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

**Nottingham University Hospitals NHS Trust, Queen's Medical Centre Campus**

**HTA licensing number 12258**

**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**

**3-4 April 2012**

## 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.

Queen's Medical Centre (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 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

The establishment consists of premises at the Queen's Medical Centre, the hub, and premises at the City Hospital campus of the Nottingham University Hospitals Trust, the satellite. Post-mortem examinations for diagnosis are all undertaken at the hub premises. A body store is located at the satellite premises, with bodies being transferred to the hub if they are to undergo post-mortem examination for diagnostic purposes. The satellite site undertakes post mortem examination as part of activity linked to development of a national repository for surgical training. The establishment undertakes both adult and paediatric post-mortem examinations on behalf of multiple Coroners in addition to undertaking consented, hospital post-mortem examinations.

Routine post-mortem examinations are undertaken in the main examination suite. There is an additional, isolated examination suite which is used for performing high risk post mortem examinations.

During the inspection, areas where removal of tissue from the deceased may take place other than the mortuary were also visited and included the emergency department, maternity ward and neo-natal intensive care at the hub premises and the maternity ward and neo-natal intensive care at the satellite premises. In all of these areas, a Person Designated (PD) has been identified, who works within the establishment's governance system, maintains local

standard operating procedures (SOPs) and undertakes audits, risk assessments and compliance reviews.

In addition to the post mortem activity taking place under the licence, the establishment stores bodies and tissue for use for scheduled purposes.

At the hub premises there is a neuropathological archive used for research and teaching purposes. At the satellite premises there is a research tissue bank which has received generic ethical approval. Finally, at the satellite premises there is a group based within the clinical skills training centre which has started a program that accepts bodies donated for use in surgical training. The plans for this group, called the National Repository by the establishment, are ultimately to receive and distribute tissue for use in surgical training. To date, two bodies have been donated; however no tissue has yet been distributed.

All non post-mortem activity taking place under the licence is subject to oversight by the DI, with PDs having been identified in each area and working to the same system of governance.

All areas where licensable activity is undertaken were visited as part of the inspection. Advice has been given to the DI below relating to some of the licensable activities, and for clarity this has been given separately for each area of activity.

The establishment has been licensed by the HTA since August 2007 and this routine inspection was the second site visit since that time. The timetable for the site visit was developed in consideration of the original desk-based assessment of the establishment's licence application, the establishment's recent self-assessment, previous inspection report and pre-inspection discussions with the DI. During the visit, a visual inspection of the premises, review of the establishment's documentation and interviews with establishment staff were undertaken.

Audits were undertaken throughout the inspection and they have been summarised below by area of activity:

**Post Mortem and Neuropathological Archive**

Body location checks were undertaken at both the hub and satellite sites, where identifiers on three bodies were taken and checked against the mortuary database. In addition, their locations were cross checked against the location records. No anomalies were found. Also, details were taken of a body transferred from the satellite site to the hub for post-mortem examination. Records were checked for transport out of the satellite and receipt at the hub. Again, no anomalies were found. Three cases were chosen where tissue had been taken during post-mortem examination. Blocks and slides were sought and checked against either the consent form or coronial families' wishes form. One small anomaly was found (see item 4 in the advice section below). Finally, details of a brain that was in storage were taken and cross referenced against the laboratory database and consent to donate form. No anomalies were found.

**National Repository**

Identifiers from a body part in the freezer were taken and cross referenced against the repositories database and record of consent. No anomalies were found.

**Biobank Tissue Bank**

Details of three samples in the freezer were taken and cross referenced against the biobank's database and consent form. In addition, details of two tissue blocks were taken and again were cross referenced against the repositories database and record of consent. In all cases, no anomalies were found.

## 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. | C1 **National Repository** | The National Repository does not yet have a dedicated SOP for obtaining consent for body donation. From discussions with establishment staff, it was found that the two consents taken to date followed the procedure for consent for a post mortem examination.<br>The DI is advised to develop a dedicated SOP for the seeking of consent for the National Repository. |
| 2. | GQ1 **National Repository** | The National Repository is still developing many of its procedures. SOPs are in place for most activities; however these are basic and do not yet contain the necessary level of detail that will be needed as activity increases.<br>SOPs should include full details of all processes taking place. Extra details required include, but are not limited to, the body identification procedures, procedures used when processing tissue prior to storage, serology testing and interpreting results, tracing body parts that have been distributed for teaching purposes and transport of body parts procedures. |
| 3. | GQ2 **National repository** and **Biobank** | In the Biobank there are laboratory procedures which are used locally in laboratory areas, however these are not subject to any formalised document control system increasing the risk that out of date procedures could be in circulation.<br>Some other documents both in the Biobank and the National Repository are not covered by a formal document control system.<br>The DI is advised to implement a formal document control system for all documents related to licensable activity. |
| 4. | GQ6<br>**Post-mortem** | During the audit there was a discrepancy between the ID number on tissue blocks recorded in the establishment's database and the ID number on blocks and slides located in the archive. Establishment staff determined that this was due to a human labelling error and quality control failure while tissue was being processed.<br>There are existing sample audits of blocks and slides taking place at the establishment . The DI is however advised to undertake more frequent process audits of staff undertaking the procedurs to help verify that the establishment's procedures are being followed appropriately. |
| 5. | GQ7<br>**Biobank** | Records of adverse events at the Biobank were reviewed during the inspection. Whilst reviewing records of disposal, it was learned that a set of samples had been disposed of after thawing when a sample box was overturned. Although |

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| | and **National Repository** | recorded in the disposal log, there was no record of an adverse event being reported. Recording and investigating such events will help preventing them occurring again in the future.<br><br>The DI is advised to review the adverse event reporting procedures at the Biobank and if necessary amend the procedure or retrain staff to ensure that all adverse events involving relevant material are recorded and investigated.<br><br>The DI is also advised to develop and implement a robust procedure for the recording and investigation of adverse events at the National Repository. |
| 6. | GQ8<br><br>**National Repository** and **Post-mortem** | Some risk assessments are in place at both the National Repository and in the mortuary. In the National Repository these risk assessments are mainly health and safety orientated.<br><br>The DI is advised to asses all risks involved in the practices and procedures of the National Repository and document these formally. These risks should include the risks to the tissues themselves as well as the health and safety of staff. These risks include, but are not limited to, risks of failure to take fully informed consent, risks to stored tissue during transport and the risks of freezer failure where tissue is stored.<br><br>In the mortuary, the risk assessments do include some non-health and safety risks; however, they do not cover all potential risks such as misidentification of bodies.<br><br>The DI is advised to review the risk assessments in place against the 'clinical practices' taking place in the mortuary and expand these to include practices such as body identification and consent seeking. |
| 7. | PFE3<br><br>**Biobank** | The Biobank freezers have two sets of temperature monitoring equipment in place. The freezers' own internal temperature readout and also an external temperature monitoring system that covers all of the freezers. The Biobank staff check the difference between these two temperature readouts daily to check that the temperature monitors are functioning properly. Defined limits to any temperature difference between the two systems have also been set, which, if reached, trigger a maintenance visit to re-calibrate the monitors or detect any faults. This daily monitoring is recorded on a paper record system which is attached to the front of each freezer.<br><br>Although the daily comparison between both temperature monitoring systems represents good practice and would provide Biobank staff assurance that the temperature monitoring equipment is functioning as it should, the expected operating temperature of each freezer is not included on the temperature record sheet.<br><br>The DI is advised to amend the temperature monitoring sheet to include expected operational temperature ranges for each freezer and to include these limits on the freezer temperature monitoring sheet. This will help to ensure that if a freezer's temperature falls outside of the expected range, Biobank staff will be alerted during the daily temperature checks. |
| 8. | PFE4<br><br>**Post-mortem** | When transporting bodies between the satellite and hub premises for a consented post mortem, the establishment uses an undertaker to provide the transport service.<br><br>The DI is advised to put an agreement in place with the undertaker which details the expected levels of service being provided. |

## Concluding comments

Areas of good practice were observed throughout the inspection and of particular note are the systems of governance that the DI has implemented across the various areas operating under the licence.

Not only has a Person Designated (PD) been nominated in each area, the DI has strengthened the governance systems in place locally by delegating tasks to each PD such as ensuring local SOPs are in place and that they are kept up to date. In addition each PD is expected to undertake local audits and risk assessments of the practices taking place. Each PD is expected to keep records of these activities in a local 'HTA folder'.

The DI and Quality Manager have implemented a system of annual review of the activities taking place in each area. Firstly a self assessment questionnaire is sent to each PD, the results of which are used to inform a visit by the DI and Quality Manager who then review local records of activities in more detail.

The system of governance implemented by the DI helps to keep staff aware of the regulatory requirements and their responsibilities under the licence.

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

**Report sent to DI for factual accuracy: 4 May 2012**

**Report returned from DI: 14 May 2012**

**Final report issued: 1 June 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 |
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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 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.<br>• Refrigerated storage units are in good working condition and well maintained.<br>• Surfaces are made of non-porous materials.<br>• The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).<br>• 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).<br>• There is appropriate PPE available and routinely worn by staff.<br>• There is adequate critical equipment and/or PPE available for high risk post mortems.<br>• There are documented cleaning and decontamination procedures.<br>• 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.<br>• Temperatures of fridges and freezers are monitored on a regular basis.<br>• There are documented contingency plans in place should there be a power failure, or overflow.<br>• Bodies are shrouded whilst in storage.<br>• 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.