Site visit inspection report on compliance with HTA minimum standards

Norfolk and Norwich University Hospital
HTA licensing number 11208

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**

13 September 2012

Summary of inspection findings

The establishment was found to have met the majority of HTA standards. However, one minor shortfall in relation to premises, facilities and equipment (PFE5) was identified. Staff working under the licence are unaware as to whether the alarm monitoring system for refrigeration units is routinely tested. This shortfall has been addressed by the establishment to the satisfaction of the HTA prior to the final report being issued.

The HTA found the Designated Individual (DI), the Licence Holder (LH), the practices and all aspects of the premises to be suitable in accordance with the requirements of the legislation, subject to the identified shortfalls.

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.

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

Norfolk and Norwich University Hospital (NNUH, the establishment) provides a range of acute clinical services with several specialist units. The Histopathology Department is part of the Medicine and Clinical Support Division and the Directorate of Cellular Pathology. The Cellular Pathology Directorate forms part of the Norfolk & Waveney Cellular Pathology Network and includes a busy mortuary service.

The mortuary receives approximately 3,200 deceased persons per annum and undertakes over 1,000 post mortem (PM) examinations a year at the request of HM Coroner (Norfolk). In addition, approximately 30-35 hospital post mortem (PM) examinations take place each year.

The mortuary has six full time Anatomical Pathology Technicians (APTs), a mortuary office assistant and an assigned porter for mortuary duties. The chief APT is also the Mortuary

Manager. The DI is a consultant histopathologist and the named licence holder contact is the Medical Director.

NNUH also houses a Research Tissue Bank (established in 1999 – 2000), which is managed under this licence. The bank holds frozen tissue samples from over 1,300 cases including urological, gynaecological and colorectal specimens, some of which are 'existing holdings' which pre-date the implementation of the Human Tissue Act requirements (on 1 September 2006). Consent to use material for research purposes has been obtained for specimens collected subsequent to this date. The bank itself holds National Research Ethics Service (NRES) approval and activities within the bank are co-ordinated by a Chief BMS.

The establishment was first inspected in March 2009 and one condition was imposed on its licence at that time. Evidence received by the HTA following the 2009 inspection was assessed and the condition was deemed to have been subsequently met. This latest inspection, undertaken on 13 September 2012, was a routine inspection, which provided an opportunity for the HTA to review again governance arrangements in respect of licensed activities.

The visit included a visual inspection of the body store, post mortem room, laboratory facilities and research tissue bank, and formal interviews with the Desigated Individual, the Clinical Director for Histopathology representing the Corporate Licence Holder Contact, Chief BMS/Tissue Bank Co-ordinator, Chief APT/Mortuary Manager, senior APT, Pathology Liaison & Bereavement Nurse and senior Coroner's Officer for Norfolk.

A number of traceability checks were conducted. The identification tags of two bodies stored in the mortuary were checked and all associated paper and electronic records were reviewed. An audit trail on four further coronial cases where histology had been taken was conducted. All paper and electronic records were reviewed and the number of blocks and slides stored in the Pathology Laboratory was also checked. Additionally, an audit trail on three specimens stored in the tissue bank freezer was also undertaken.

A document review of the establishment's policies and operational procedures was conducted. This included review of risk assessments, audit schedule for 2011/12, incident reports, meeting minutes, maintenance records and the quality manual (Cellular Pathology).

Inspection findings

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

Although hospital (consented) PM examinations are rare, procedures are documented and are compliant with HTA requirements.

With regard to the audits of traceablility undertaken, there were no discrepancies found on the selected examples either within mortuary, histology or tissue bank records.

Compliance with HTA standards

HTA standards not met:

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE 5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored	Although there is an alarm monitoring system for refrigeration and freezer units, this is not subject to routine testing. Mortuary staff are unaware as to whether the alarm system is functional. *The establishment has submitted two updated standard operating procedures which detail routine alarm testing requirements. Additionally, the establishment now maintains copies of test results within the department. The HTA has assessed this information as satisfactory to address this shortfall.*	**Minor**

Advice

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

No.	Standard	Advice
1.	C2	Information relating to the consent process is available. However, an updated and more detailed consent information booklet is currently in draft form awaiting approval at corporate level, and should be published in the near future. The HTA endorses the use of this new booklet, which provides additional information regarding the PM examination process and describes HTA requirements regarding qualifying relationships. The booklet will allow individuals to make a more informed decision.
2.	GQ4	As there is potential anticipated growth in demand for material from the tissue bank, the DI may wish to consider establishing a standard request template for researchers to use when wishing to access material held within the facility.
3.	GQ6	A number of PM examinations are conducted simultaneously on a daily basis. The DI is advised that an identification system, for example, numbering or colour coding mortuary tables and the bowls used to move organs to / from dissection boards, may mitigate the risk of organs being inadvertently repatriated with the wrong body.
4.	GQ8	While the establishment has completed a number of risk assessments, additional risk assessments based on HTA SUI categories would help mitigate risks to the bodies and tissue in the care of the mortuary.
5.	D2	The DI is advised to introduce a mechanism whereby an establishment receiving material for defined research purposes confirms to the tissue bank that remaining tissue has been appropriately disposed of once the project has ended.

Concluding comments

The establishment has an experienced team, which is fully engaged and committed to delivering a high quality service, and there is clear evidence of a culture of continuous improvement. The DI communicates effectively with mortuary staff, primarily through the Chief APT/Mortuary Manager (PD), and with the Chief BMS (also a PD) for activities relating to the tissue bank.

A number of examples of strength and good practice were seen. For example: the establishment has a good working relationship with HM Coroner; maintains meticulous record-keeping both for the mortuary and tissue bank (supported by 100% traceability for selected samples); the use of a formal porters admission log (MORT FORM 035); and multiple step checks on receipt of the deceased and end-of-day verifications for the body store. At Directorate level, an extensive and detailed Management Review for Cellular Pathology is produced annually and includes a number of detailed reports relating to mortuary activities (e.g. quality issues, user satisfaction surveys, audits, errors and incidents).

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.

Before the draft inspection report was finalised, the establishment submitted revised SOPs for both freezer breakdown (within the research tissue bank) and fridge-freezer failure (within the mortuary). The establishment now also holds copies of alarm test results within the department. This information has been assessed by the HTA as satisfactory to meet the identified shortfall. Consequently, there is no longer a need to complete a corrective and preventive action plan in this regard.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 10 October 2012

Report returned from DI: 22 October 2012 - no comments regarding factual accuracy

Final report issued: 15 November 2012

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.