**Site visit inspection report on compliance with HTA minimum standards**

**The Christie NHS Foundation Trust Hospital**

**HTA licensing number 30003**

**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**

**27 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.

The Christie NHS Foundation Trust Hospital (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**

The Christie NHS Foundation Trust Hospital specialises in the treatment of patients diagnosed with cancer. The mortuary conducts hospital and coronial post-mortem (PM) examinations of patients within the Trust, and also receives bariatric referrals from another HTA licensed establishment. The establishment conducts approximately 30 PM examinations each year on behalf of H.M. Coroner for Manchester, for which authorisation is received from the Coroner's Office by fax. Trained staff seek consent for hospital PM examinations, of which there are approximately five performed annually.

The deceased are received into the mortuary from wards within the hospital during and outside of normal working hours. In both instances, bodies are transported to the mortuary by trained portering staff who, working in pairs, complete the wall chart, the porters log and place the bodies into refrigerated storage. During working hours, porters are assisted in these duties by mortuary staff. Mortuary staff are responsible for completing the local register, the bereavement suite patient details form, and the pathology department's electronic database for each body received. Bodies are only released from the establishment by mortuary staff during working hours. The establishment's release procedure includes checks of all applicable documentation and confirmation of identification with the collecting funeral director.

Viewings are conducted by prior arrangement during normal working hours and are carried out by mortuary staff . Under extenuating circumstances viewing may be conducted outside of normal hours, when a member of on-call staff and/or a member of security staff attends.

The mortuary includes a single PM suite incorporating two fixed tables. There are procedures in place for known high risk cases and for instances where a case is identified as high risk during the examination procedure.

The establishment has the capacity to store 23 bodies in monitored and alarmed fridges, of which three spaces are capable of storing bariatric cases. Histology blocks and slides are stored securely within the Pathology Department, which is accredited by CPA (UK) Ltd.

This was the second inspection of the establishment, which has been licensed since 2007. A previous inspection was conducted in 2011 from which there were no outstanding shortfalls or conditions against the licence.

The inspection included a review of documentation relevant to the establishment's activities, a visual inspection of the mortuary and histology laboratory, and interviews with key members of staff including: the Designated Individual (DI) who is the Clinical Director and a Consultant Histopathologist; the Mortuary Manager, who is also the Bereavement Services Manager; the Quality and Governance Manager; and an Anatomical Pathology Technologist.

A traceability audit was conducted on the bodies of three deceased subjects. The following information where applicable was cross referenced with the mortuary register, the bereavement suite patient details form and the department's electronic records: deceased's name, date of birth, hospital number, NHS number, storage location and location from where the body was received. An audit was also conducted on the records and paraffin embedded tissue blocks relating to four post mortem cases. The following information was cross referenced where applicable: deceased's name, unique post mortem number, the number of blocks produced, and the consent form indicating the fate of the blocks and associated slides. Traceability was maintained throughout and no discrepancies were identified in the accompanying documentation.

## Inspection findings

The HTA found the Designated Individual, the Licence Holder, and the premises and practices 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. | C 1 | The establishment's consent form states that 'blocks and slides used for diagnosis will normally be retained as part of the medical records of the deceased'. The DI is advised to include the use to which the material may be put, to ensure that consent for its retention and use is fully informed. The DI may wish to consider the wording contained within the HTA's model consent form and the PM 'guidance for the families of the deceased' document available on the HTA website, which states that 'with your consent, the tissue blocks and slides may be stored as part of the record of the post-mortem examination, sometimes called the pathology or medical record, in case they are useful to your family in the future'. |

| | | |
|---|---|---|
| 2. | C 2 | The process for seeking consent includes discussion about the PM examination procedure with a member of mortuary staff; the DI should consider including these details in either the bereavement services booklet or as a separate booklet provided to the deceased's family. The DI may wish to reference the PM 'guidance for the families of the deceased' document which can be found on the HTA website. |
| 3. | GQ 1 | Standard operating procedures (SOPs) are in place for mortuary procedures. The DI is advised to ensure that SOPs including, but not limited to, those concerning receipt of a body, PM examination, and release of a body reflect current practice. Specifically, SOP documents should all list what identifiers are checked when determining the identity of a body, what these identifiers are checked against, and the procedure to be followed should a discrepancy be identified during these identity checks. |
| 4. | GQ 2 | The DI may wish to consider extending the internal audit procedures to include examination/procedural audits to assess both the suitability of the SOP being observed and the competency of staff performing the procedure. |
| 5. | GQ 7 | The establishment has an SOP which identifies responsibilities and timeframes for reporting adverse incidents to the HTA. The DI is advised to review and amend the policy to reflect the change in terminology from 'Serious Untoward Incident' to HTA Reportable Incident (HTARI), and to ensure that the SOP includes reference to all HTARI criteria. |
| 6. | PFE 3 | Fridges within the mortuary are monitored twice daily during normal working hours and their temperature recorded. In order to mitigate the risk that an equipment failure may be undetected during out of hours periods, the DI is advised to ensure that checks on the fridges are performed and recorded at least once per day during weekend periods and national holidays. |
| 7. | PFE 5 | Maintenance records and service reports for mortuary fridges are currently retained by the Estates Department. To facilitate early identification of equipment problems, the DI is advised to ensure that copies of these records are provided to the mortuary manager. |
| 8. | D 1 | The establishment's' disposal procedure does not include a check against the laboratory records to determine the number of slides that have been cut from the tissue blocks. The establishment routinely cuts extra slides from each block to perform special stains and therefore there may be multiple slides cut from a block. Without performing this check, the establishment cannot ensure that all of the slides for a particular case have been identified when carrying out the family's wishes. The DI may also wish to consider a more consistent approach for the management of forms received from the Coroner concerning the fate of tissue taken during a coronial PM examination. Forms are currently held either by the laboratory or the pathologist. |

## Concluding comments

Mortuary staff have a good working relationship with ward staff and have developed a 'transfer to bereavement suite form'. This form includes a check list to ensure that bodies are received into the mortuary with all necessary information, and forms part of the initial risk assessment for those bodies subject to PM examination.

Discussions with the families of the bereaved take place in the presence of the attending consultant clinician, and are led by the bereavement manager who is also the mortuary manager. This arrangement ensures that questions regarding the PM examination process can be answered in full. Where necessary, counselling support is also available from clinical nurse specialists.

Staff facilitate the cultural and religious needs of the establishment's patient population, for example the viewing room has been designed to accommodate ritual washing and the establishment has procedures in place to enable 24 hour religious vigils.

The HTA has assessed the establishment as suitable to be licensed for the activities specified and has offered advice on a range of issues to prompte continuous improvement.

**Report sent to DI for factual accuracy: 15 April 2014**

**Report returned from DI: 06 May 2014**

**Final report issued: 12 May 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 |
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| **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.<br>• 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).<br>• 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.<br>• Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event.<br>• 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).<br>• 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.<br>• 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.<br>• Refresher training is available (e.g. annually).<br>• Attendance at consent training is documented.<br>• 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.