Site visit inspection report on performance against HTA quality standards
Heart of England NHS Foundation Trust
HTA licensing number 12366

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**

23 and 24 August 2011

Executive Summary

A site visit inspection of Heart of England NHS Foundation Trust (the establishment) was carried out by the HTA on 23 and 24 August 2011. The establishment is formed of hospitals on two sites, Heartlands Hospital, Birmingham (the hub) and Good Hope Hospital, Sutton Coldfield (the satellite).

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

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

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

Background to the establishment and description of inspection activities undertaken

In the past year, the establishment has carried out 72 post mortem examinations, all on the hub site as none are carried out at the satellite. Of these, only two were hospital consented post mortems on adults, the remaining 70 being carried out under coronial authority. Where consent is taken for a hospital post mortem examination, both a clinician who has been involved in the care of the patient, and a consultant pathologist, are involved in seeking of that consent. There is a policy, of which all staff appeared to be aware, that no hospital post mortem examination will be carried out unless a consultant pathologist has been involved in the consent process.

In consenting for paediatric post mortem examinations, staff use consent forms and patient information leaflets provided by another licensed establishment, which also carries out the examination. Staff involved in taking consent in such cases have attended training provided by the receiving establishment. Paediatric patients are transported by dedicated courier service.

Over the two sites, there is storage space for 110 adult bodies, 57 at the hub site and 53 on the satellite site. On both sites, there is dedicated storage space for paediatric patients and products of conception.

The satellite functions primarily as a body store, and also as part of the contingency arrangements for storage during times of high capacity at the hub. It also has six dedicated spaces for bariatric patients. However, in cases of sudden infant death, tissue samples are taken in the accident and emergency department following an agreed protocol and transported to the hub for examination, and therefore the satellite does require to retain the licence for removal of relevant material from the deceased for use for a scheduled purpose.

At the hub, there are three post mortem tables in the main mortuary, with a separate, specific, provision for carrying out post mortems on known high risk patients, up to category three. Higher risk cases are referred elsewhere. There is a system of guidance forms accompanying bodies from hospital wards which provides information to mortuary staff on known high risk cases or where special precautions are needed.

The establishment primarily deals with deaths of patients in hospital, as deaths in the community are largely dealt with by a local public mortuary. Portering staff, employed by a trust contracted hotel services company, deal with the delivery of bodies to the mortuary and the completion of the relevant registers. At all times two porters are involved. Mortuary staff then check the mortuary register entries and complete measuring of the body, providing a further cross check of identity. They also annotate the register in cases of same or similar names.

Body release generally takes place during office hours, where mortuary staff are available. Again, at least two persons are involved in each release, to allow for cross checking of identification. There is also a Trust policy covering out of hours release where necessary.

Viewings at both sites are managed by mortuary staff during normal office hours and at the weekend at the satellite site. Viewing rarely takes place outside these hours, but in such cases, portering staff carry this out. For all viewings, there is a policy that a member of nursing staff, familiar with the deceased, is present to cross check identification and to ensure that suitable arrangements have been made for viewing, also acting as the initial contact for attending relatives.

Tissues taken during post mortem examination are processed at the hub prior to assessment by pathologists. The hub also processes tissues and organs taken during post mortem examinations carried out at a local public mortuary under coronial authority. The organs, blocks and slides resulting from this activity are stored on behalf of the public mortuary along with those from post mortem examinations carried out at the hub. To ensure that the risk of

retention contrary to authority is minimised, a system is in place to send facsimile lists of retained specimens to the coroner for confirmation of the need for continued retention or for permission to dispose, in line with the wishes of the relatives of the deceased.

Tissues are traced through the laboratory by being assigned a unique identification number details being entered onto the Telepath laboratory database.

Where bodies are sent from the satellite to the hub for post mortem examination to be carried out there is a system in place for recording the transfer of these bodies between sites. Similarly, where there has been consent for tissue donation, the body of the donor is transferred from the satellite site to the hub, where tissue retrieval takes place. Procedures are in place to ensure that consent to retrieval is faxed through to the establishment in advance and transport then takes place, with all transport between sites facilitated by a contracted funeral director.

The establishment is in the process of harmonising mortuary and laboratory systems and processes across both sites and many elements of documentation have been updated and revised recently.

This routine, scheduled, inspection comprised a visual inspection of both sites; a review of policies, standard operating procedures, audits and risk assessments, as well as records relating to environmental controls; audits of traceability and interviews with key staff.

Audits of traceability were carried out:

- At the hub, a body was located within the body store and the identification details were compared to the mortuary register and found to be accurate.
- Stored tissues relating to three patients were traced from their storage location through the laboratory to ensure that all appropriate consents or authorisations were in place and that the records of blocks and slides produced accorded with those in store. Only one minor anomaly was discovered and traceability was demonstrated
- At the satellite site, the location and identity details of two bodies in storage were correlated to the mortuary register and again found to be in order.

During the inspection, the HTA observed the release of one body to funeral directors at each site and noted that the procedure followed exactly mirrored that described in the relevant standard operating procedure (SOP).

Meeting the HTA's licensing standards

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

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

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

HTA standards not met

Consent

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the Code of Practice. C2 Information about the consent process is provided and in a variety of formats. C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	There is a policy, at present undocumented, that seeking consent for a hospital post mortem must involve both the treating clinician and a consultant pathologist. There is no documented procedure on the process for obtaining consent and the information to be given to the bereaved. The consent form used for hospital consented post mortems does not meet the requirements of the HTA Code of Practice 1 on consent, in particular in relation to the potential uses or options for disposal of tissue taken during post mortem examination.Those consenting are given verbal information on the post mortem process and the potential uses of tissue removed (and translation services are available if needed), and are also given any explanatory leaflet to take away and reflect on together with a copy of the signed consent form. However, the booklet has not been reviewed to ensure it is accurate and clear with regard to reasons for retention of tissues and consent relating to that. Specific training on consent for those involved in the process has not been recorded and there is no provision for ongoing updating of training. There is a risk that, in seeking consent for hospital post mortem examinations, the requirements of the relevant legislation and codes of practice are not being adhered to.Taken together, these shortfalls constitute a major shortfall.	**Major**

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	Risk assessments have been carried out and documented, but these are primarily related to health and safety risks. It is apparent that risks inherent in the carrying out of the licensed activity have been considered during the drafting of the relevant Standard Operating Procedures (SOPs), but with one exception these have not been formally documented. In particular there has been no formal assessment of the risk of consent being taken from the wrong person in the qualifying relationship, nor of risks of errors arising from storage of individuals with the same or similar names. The risks inherent in hospital or service employees other than mortuary staff being involved in entering the details of the deceased into the mortuary register, handling and moving bodies or dealing with out of hours viewings appear to have been considered in the drafting of the relevant SOPs, but have not been formally documented. Risks can therefore not be accurately monitored or updated and there is no formal schedule for updating any risk assessments carried out.	**Minor**

Advice

Below are matters which the HTA advises the Designated Individual (DI) to consider.

No.	Standard	Advice
1.	C1	The DI is advised to consider making provision for recording confirmation by those involved in taking consent that the appropriate person in the qualifying relationship has given consent.
2.	GQ1	The DI is advised to consider having periodic meetings to which all members of staff involved in the carrying out of the licensed activity are invited, to provide for discussion of matters relating to those activities. These meetings should be minuted and minutes distributed appropriately.
3.	GQ1/PFE4	The DI is advised to formally document the current procedures for transport of bodies between the satellite and the hub for the purposes of post mortem examination or tissue donation and as part of that process to risk assess the

		process and the method currently used to record such transfer.
4.	GQ1	The DI is advised to consider producing flowcharts or advice cards, to be available to porters and tissue retrieval teams, to act as an aide memoire regarding the procedures to be followed when in the mortuary out of normal working hours.
5.	GQ1	The DI is advised to ensure that the current SOP relating to transfer of tissues between mortuary and laboratory (MO.S009) is finalised and made available to staff.
6.	GQ3	The DI is advised to ensure that, where individual staff members have particular knowledge of a process or system, such as the method used to audit stored tissues and seek confirmation of authority to dispose, that this knowledge is documented and shared with others.
7.	GQ3	The DI is advised to finalise the induction training programme for porters and to ensure that on initial visits to the mortuary staff, porters are provided with instruction on how to carry out their allotted tasks as well as being familiarised with the procedure for notifying relevant staff of any untoward incident or accident or equipment issue.
8.	GQ4	The DI is advised to ensure that the copy authorisation of post mortem examination and release of body forms received from the coroner are stored within a ring binder or similar, in chronological order, so as to facilitate easy review.
9.	GQ5	The DI is advised to ensure that the Telepath record is updated whenever a slide is broken or disposed of, or where the number of slides produced from tissue block varies from that anticipated.
10.	GQ7	The DI is advised to formally document the procedure currently in place for reporting Serious Untoward Incidents (SUIs) to the HTA by the production of a policy and procedure at local level or by having the Trust Incident reporting and SUI policies amended accordingly.
11.	PFE3	The DI is advised to ensure that the daily temperature logging of the fridges at the hub takes place before the fridges have been accessed for the purposes of body measurement in order to ensure that temperatures are stable, thus allowing for trend analysis.
12.	PFE5	The DI is advised to ensure that the fridge temperature recording equipment used at both sites is routinely validated to ensure its accuracy.

Concluding comments

The HTA was pleased to note various elements of good practice during the inspection.

The standard of governance documentation was good, with SOPs being clearly drafted, using easily understood language.

The establishment has installed a proprietary document management system and uses its functionality to schedule a comprehensive suite of audits, including practices against SOPs, as well as to provide reminders to update SOPs and risk assessments.

Where bodies from the ward present a risk of infection to staff or other persons, there is a guidance sheet provided with the deceased to clarify that risk and to alert those involved to any need for special precautions in handling the body.

At each site there is a daily checklist for completion and retention by mortuary staff detailing and confirming duties to be carried out.

The establishment staff carry out regular audits of tissues and organs retained and have implemented a procedure to obtain instructions from one coroner for continued retention or disposal. With regard to the other coroner for whom post mortem examinations are carried out, an agreement has been reached to allow for scheduled disposal of tissues retained at post mortem, unless advised to the contrary.

There was clear evidence of excellent communication between staff members and of good team working across both sites. Advice provided above is intended to assist the DI in maintaining this when located away from the hub site.

The HTA are confident that the DI and staff working under the licence will seek to implement the items of advice provided as part of the continued harmonisation of processes across the two establishment sites.

Report sent to DI for factual accuracy: 2 September 2011

Report returned from DI: 16 September 2011

Final report issued: 21 October 2011

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.

Date: 03 January 2012

Appendix 1: HTA inspection process

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

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

Inspections

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

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

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

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

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

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

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

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

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

Appendix 2: HTA standards

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

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

Governance and quality system standards

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

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

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

GQ2 There is a documented system of quality management and audit

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

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

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

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

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

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

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

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

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

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

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

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

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.
- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- Risk assessments include how to mitigate the identified risks; this includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

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

PFE 2 Environmental controls are in place to avoid potential contamination

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

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

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

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

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

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

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

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

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

Disposal Standards

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

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

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

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

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

Appendix 3: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. Critical shortfall:

A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

or

A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

A critical shortfall may result in one or more of the following:

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

(2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall that:

- poses a risk to human safety and/or dignity, or
- indicates a failure to carry out satisfactory procedures, or
- indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

Follow up actions

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

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

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

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