Site visit inspection report on compliance with HTA minimum standards

Doncaster Royal Infirmary

HTA licensing number 12268

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**

22-23 July 2014

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.

Although the HTA found that the Doncaster Royal Infirmary (the establishment) had met the majority of the HTA standards, a minor shortfall was found in relation to the establishment's procedural documentation. However, following the inspection and prior to the draft report being issued, the establishment provided evidence to the HTA demonstrating that the relevant documents have been updated. Having reviewed this evidence, the HTA now considers the standard to be fully met.

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, 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

For the purposes of HTA licensing, the establishment consists of a hub site, Doncaster Royal Infirmary, and a satellite site, Bassetlaw Hospital. The hub site consists of a body store and post mortem suite, with laboratory facilities located nearby. The body store has 99 fridge spaces, including two for bariatric cases. Extra fridge capacity has recently been installed in the body store by converting a former high risk post mortem room to a large fridge containing racking. This overflow body store facility has capacity to store a further 20 bodies, which helps to alleviate capacity issues during busy periods over the winter.

The satellite site, Bassetlaw Hospital, consists of a body store only. Although bodies are only stored there pending transfer to other licensed premises for post mortem examination, or to funeral directors for burial or cremation, an HTA licence is maintained as removal of tissue may occur in the emergency department of the hospital in cases of sudden unexpected death of an infant.

At the laboratory located at the hub premises, tissue taken during post mortem examinations is processed into blocks and slides, reviewed by pathologists and stored until being archived, disposed of or returned, in accordance with the consent given.

The establishment undertakes adult post mortem examinations, either on behalf of the Coroner or with the consent of the deceased's family where there is clinical interest in a case. Around 800 coronial adult post mortem examinations are performed at the hub premises annually. Paediatric post mortem examinations are not undertaken, and these cases are transferred to another licensed establishment. Some known high risk PM examinations are performed following risk assessment, including for HIV, hepatitis B, hepatitis C and tuberculosis. Personal protective equipment is available for mortuary staff to use when undertaking these.

The establishment reported that the most recent adult, consented, hospital post mortem examination took place in 2012. On the rare occasion that these are undertaken, consent is sought by the clinician who was involved in the treatment of the deceased prior to death. Clinicians are supported by a member of the establishment's bereavement team; they have been trained in how to seek consent by a consultant pathologist, who is also the lead pathologist for the service and a Person Designated on the HTA licence. The bereavement staff are able to answer any questions that the family may have regarding the post mortem examination procedure in addition to helping ensure that all aspects of the consent form are covered in the conversation and recorded appropriately.

Post mortem examinations of infants are undertaken at another licensed establishment; however, consent for these is sought by registrars in the maternity department supported by a bereavement midwife who has received training in the seeking of consent and the use of the appropriate forms. The process of seeking consent is supported and recorded using the documentation provided by the other licensed establishment.

It was confirmed during the inspection that removal of various tissue samples may take place in other areas of the hub and satellite hospitals; these include blood, swabs and lavages from deceased children that have either arrived dead or die in the establishment's accident and emergency (A&E) department. The HTA visited the A&E department at Doncaster (the hub) Hospital, and the area where such samples would be taken was inspected. Samples are taken in a dedicated bay in the paediatric resuscitation area, which is private and is suitable for the procedure. Staff have guidance documents to follow, which detail the types of sample to be taken; only paediatric consultants are able to undertake the procedure. The coroner has also been made aware of the potential samples that may be taken in such cases and has given their approval for this to occur. Although appropriate procedures have been developed and a suitable area for the removal to take place has been identified, the DI has not nominated a Person Designated to act as a link to this activity taking place under her licence (see advice item 4).

In the establishment's maternity department, the remains of stillborn babies or fetuses may be stored temporarily prior to being moved to the mortuary so that, where appropriate, parents have the opportunity to view them on the ward. Remains are stored in a fridge that is kept in a small room, away from the main ward. The fridge's temperature is monitored and recorded daily as part of the department's daily essential equipment checks. These checks help to assure the DI that any failure of the fridges would be detected within a 24 hour period, even during holiday periods. In this area too, the nomination of a Person Designated to act as a link and oversee the conduct of licensed activities taking place in the department is recommended (see advice item 4).

This was the second site-visit inspection of the establishment and was a routine inspection to assess whether it continues to meet the HTA's standards. The timetable for the site visit was developed in consideration of the establishment's last self-assessed compliance information, as well as pre-inspection discussions with the DI and review of the previous inspection

findings. During the site visit, a visual inspection of the premises, review of documentation and interviews with establishment and coroner's office staff were undertaken.

An audit of bodies stored at both the establishment's hub and satellite premises was undertaken. Three bodies were chosen at random at each site and the identification details recorded on body tags were checked against details on the mortuary fridge doors in the case of the hub site, and on the location white board at the satellite site. In addition, and again at both sites, the body identification details from the wrist tags were cross checked against the mortuary registers. No anomalies were found during this audit.

A tissue traceability audit was also undertaken during the inspection. Four coronial post mortem examinations that were undertaken at the hub premises were chosen at random. In all four cases the physical blocks were sought and their details cross checked against the mortuary records, the establishment's laboratory's electronic tracking system and the post mortem tissue tracking excel database. In addition, the family's wishes forms were sought and it was verified that retained tissue had been treated in accordance with these wishes in each case. Again, no anomalies were found during the audit. It was noted during the traceability audit, however, that when disposing of tissue sensitively in accordance with families' wishes, the numbers of blocks and slides are not recorded. Instead, only the date of disposal is recorded (see advice item 8).

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

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	The establishment has two procedures relating to the identification of bodies prior to the post mortem examination taking place – SOP008 'Technical procedures post mortem' and SOP018 'Identification and post mortem checklist'. Neither of these makes it clear that both the mortuary technical officer (MTO) and the pathologist must perform identity checks on bodies prior to the examination starting. Additionally, the SOPs are not clear about whether evisceration without a pathologist being present is allowable. It should be noted that although the SOPs were not clear, the establishment reported that a pathologist always checks the identity of the deceased with the MTO prior to the post mortem examination taking place, and is required to authorise evisceration; however, the procedural documents do not reflect this adequately. *Following the inspection and prior to the draft report being issued the establishment has provided evidence to the HTA demonstrating that the documents have been updated. Having reviewed this evidence the HTA now considers the standard to be fully met.*	**Minor** ***Now fully met***

Advice

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

No.	Standard	Advice
1.	C3	Consent training was given to bereavement staff, who sit in with clinicians during the consent seeking process, around twelve months ago. The DI is advised to provide refresher training for bereavement staff who may be involved in a consent seeking process, to ensure that their knowledge is current. In addition the DI is advised to amend the consent SOP to reflect the new role of the bereavement staff in the consent process.
2.	GQ1	The establishment's receipt and release of bodies SOPs refer to identity checks, but do not fully detail what points of identification should be checked and what they should be checked against when receiving and releasing bodies.

		In addition, the SOPs do not include what to do if a discrepancy between any of the information being checked is found. The DI is advised to review and update these procedures to include specific details about the identity checks that are performed, how they are performed, who should perform them and what action to take if a discrepancy is found. The DI may also wish to consider creating separate sections in each procedure dealing with bodies from the community and bodies from the hospital, to highlight the differences in checks performed.
3.	GQ1	Staff at the establishment undertake regular checks on the bodies that are in storage to identify any which are being stored for longer than expected. This procedure however is not documented. The DI is advised to develop a new SOP which describes the audits of stored bodies and detail the steps to be taken if any such bodies are identified.
4.	GQ2	The DI is advised to appoint Persons Designated (PD) in the accident and emergency department and maternity department to act as a point of contact in relation to the licensed activity taking place. In this way, the DI will be made aware of any issues that arise and will, in turn, be better able to disseminate any licensing updates or information to staff in these areas. The DI is also advised to invite the PDs to governance meetings so that information regarding licensable activity can be shared.
5.	GQ6 GQ8	The establishment's mortuary register, a key tractability data record, dates back to 2009. Much of the information contained within the register is not replicated elsewhere. The DI is advised to risk asses the loss of or damage to the mortuary register and the resulting loss of tractability data. This risk assessment should include identifying and taking measures to mitigate the risk of such loss.
6.	GQ6 GQ1	It is Trust policy to attach an ankle id band to all deceased patients who die in the hospital. The DI is advised to review how the ankle identity information is used by staff in the mortuary and to reflect its use in the appropriate SOPs.
7.	PFE5	The establishment has wooden head blocks in the mortuary post mortem examination room. The HTA advises against the use of such porous materials in the post mortem examination room as they are a potential source of cross contamination or infection risk. The establishment is aware of this position and has undertaken a risk assessment regarding the use of the wooden blocks. The risk assessment detailed that some pathologists consider the risks of slippage when using wooden blocks to be reduced by their use and therefore, with a thorough post use cleaning and disinfection regimen in place have considered their on-going use as suitable. The DI is advised to keep this under review.
8.	D2	The DI is advised to develop a procedure by which the numbers of individual blocks and slides that are being disposed of sensitively by the establishment are recorded so that a full audit trail of all tissue from retention to disposal is maintained.

Concluding comments

Good practices were observed during the inspection, some examples of which are included below.

The establishment has developed a system to monitor fridge space capacity at the hub premises. The bodies being stored are counted twice daily and the resulting figure used to assign a red, amber or green status for the mortuary capacity. Red and amber levels of alert trigger various actions to help ensure that the establishment does not become short of storage space for bodies.

The establishment's Trust has developed a 'Death of a Patient Operational Policy' which brings together many aspects of care of the deceased from the ward through to the mortuary. The policy is based around ensuring that the dignity of the deceased is maintained and reflects the care shown to the deceased that families would expect.

There are a number of areas of practice that require improvement, including one minor shortfall. The HTA has given advice to the Designated Individual on a range of issues, including documentation, records management and governance.

The HTA requires that the Designated Individual 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). However, evidence has been provided to the HTA by the establishment to show that the shortfall is now being fully met. Upon review of this evidence the HTA now considers all standards to be fully met and therefore a CAPA plan is no longer required.

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

Report sent to DI for factual accuracy: 19 August 2014

Report returned from DI: 5 September 2014

Final report issued: 25 September 2014

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. • There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination). • There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. • Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). • Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. • Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent. • Refresher training is available (e.g. annually). • Attendance at consent training is documented. • If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

• Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
  ○ post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
  ○ record keeping
  ○ receipt and release of bodies, which reflect out of hours arrangements
  ○ lone working in the mortuary
  ○ transfer of bodies and tissue (including blocks and slides) to other establishments or off site
  ○ ensuring that tissue is handled in line with documented wishes of the relatives
  ○ disposal of tissue (including blocks and slides)
(Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
• Policies and procedures are regularly reviewed (for example, every 1-3 years).
• There is a system for recording that staff have read and understood the latest versions of these documents.
• Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit
• There is a quality manual which includes mortuary activities. • Policies and SOPs are version controlled (and only the latest versions available for use). • There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits). • Audits include compliance with documented procedures, records (for completeness) and traceability. • Audit findings document who is responsible for follow up actions and the timeframe for completing those actions. • Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why. • There is a complaints system in place.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
• Staff are appropriately trained/qualified or supervised. • Staff have annual appraisals. • Staff are given opportunities to attend training courses, either internally or externally. • Attendance by staff at training events is recorded.

- There is a documented training programme for new mortuary staff (e.g. competency checklist).

GQ4 There is a systematic and planned approach to the management of records

- There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.
- There are documented SOPs for record management.

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.