review governance arrangements in respect of licensed activities. It included a visual inspection of the body store and post mortem room, and formal interviews with the Designated Individual, Head BMS, Mortuary Manager,

Pathology Quality Manager, Senior Bereavement Officer and Coroner's Officer (Berkshire). A number of traceability checks were conducted. The identification tags of three bodies stored in the mortuary were checked and all associated paper and electronic records were reviewed. An audit trail of three further cases where histology had been taken was conducted. Records were reviewed against the consent details for retention, repatriation or disposal of tissue samples, and the number of blocks and slides stored in the histology laboratory were also checked against relevant records. No anomalies were found.

A document review of the establishment's policies and operational procedures was also undertaken. This included review of risk assessments, audit reports for 2011/12, incident reports, meeting minutes and the Pathology Quality Manual.

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

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.	Consent forms currently in use do not fully reflect the requirements of the HTA Code of Practice on consent (code 1); e.g. the establishment uses a 'Hospital PME Consent Form (adult) (February 2008)' which does not clearly state whether samples are held as part of the medical record. The current form does not indicate that appropriate consent is required in accordance with Section 3 of the Human Tissue Act 2004 and does not sufficiently clarify that relevant material may be stored for potential use for a scheduled purpose. Although there is a documented 'Hospital PM Consent Checklist (May 2007)', which informs the consent procedure, there is no documented policy on consent setting out the consent process and including, for example, those able to take consent and details of mandatory training requirements.	**Minor**

C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	There is currently no established consent training programme for clinical staff who may be involved in taking consent for PM examination, as required by the HTA code of practice. Mortuary staff, who have attended AAPT/HTA courses on taking consent for PM examination, sit in on each consent process. However, consent is taken by clinicians who may not have received specific consent training or indeed attended a PM examination.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE1 The premises are fit for purpose.	Areas of flooring in the PM room show evidence of moderate cracking and peeling. This is exacerbated by problems relating to the water supply, resulting in significant limescale deposition across the floor of the room. Since known high risk PM examinations are undertaken at the mortuary, there is a risk that the floor cannot be effectively decontaminated following PM examinations, posing a potential health and safety risk.	**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 Given the relatively small number of hospital PM examinations, the DI may wish to consider whether staff routinely involved with the process of PM examination, e.g. histopathologists or APTs, might be included amongst those able to take consent.
2.	C1, C2,	The Sudden and Neonatal Death Charity (SANDS) will be publishing a model

	C3	consent form, guidance for consent takers and information for bereaved parents early in 2013. The DI is advised to review the establishment's paediatric consent procedures in light of these imminent developments.
3.	C3	The DI is advised to maintain an active list of individuals, including clinicians and any other staff, who have been formally trained to take consent.
4.	GQ7	To further raise awareness of SUI reporting requirements, it is recommended that the DI considers maintaining a checklist of SUI reporting categories within mortuary premises in a location easily referred to by staff.
5.	GQ8	While the establishment has completed a number of risk assessments, these should be extended to include all HTA SUI categories in order to mitigate risks to the bodies and tissue in the care of the mortuary.

Concluding comments

The establishment has an experienced team, which is fully engaged and committed to delivering a high quality service. The DI communicates effectively with mortuary staff, primarily through the Mortuary Manager (Person Designated).

A number of examples of strength and good practice were seen. For example, the establishment has a comprehensive schedule of regular audits covering a range of mortuary activities and there was documented evidence of corrective and preventive actions being tracked through to resolution and closure. Bereavement services and coroner's officers are co-located within the mortuary premises and this aids effective communication between the Coroner's office and mortuary staff, particularly in relation to ensuring that families' wishes for disposal/return or repatriation of tissue samples are dealt with accordingly. There are a number of step checks in place for both receipt and release procedures within the mortuary and for movement of relevant material within the histology department. The monitoring of the main body store fridges is also comprehensive and rigorous. Temperatures are continuously monitored and recorded electronically (using a commercial off-the-shelf system) and manually checked on a daily basis by mortuary staff. Summaries of temperature readings are reviewed by the mortuary manager on a daily and weekly basis. The alarm system is also continuously monitored electronically by the software system in place. A number of PM examinations are routinely conducted simultaneously on a daily basis. Each PM table has a dedicated dissection bench, and tables and bowls for organs are colour coded, mitigating the risk of organs being inadvertently returned to the wrong body.

As highlighted above, there are some areas of practice that require improvement and the HTA has given advice to the DI with respect to these.

The HTA requires that the DI addresses the three identified 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 shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 3 January 2013

Report returned from DI: 4 January 2013 – no comments regarding factual accuracy

Final report issued: 4 January 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: 26 July 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.

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 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.