Site visit inspection report on compliance with HTA minimum standards

Birmingham Children's Hospital

HTA licensing number 12132

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**

10 January 2017

Summary of inspection findings

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

Birmingham Children's Hospital (the establishment) was found to have met all HTA standards.

Advice has been given in relation to standards on consent, governance and quality and premises, facilities and equipment.

Particular examples of 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 (DI), Licence Holder (LH), premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004 (HT Act) 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

The mortuary at Birmingham Children's Hospital (BCH; the establishment) carries out only two to three hospital consented post mortem (PM) examinations each year. Coronial cases are transferred to another HTA-licensed establishment for PM examination. The DI is a consultant Microbiologist and the Licence Holder is Birmingham Children's Hospital NHS Foundation Trust. The HTA licence also covers the emergency department, where removal of tissue samples in the case of Sudden Unexpected Death in Infancy (SUDI) may take place, and the paediatric intensive case unit where small biopsies may be taken to help determine the cause of death. Tissue samples for use for research are also stored under the HTA licence.

The porters, who are trained by mortuary staff, bring bodies to the mortuary accompanied by a nurse from the relevant ward. Babies and infants are transferred in a pram and older children in a concealment trolley. Occasionally parents may wish to take the child to the mortuary themselves; in this case, staff meet them in the viewing suite.

The nursing staff are responsible for completing the mortuary record book and for starting the 'mortuary activity sheet', a document used throughout the period the deceased infant or child is in the mortuary. It records any possessions, viewings, contact with the parents, other family

or the funeral director, if clothing is brought in or removed by the parents and any other relevant details pertinent to the case.

The mortuary is secured by key code locks and only authorised staff have access to the code. At the time of the inspection, the hospital was undergoing building work and a temporary area had been set aside for the release of bodies to undertakers. This involved transferring the deceased along a corridor frequently used by the public to access other departments; a process had been put in place to close off the corridor during transfers to ensure privacy. The temporary area used by funeral directors was well concealed from the public, with a covered area for vehicles and a large shutter door that was closed upon arrival to ensure complete privacy. It was also monitored by CCTV.

The body store contains eight double-sided fridge spaces that open into the PM suite. The fridges have a proprietary remote call-out system that alerts the on-call Histopathologist if the alarm is triggered. The temperature is monitored weekly and the alarms are tested regularly. The mortuary power supply is connected to the main hospital generator system.

There is one APT working in the mortuary; due to the low volume of activity, she also works in the pathology lab and other histopathology staff provide cover when she is unavailable. In order to keep her skills up to date, the APT attends another HTA- licensed establishment once a week to assist in PM examinations.

The mortuary receives an average of three bodies per week; however, families often wish to visit everyday up until the point of release, so the viewing suite can be busy. Viewings of the deceased are co-ordinated by the hospital bereavement service, a member of which accompanies the family to the viewing suite. The hospital bed manager oversees out of hours viewings. There are panic alarms on the wall in the viewing room and in the family waiting area that connect through to security; these are regularly tested.

The PM suite has one PM table and two downdraft dissection benches. Protective equipment for conducting both routine and high-risk post mortem examinations is available. The PM suite is generally in good condition; however, there is a crack in the floor that could compromise decontamination of the suite (see advice item 3). As part of the inspection, maintenance records for the air ventilation system were reviewed. There are 15 air changes per hour for output, but the system had been failed with only five input air changes, the estates team are working with contractors to identify how to increase the supply of air (see advice item 7).

As part of the inspection, an audit of the body store was undertaken. Two bodies were selected at random. Details from the identification tags were cross-checked against the establishment's mortuary book and activity sheets. Additionally, details of tissue retained during three PM examinations were compared with records documenting the wishes of the family and tissue stored in the laboratory. No anomalies were found during these audits.

There are two separate research tissue collections stored under the licence, the Children's Cancer and leukaemia Group (CCLG) and the Liver Unit (LU). In addition to interviews with staff in these areas and a visual inspection of storage areas, traceability audits comparing details of the location of tissue held in freezers against the details held is the respective databases were undertaken at both tissue banks. No anomalies were found; however, there are approximately seven thousand samples in the LU collection that are traceable to a specific box in the freezer and, as the boxes are not mapped, samples may be out of storage for longer than necessary while the relevant sample is being found (see advice item 6).

The establishment has been licensed since 2007 and this was its third routine site-visit inspection. In addition to the audits mentioned above, the HTA conducted a visual inspection of the premises, reviewed documentation and carried out interviews with the Designated Individual and establishment staff.

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.	GQ6	Whilst audits are a strong feature of the mortuary, the CCLG does not have an audit schedule in place for tissue in storage; the DI is advised to ensure regular audits are undertaken.
2.	GQ8	The are risk assessments in place but not all risks associated with mortuary activity have been assessed. The DI is advised to consider the possibility of an HTA reportable incident occurring, using the categories as the basis for additional risk assessments.
3.	PFE1	The crack on the floor of the PM suite may prevent staff from being able to fully decontaminate the area and, if it were to worsen, might present a trip hazard. The DI is advised to arrange for the area to be sealed.
4.	PFE3	The fridges are set to run between six and seven degrees Celsius. This is higher than the normal temperature of four degrees, and should be adjusted.
5.	PFE3	At the time of inspection, the contingency storage freezer for tissue at LU was in use. Alternative contingency arrangements were available elsewhere; however, the DI is advised to ensure that contingency plans are kept up to date to avoid any confusion in the event of a freezer breakdown.
6.	PFE3	The DI is advised to put a mapping system for any future tissue samples going into storage at LU in order to help to locate the samples quickly in order to reduce the amount of time tissue is out of the freezer, which in turn will reduce the risks to the integrity of the tissue.
7.	PFE5	The DI is advised to ensure the estates department continue to work with contractors to ensure the air supply meets the requirements laid out by the Department of Health https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/144029/HTM_03-01_Part_A.pdf.

Concluding comments

There are good relationships between the teams, who support one another to offer parents a good service at a difficult time. There were a number of areas of good practice observed during the inspection:

- the mortuary activity form is a good way of keeping all staff informed of the progress of each case, while a body is in the care of the mortuary;
- parents are able to visit their baby or child in the paediatric mortuary as often as they wish; mortuary staff are flexible with viewings and will ensure the viewing suite is set up in a manner suitable to the age of the child;
- allowing the APT to travel to another establishment ensures her skills are kept up to date when PM examinations are requested at BCH;
- there is good oversight of the SUDI protocol in the Emergency Department and clinicians there are working closely with the coroner to streamline some of the paperwork;
- consent training is well managed and to the use of actors helps prepare staff tasked with seeking consent to deal confidently with difficult situations.

The HTA has given advice to the Designated Individual with regard to governance and quality systems and premises, facilities and equipment.

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

Report sent to DI for factual accuracy: 2 February 2017

Report returned from DI: 13 February 2017

Final report issued: 16 February 2017

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.

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 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.