Site visit inspection report on performance against HTA quality standards
Addenbrooke's Hospital
HTA licensing number 12318

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**

14-15 September 2011

Executive Summary

A site visit inspection of Addenbrooke's Hospital (the establishment) was carried out by the HTA on 14-15 September 2011.

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. Some shortfalls were found, particularly in relation to governance and quality systems. Any particular examples of strengths or good practice 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

Addenbrooke's Hospital has a mortuary where both coronial and hospital (consented) post mortem (PM) examinations are carried out. Paediatric PM examinations are performed in a separate paediatric PM examination suite and known high risk cases such as HIV and TB are performed in a high risk isolation suite

This was the second site-visit inspection of the establishment and was a routine inspection to assess whether the establishment is continuing to meet the HTA's standards. The timetable for the site visit was developed in consideration of the establishment's recent self assessment compliance information and audit of stored material, as well as pre-inspection discussions with the DI. During the visit a visual inspection of the premises, review of documentation and interviews with establishment staff were undertaken.

An audit of three bodies in the body store was undertaken. Identification details contained on body tags were checked against details in the mortuary register and on the mortuary white board; no anomalies were found.

Details of three coronial post-mortem examinations and one hospital consented post-mortem examination were also audited. Tissue had been taken in all cases. Blocks, slides, and where applicable, wet tissue, were located. All wet tissue, as detailed in the establishment's electronic records, were found in the storage location indicated or had further records detailing the return of tissue to the body of the deceased. No anomalies were found.

The number of tissue blocks in all four cases correlated with the establishment's electronic records in the histopathology laboratory's laboratory information management system (LIMS) and no anomalies were found. In all four cases however, the number of slides that had been cut from the tissue blocks, did not correlate with the electronic LIMS records (see shortfall below).

In all four cases, hospital consent forms or coronial family's wishes forms were reviewed and all indicated that consent had been attained for the retention of the stored tissue.

Included in the visual inspection of the premises were the areas where tissue may be removed from the bodies of the deceased outside of the mortuary. These areas included the Emergency Department, Neo-natal Intensive Care Unit and the Paediatric Intensive Care Unit. A good level of compliance with HTA standards was found and it was notable that the Persons Designated on the licence in each department were aware of the establishment's procedures and governance systems and that the DI has oversight of the activity taking place in these areas.

The establishment is a large teaching hospital and has multiple areas where tissue from the deceased is being stored for use for research and training. All of these areas were visited as part of the visual inspection and the person designated (PD) on the licence, or a suitable representative for each area, was interviewed. In each area, assurance was sought that the establishment's governance systems have been implemented and that the DI has oversight of the activities taking place. The departments visited were:-

The Clinical School Museum
Medical Genetic Laboratories
Microsurgical Training Laboratory
Main Theatres
Bone Bank
Brain Bank

An audit of stored tissue in the brain bank was also undertaken. A pot containing wet tissue was selected at random from the stored material. The identifying information and location details of the wet tissue were cross checked with the Brain Bank's electronic LIMS; no

anomalies were found. In addition, the consent documentation for the tissue was sought and a signed informed consent form was reviewed; again no anomalies were found.

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

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	During the audit of retained tissue, four post mortem examination cases were selected at random and the blocks and slides produced from the tissue taken were sought. In all cases the number of blocks correlated with the electronic records in the histopathology LIMS. However, the number of slides stored in each of these cases did not correlate with the information contained in the LIMS. This discrepancy between the electronic records detailing the number of slides cut from tissue blocks and the actual number being stored compromises full traceability of tissue.	**Minor**

Advice

Below are matters which the HTA advises the DI to consider.

No.	Standard	Advice
1.	GQ1	The DI is advised to ensure that the same/similar name procedures are always initiated when bodies of deceased with similar names are brought to the mortuary's body store. In addition, the DI is advised to expand the scope of the SOP which covers this process, to include the addition of an indicator on the wrist band of the deceased, so that the person who is identifying the body is made aware that there are other bodies with same/similar names within the body store. This will provide an additional reminder and check, should the mark on the whiteboard be accidentally removed.
2.	GQ1/GQ6	The DI is advised to amend the procedure for the labelling of bodies with unknown identity to make the unique identifier more robust. The establishment currently registers bodies of unidentified persons as 'Unknown Male/Female 1, Unknown Male/Female 2...' along with the the date. All bodies received into the mortuary receive a unique 'booking in' number. The DI is advised to include this number on the wrist band of the deceased to provide another unique number to strengthen identification procedures.
3.	GQ1	The establishment has an SOP covering post mortem examination. This states that removal of a body from the body store prior to post-mortem examination is a two person task; however it does not state that identification of the deceased is a two person task. The DI is advised to review the SOP to ensure that instructions on identification of the deceased are clear and mitigate the risk of mis-identification. In addition, the DI may wish to consider documenting that the identification has taken place and by whom in a similar way to the establishment's new procedure for checking which type of post-mortem examination (limited or full in consented post-mortem examinations) is to be carried out.
4.	GQ6	When receiving bodies into the establishment, details of the deceased are recorded in various paper records and electronic systems. These were reviewed during the visual inspection of the premises and no discrepancies were found. However, the DI is advised to include all records of the deceased in audits of documentation, to mitigate the risk of transcription errors or inconsistencies between the various records.
5.	PFE2	There are two places within the mortuary where staff may pass from a designated dirty zone into a transitional zone. The practice of crossing between these two zones has been risk assessed and, the types of clothing to be worn by staff in these areas are defined within the establishment's 'Mortuary Health and Safety Code of Practice' and procedures for cleaning of PPE when crossing these zones are defined within relevant SOPs. The establishment has concluded following the risk assessments that crossing between the dirty and transitional zones is necessary due to the layout and space restrictions within the premises, however risks of contamination are minimised by following the establishment's procedures. The DI is advised to :- 1) Keep the practice of transiting between the PM suite 'dirty zone' into the body store 'transitional zone' under review to ensure that there is

		minimal contamination of the transitional zone from the dirty zone. The DI may wish to minimise any transit between the zones while PM examinations are taking place. In addition the DI is advised to amend the relevant SOPs to include more detailed instructions to staff on how to clean PPE and what to use for cleaning when transiting the zones. The DI is also advised to include the mortuary trolleys, which transit between the two zones, in the weekly cleaning schedule, so that the risk of a build up of contamination on the trolleys is minimised. 2) Keep the practice of transiting between the PM suite 'dirty zone' into the changing area 'transitional zone' under review to ensure that there is minimal contamination of the transitional zone from the dirty zone. There is a foot bath washing station at the interface between the two zones, however, during the inspection some boots being stored in the transitional zone were observed to be dirty. The DI is advised to amend the relevant SOPs to include more detailed instructions to staff on how to clean PPE and what to use for cleaning when leaving the dirty zone in wellington boots into the changing transitional zone.
6.	PFE5	The DI is advised to instigate testing of the fridge alarm system to ensure that switchboard personnel receive the alert and contact relevant mortuary staff if the temperature reaches the maximum permitted level. In addition, the electronic temperature readouts of the fridges and freezers should be cross checked with an independent thermometer to ensure that they are calibrated appropriately.
7.	C3	The DI is advised to continue with plans to train staff within the Medical Genetics Department, who seek consent to genetic testing, on the requirements of the Human Tissue Act 2004 (HT Act) and the code of practice on Consent.
8.	GQ1	The Clinical School Museum is not currently in use by students; however it is envisaged that it will be in the coming months. Some procedures and SOPs have already been developed covering the museum and its use. The DI is advised to develop a 'code of conduct' governing behaviour and compliance with the DI's procedures when students are using the museum facility. The code of practice should include, but not be limited to, restrictions on the use of cameras for unauthorised photography by students.
9.	GQ4, GQ6	The PD within the Microsurgical training facility has developed a good system of traceability recording which tissue has been used, when and by whom. However, these are hand-written records are which are not backed up. . The DI is advised to develop a system whereby the hand written notes are regularly copied, so there is a back-up should the register by lost or damaged.
10.		The DI is advised to continue with plans to add the main theatres to the areas covered by the post mortem licence, as it is envisaged that occasionally licensable activity may take place within theatres. By adding the theatres to the licence and nominating a PD, the DI will strengthen her oversight of the licensable activity taking place under the licence.

Concluding comments

Areas of good practice were observed during the inspection, some examples of which have been included below.

The establishment's APT staff each have a 'Post Diploma APT Assessment' book to record ongoing training and assessment. This helps provide a framework for continuous professional

development amongst APT staff.

In the neo-natal intensive care unit, the PD has developed a system where all documentation required to support the seeking of consent has been organised into a single plastic file. This file is available in the PD's office and can be quickly located if required. The organising of documentation in this way means that, should the PD be approaching families of deceased infants for consent to undertake a post-mortem examination, he can be sure that he has everything required, preventing any delays and helping to minimise distress to families. Finally, it was observed that the DI has implemented good systems of governance covering areas of the hospital other than the mortuary were licensable activities taken place, and the staff involved in undertaking the activities. Through a combination of email and formal meetings between the DI and PDs, all staff are aware of their responsibilities and the DI is able to maintain oversight of the activities giving her the opportunity to provide guidance on regulatory issues.

Report sent to DI for factual accuracy: 5 October 2011

Report returned from DI: 12 October 2011

Final report issued: 14 novemebr 2011

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.