Site visit inspection report on compliance with HTA minimum standards

Royal Victoria Infirmary

HTA licensing number 12341

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**

16-17 July 2015

Summary of inspection findings

This inspection was conducted jointly with assessors from the United Kingdom Accreditation Service (UKAS), who assessed the mortuaries and histopathology laboratory against selected licensing standards on behalf of HTA.

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 HTA found that Royal Victoria Infirmary (the establishment) had met the majority of the HTA standards. Minor shortfalls were found regarding the information leaflet for parents on perinatal PM examinations, training for hospital portering staff and documented risk assessments.

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 (DI) are set out in Section 18 of the Human Tissue Act 2004 ('the 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 licenses 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 comprises Royal Victoria Infirmary ('the hub') and two satellite sites (Freeman Hospital and the Campus for Ageing and Vitality, Newcastle General Hospital).

Over 700 adult post mortem (PM) examinations are performed each year in the mortuaries at the hub and at Freeman Hospital. These are mainly under the authority of HM Coroner for Newcastle upon Tyne, including some Home Office cases. The establishment also performs a small number of adult hospital (consented) cases each year. High-risk cases (up to Category 3) are conducted at the hub. The establishment also performs consented perinatal and paediatric PM examinations, including cases from other nearby NHS hospitals.

At the hub, tissue samples may be taken from deceased infants in the Paediatric Emergency Department under sudden unexpected death in infancy (SUDI) protocols, and in the Maternity Unit from stillbirths for cytogenetic testing.

A collection of pathology specimens used for undergraduate medical teaching is stored in the mortuary at the hub (refer to advice item 5). These specimens are existing holdings. In addition, liver and pancreas tissue samples donated by patients undergoing surgical procedures at Freeman Hospital for use for research are stored under other HTA licences.

The only licensable activity at The Campus for Ageing and Vitality is the storage of archived PM tissue blocks and slides. These are stored in separate rooms from diagnostic samples

taken from living patients. This storage area is monitored on closed circuit television by the Security Office, and access is restricted to staff from the Pathology Department.

Consent for adult PM examinations can be sought by any hospital clinician who has completed Trust consent training. This will change in the near future; a smaller core group of trained staff will, instead, be responsible for seeking such consent. Consent for perinatal PM examination is sought by consultant or specialist trainee obstetricians using a modified version of the Stillbirth and Neonatal Death charity (Sands) consent form. The Trust information leaflet for parents 'A guide to the post mortem examination of a baby' contains some information which is not compliant with the HT Act (refer to shortfall against standard C2).

The mortuary at the hub has refrigerated storage capacity for up to 105 bodies, including 35 bariatric spaces, five spaces for paediatric cases, and five in deep freeze. There is a stand-alone refrigerator in the mortuary for perinatal cases. This mortuary has a second, dedicated, suite for performing high risk PM examinations. Freeman Hospital mortuary has recently been refurbished and has refrigerated storage capacity for up to 95 bodies, including 30 bariatric spaces, five spaces for paediatric cases, and three in deep freeze. At each site, fridge temperatures are recorded manually each working day by mortuary staff. Fridge alarms, which ring to the Estates Department, are tested weekly. The temperature of the fridge in the Maternity Unit for temporary storage of stillbirths is recorded manually each day, its alarm rings locally within the Unit (refer to advice item 9).

All PM tissues for histopathological examination are processed into paraffin wax embedded tissue blocks and microscope slides at the hub. The establishment carries out neuropathological analysis of brains, including referrals from other HTA-licensed establishments. Other organs requiring specialist analysis, and toxicology samples, are sent to other HTA-licensed establishments.

The establishment has been licensed by the HTA since August 2007. Two previous site visit inspections have taken place (in May 2008 and June 2011). This report describes the third routine site visit inspection of the establishment, which was conducted jointly with the United Kingdom Accreditation Service (UKAS), who gathered evidence against selected licensing standards on behalf of HTA. The HTA inspector met with staff involved with licensable activities and reviewed documentation.

Storage locations and identifiers for three adult bodies (one at the hub, two at Freeman Hospital) were audited. The date of birth of one person had been written incorrectly on their wrist band when they were on the hospital ward. No other anomalies were found in this person's records, or in the other two cases audited. Records for a further four adults who had each been subject to a coronial PM examination were audited. For one case, the body admission number had been entered incorrectly in the mortuary register. All other records for this person, and for the other three cases audited, were correct.

The establishment stores brains taken under police authority during Home Office PM examinations performed here, and at other HTA-licensed establishments in the North East of England, by Home Office registered forensic pathologists who work for the Trust. Under s39 of the HT 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, the 2012 report of the Association of Chief Police Officers' (ACPO) audit of tissue held under police authority contained a recommendation that police exhibits held on HTA-licensed premises should be included within the regular HTA inspection process. Therefore, procedures for Home Office PM examinations and the management of tissues and organs taken for criminal justice purposes were reviewed by HTA at this site visit inspection. Any findings in relation to Home Office PM examinations and police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

Newcastle upon Tyne Hospitals NHS Foundation Trust holds other HTA licences under the Human Tissue (Quality and Safety for Human Application) Regulations 2007, HT Act and the Human Tissue (Quality and Safety of Organs Intended for Transplantation) Regulations 2012 (licensing numbers 11122, 12193 and 40045 respectively). The removal of relevant material from deceased donors in operating theatres for use for research takes place at the hub and at Freeman Hospital under satellite licences of NHS Blood and Transplant (licensing number 12608). Activities taking place under these other licences were not reviewed at this inspection.

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

Consent

Standard	Inspection findings	Level of shortfall
C2 Information about the consent process is provided and in a variety of formats.	The Trust information leaflet for parents 'A guide to the post mortem examination of a baby' states that PM tissue blocks and slides may be kept as part of the baby's medical record, and that such samples may also be used for teaching, quality assurance and clinical audit. However, this leaflet does not explain that storage of PM tissue samples for use for such purposes requires valid consent from the family. *(Refer to advice item 4)*	**Minor**

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	Senior portering staff train new porters in how to admit bodies to the mortuary. However, mortuary staff are not involved in the development or delivery of this training. Also, no records are kept of completion of training or of assessment of competence of portering staff.	**Minor**

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	Mortuary risk assessments generally focus on health and safety issues. Risks associated with key processes such as the identification of bodies, the traceability of tissues and organs removed at PM examination, and the seeking of consent for PM examination have not been assessed. *(Refer to advice item 8)*	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to re-design the sections of the Trust's 'Request & consent for adult post mortem examination' form relating to tissues and organs taken at PM examination, to give relatives more flexibility to choose which scheduled purposes these may be stored for in the future. For example, the choice to consent for retention for review in the future for the benefit of the family, for ethically approved research projects, and for teaching and quality control, could be given as separate options on the form.
2.	C1	Appendix 6 of the Trust's 'Care After Death policy', which covers hospital PM examinations, does not explain that a nominated representative may give consent for a PM examination on behalf of a deceased person, if that person had not done so or objected in life. The DI is advised this policy should refer to the nominated representative when it is next updated.
3.	C1	The DI is advised to discuss with HM Coroner for Newcastle upon Tyne whether the options on the Annex C form for disposal and retention for research of an organ could be more clearly separated. The options are adjacent to one another on this form, creating a potential risk that relatives are confused and select both in error.
4.	C2	The DI is advised to ensure that all staff seeking consent for perinatal PM examination are informed the outdated information leaflet has been replaced, and to remove outdated versions of this leaflet from circulation.
5.	GQ1	The DI is advised to review all standard operating procedures (SOPs) to ensure these contain an appropriate level of detail. For example, the 'Performing a Post mortem examination' SOP (reference AFMU054) does not state turnaround times for preparation of slides in priority and urgent cases, and the References section of some SOPs do not specify the documents to be referred to. Also, SOP CPQF021, which has inaccurate information about HTA Reportable Incidents (HTARIs), should be archived and reference to this document in other SOPs, such as HIMO050, should be removed.
6.	GQ2	The DI is advised to periodically review the findings of procedural and traceability audits, including how any non-conformances identified are being addressed, so he has ongoing assurance on the suitability of practices taking place under the licence.
7.	GQ6	The DI is advised to keep records of the removal of pathology specimens from

		the mortuary for use for teaching, and their return there after use, to ensure these specimens are traceable at all times.
8.	GQ8	The DI is advised to use the HTARI categories as a basis for identifying potential risks to be assessed. Risk assessments should clearly set out all existing risk control measures, any additional actions which may be taken to further reduce risks, and the timeframes and responsibilities for completion of such actions.
9.	PFE5	Regarding facilities and equipment, the DI is advised: • that the alarm on the Maternity Unit fridge should be tested regularly, and records of such tests be kept, and; • to retain local copies of records of mortuary equipment maintenance visits by the Estates Department or its subcontractors, as evidence these have taken place. Records are currently kept by the Estates Department.

Concluding comments

Despite the minor shortfalls, several strengths were identified. The DI receives strong support from his Persons Designated and from senior personnel at the Trust. The establishment enjoys a good working relationship with the office of HM Coroner for Newcastle upon Tyne. There is a comprehensive consent training presentation for adult PM examinations. The establishment's handbook for SUDI cases, that describes local protocols and is used to record tissue samples taken, is well-designed. Mortuary premises at each site are well maintained, spacious and fit for purpose following recent refurbishment.

A number of areas of practice require improvement, including three minor shortfalls. The HTA has given advice to the DI with respect to consent documents, SOPs and risk assessments, and facilities and equipment.

The HTA requires that the DI addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 07 August 2015

Report returned from DI: 13 August 2015

Final report issued: 13 August 2015

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 18 January 2016

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 thatneed 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).

PFE2 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.

PFE4 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.