Site visit inspection report on compliance with HTA minimum standards

Sheffield Teaching Hospital NHS Foundation Trust

HTA licensing number 12427

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 and 12 March 2014

Summary of inspection findings

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

Sheffield Teaching Hospitals NHS Foundation Trust (the establishment) was found to have met all HTA standards.

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 Section 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

Sheffield Teaching Hospitals NHS Foundation Trust (the establishment) comprises the Northern General Hospital (NGH), the Royal Hallamshire Hospital (RHH) and the Jessop Wing Hospital (JWH).

NGH and RHH carry out approximately 50 post mortem (PM) examinations annually, including consented adult hospital PM examinations. Removal of organs and tissue for research also takes place on the premises. The establishment does not undertake paediatric or perinatal cases, which are referred to another HTA-license establishment. Not does it undertake coronial or forensic cases. However, the RHH is a national specialist referral center for cardiac and neuropathology, and on occasion receives organs retained by the police or HM Coroner for specialist examination.

The JWH comprises a paediatric body storage facility with eight spaces for babies, foetal remains and placentas. Storage is usually incidental to transportation to other HTA licensed premises for PM examination; however, on occasion babies can be stored for longer and for this reason the HTA licence has been extended to cover this area of the Trust. Fridges and temperatures are monitored and alarmed. There is also a small fridge on the gynaecology ward used for the storage of products of conception pending transfer to the main JWH mortuary.

Consent for adult hospital PM examinations is overseen by the Medical Examiner's Officer, who supports staff across the Trust when they seek consent from families.Consent for perinatal PM examination is sought by the consultant involved in the care of the mother. The Sheffield Children's Hospital consent form and patient information leaflet are used in all cases, and there appears to be excellent communication between staff at the two Trusts.

NGH mortuary is staffed by three full time members of staff, who supervise activities during working hours, whist the Site Manager/Matron co-ordinates out of hours viewings and the

occasional release of a deceased for religious purposes. Porters are responsible for admitting bodies from the wards and are trained in mortuary procedures. No bodies from the community are admitted into the mortuary. Although there is no formal on call system, a member of staff is always contactable in the event of an emergency. There is storage capacity for 65 adult bodies, with five fridge spaces able to be used as freezer storage if required. There is a cooling system in the body store room which can be used as emergency storage, and additional racking available as part of the Trust's contingency plan for both sites. Temperature and alarm systems are monitored and recorded electronically every 4 hours. In the event of the alarm being triggered, the Trust control room is alerted and contacts the on call APT.

The PM Suite comprises four down-draught tables and a galleried viewing area for teaching purposes. Consented adult hospital PM examinations are carried out after a full risk assessment of the deceased and identification check by the Pathologist and Anatomical Pathology Technologist (APT). Any samples that are taken for histology are given a unique PM Number and tissue is transferred to the RHH for processing. No tissue is stored at the NGH site except for tissue needed for medico legal purposes,for which there is consent.

RHH is staffed by two full time members of staff, who follow the same admittance and release procedures as at NGH. Out of hours activities are also overseen by the Site Manager/Matron. The main body store area has capacity for 36 bodies, whilst a second fridge area has the capacity for an additional 12, including four bariatric spaces. The temperature and alarm systems are recorded and tested manually. In the event of the alarm being triggered outside of normal working hours, the oncall APT is contacted via the control room.

The PM suite at RHH comprises three PM examination tables with individual cut-up facilities. There is also a galleried viewing area for teaching purposes. The same checking procedures are followed as at the NGH prior to evisceration. Tissue taken at PM examination is placed into a storage container and the Histology Request Form accompanies the tissue to the laboratory. There is a signed receipt system at the specimen reception and a copy of the receipt is returned to the mortuary for traceability purposes.

Tissue samples are received at RHH from both mortuaries and are given a unique histology number and a disposal grid sheet. This is used for the tracking of retained tissue, along with the consent form or coroners "form 2", which states the wishes of the family. Wet tissue is stored in a designated area within the laboratory with consent. Blocks and slides are stored in a separate area within the laboratory.

Both sites are governed by the same quality management system in relation to HTA licensed activities. All documentation is managed using a document control system and hard copies are available in the relevant areas.

This was the second routine inspection of the establishment. Included in the two day inspection was a visual inspection of all facilities, a document review and interviews with key members of staff. During the visual inspection of the NGH mortuary, the HTA was able to observe the procedure for releasing a body to the funeral director.

Traceability audits were completed as part of the inspection as detailed below:

- Two bodies were selected using the mortuary daily log book and found to be in the specified location in the mortuary; the identification tag on the deceased, the identification label on the fridge door and the label on the body bag were checked.

The information was also verified against the electronic mortuary register. The same or similar name process was observed throughout the audit.

- A case where a deceased had been transferred from the Accident and Emergency department was reviewed and the identity confirmed using the same identifiers as above.
- Two babies were located in the Jessop Wing Hospital mortuary and their identities confirmed by checking the identification wristband and comparing the details with those in the mortuary record book and mortuary register.
- Two traceability audits of whole organs and tissue samples taken at PM examination at NGH were traced through the histopathology laboratory database and storage areas, and the relatives' wishes for the retention or disposal of this tissue were verified.
- A further two traceability audits of whole organs and tissue taken at PM examination at RHH were traced using the same process as above.

Under s39 of the Human Tissue Act 2004 ('the Act'), relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' (ACPO) audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings were reviewed by HTA at its site visit inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the Act.

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

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	C3	Consent training in adult hospital PM examinations has been updated. This is undertaken by a core team of staff and includes key areas such as qualifying relationships in relation to seeking consent and the options available to families concerning disposal and rentention of tissue samples. There is refresher training available, which at present is every five years, so key members of staff have not updated their skills since 2010. The HTA had considered this is to be a minor shortfall as the process has undergone considerable change since the last inspection. However, staff are booked onto the AAPTUK training course next month and therefore this has been noted as an item of advice and guidance. The DI is advised to reduce the length for refresher training to two years.

		Furthermore, the DI is advised to consider training a member of the mortuary staff on the RHH site to ensure there is a fully trained person to assist clinicians with the process on site if required, to ensure that informed consent is sought from families.
2.	GQ1	Standard Operating Procedures are managed using a document control system. Since the last revision, some activities have ceased and practices have changed. The DI is advised to revise and amend relevant SOPs to reflect working practice. For example; • Coronial PM examinations are no longer undertaken with the Trust • Same or similar name procedure is not documented in an SOP • Roles and responsibilities for out of hours activities should be documented
3.	GQ4	The mortuary has two log books in use, one which contains details of body receipt including a record of valuables; the other contains details of PM examinations. The information recorded is not always consistent. For example, the full date is not always used and this can cause some confusion when searching for previous patient information. The DI is advised to consider formalising record keeping in manual logs to improve traceability.
4.	GQ6	There are risk assessments in place for the mortuary, including an assessment of the premises. The DI is advised to extend the suite of risk assessments to cover all of the HTA reportable incidents classifications.
5.	GQ7	There is a policy for HTA reportable incidents, which covers the procedure for reporting an incident to the HTA. The DI is advised to expand the current policy to include the reporting time frames and classifications. The HTA has produced guidance on HTARI reporting, which the DI may find useful when revising the policy. http://www.hta.gov.uk/_db/_documents/Guidance_for_reporting_HTARIs.pdf
6.	GQ8	Tissue taken at the time of PM examination at the NGH is assigned a unique reference number and is then transferred to the histopathology laboratory. The tissue is accompanied by the histology request form stating the amount of tissue taken. The laboratory at NGH signs for receipt of the tissue and then packages and sends the samples, with the histology request form, to the RHH for processing. However, there is no record of tissue retained kept at either the mortuary or the laboratory at NGH, nor is there an indication of whether the samples are from the living or the deceased. The DI is advised to keep a record of PM tissue samples that have been sent to the RHH to improve traceability.
7.	PFE2	At the RHH, a deep clean of the fridges is carried out twice yearly. The alarm is tested, though this is on an irregular basis. The DI is advised to consider formally recording these activities so that there is a record of cleaning and equipment maintenance.

8.	PFE3	The small fridge on the gynaecology ward within the JWH holds products of conception for a short period of time prior to transfer. The DI is advised to consider displaying instructions on the fridge covering temperature monitoring and the procedure to be followed in the event of fridge failure.

Concluding comments

During the inspection, examples of good practice were observed.

Although activity under the licence is not undertaken outside of the mortuary at NGH, there is good communication with the accident and emergency department in relation to the chain of custody for deceased being transferred directly to the Medico-legal Centre for forensic PM examination.

Members of the mortuary staff have a comprehensive competency training record covering all aspects of mortuary procedures including security, viewings, release of a deceased and PM examination processes. This is revised every two years and ensures staff are competent to carry out the activities under the licence.

The RHH laboratory receives samples of tissue from various external establishments for examination to determine the cause of death of the deceased and for the purpose of research. There is a good system in place to ensure traceability of tissue from arrival into the RHH laboratory to the disposal or retention of tissue and organs in line with the family's wishes.

The PD for the Jessop Wing mortuary has good oversight of the activities taking place under the licence. There is good communication between establishments on the consent and PM examination process and any concerns are raised at regular meetings between staff from both Trusts.

The HTA has given advice to the Designated Individual with respect to some elements of governance systems, updating SOPs, extending risk assessments to cover more of the HTARI classifications, as well as recording cleaning and equipment maintenance of the fridges used for storage under the premises, facilities and equipment standards.

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

Report sent to DI for factual accuracy: 2 April 2014

Report returned from DI: 14 April 2014

Final report issued: 29 April 2014

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 and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- 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.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

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.