Virtual Regulatory Assessment (VRA) inspection report on compliance with HTA licensing standards
Inspection date: **9-10 June 2021**

# University Hospital of North Tees

HTA licensing number 12446

Licensed under the Human Tissue Act 2004

**Licensed activities**

The table below shows the activities this establishment is licensed for and the activities currently undertaken at the establishment.

| Area | 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 | Storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose |
|---|---|---|---|
| **Hub site**<br>**University Hospital of North Tees** | Licensed | Licensed | Licensed |
| **Mortuary** | | | *Carried out* |
| **Pathology lab** | | | *Carried out* |
| **Maternity** | | *Carried out* | *Carried out* |
| **A&E** | | *Carried out* | *Carried out* |
| **Satellite site**<br>**Hartlepool Hospital** | Licensed | Licensed | Licensed |
| **Mortuary (satellite site)** | | | *Carried out* |
| **Maternity** | | *Carried out* | *Carried out* |

**Summary of inspection findings**

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that University Hospital of North Tees (the establishment) had met the majority of the HTA's standards, eleven major and five minor shortfalls were found against standards for Consent, Governance and Quality, Traceability and Premises, Facilities and Equipment.

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.

**Compliance with HTA standards**

***Major shortfalls***

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| **C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice** | | |
| b) There is a documented standard operating procedure (SOP) detailing the consent process | There is no documented SOP in place detailing the process for seeking consent for adult and perinatal/paediatric hospital post mortem (PM) examinations. | **Major** |
| **C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent** | | |
| a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice | There is no training for those seeking consent for perinatal/paediatric hospital PM examinations. | **Major (Cumulative)** |

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|---|---|---|
| b) Records demonstrate up-to-date staff training | *Perinatal/Paediatric PM examinations:*<br>No records were provided to demonstrate staff have up-to-date training. No accessible records are held for staff to determine who is appropriately trained to seek consent. | |
| d) Competency is assessed and maintained | Staff competency in seeking consent for perinatal/paediatric PM examination is not assessed. | |
| **GQ1 All aspects of the establishment's work are governed by documented policies and procedures** | | |
| a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath | SOPs do not include sufficient detail of procedures for:<br>• Transfer of bodies to freezer storage;<br>• Identification of deceased for viewing of bodies; and<br>• Transfer of deceased does not include the required check of three identifiers of the deceased at all stages of the procedure.<br>The SOPs describing the mortuary procedures do not include the use of the electronic mortuary management system, EDEN.<br>There are no SOPs in place for:<br>• Repatriation of tissue to bodies prior to release; and<br>• PM examination process in the event of the contingency plan being activated. | **Major** |
| c) Procedures on body storage prevent practices that disregard the dignity of the deceased | The establishment does not have a procedure in place for checking and documenting the condition of bodies during the length of stay in the mortuary. | **Major** |
| **GQ2 There is a documented system of audit** | | |

| | | |
|---|---|---|
| a) There is a documented schedule of audits | The scope of the audit schedule for licensed activities conducted under the licence is limited. The audit schedule does not include sufficient vertical or horizontal audits to check compliance with documented procedures, the completion of records and traceability of bodies. | **Major** |
| **GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks** | | |
| c) Staff are assessed as competent for the tasks they perform | Although staff have been initially 'signed off' on completion of training, there is no on-going competency assessments for staff. | **Major** |
| **GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored** | | |
| a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis | The risk assessments do not cover all HTARI categories or the risks of incidents occurring. | **Major** |
| **T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail** | | |
| c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier | The procedure for conducting viewings does not include steps to check a minimum of three identifiers of the deceased, provided by relatives, against the identification on the body before a viewing takes place. | **Major** |
| g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings) | The establishment only receive telephone confirmation that cytogenetic specimens sent off-site have arrived at the receiving laboratory. There is no documented procedure in place for sending specimens off-site for analysis. | **Major** |
| **PFE2 There are appropriate facilities for the storage of bodies and human tissue.** | | |

| | | |
|---|---|---|
| e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range | There is no formal testing of the fridge and freezer temperature alarms to ensure call-out procedures work and are followed. | **Major** |
| **PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored** | | |
| c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually | The establishment cannot provide evidence that the PM room ventilation system has been serviced regularly. The last available report was from 2017. | **Major** |

***Minor Shortfalls***

| **Standard** | **Inspection findings** | **Level of shortfall** |
|---|---|---|
| **C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice** | | |
| d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives | The adult PM examination consent form does not include the option for repatriation of an organ to the body. | **Minor** |
| **GQ5 There are systems to ensure that all untoward incidents are investigated promptly** | | |

| | | |
|---|---|---|
| a) Staff know how to identify and report incidents, including those that must be reported to the HTA | The inspection team identified an incident in the establishment's incident log that should have been reported to the HTA as a HTARI. | **Minor** |
| d) Information about incidents is shared with all staff to avoid repeat errors | The portering team is not represented at governance meetings relating to the HTA licence. | **Minor** |
| **PFE2 There are appropriate facilities for the storage of bodies and human tissue.** | | |
| f) Temperatures of fridges and freezers are monitored on a regular basis | The establishment does not have a formal system to review and record trends in storage temperatures. | **Minor** |
| **PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored** | | |
| f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept | The establishment cannot provide evidence that the trolleys and hoists have been serviced regularly. | **Minor** |

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, 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.

**Advice**
The HTA also advises the DI to consider the following to further improve practice:

| Number | Standard | Advice |
|---|---|---|
| 1. | C1g | The DI is advised to update the adult PM examination consent seeking form to include the hierarchy of qualifying relationships in the consent seeker notes section. |
| 2. | GQ1d | The DI is advised to ensure documents are authorised by a person other than the author. The SOP for transferring |

| | | |
|---|---|---|
| | | bodies to other establishments was written and authorised by the same person. |
| 3. | GQ3g | The DI is advised to have a training and induction plan for using the PM examination suite if the contingency plan is activated. |

**Background**

University Hospital of North Tees (UHNT) is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

UHNT has been licensed by the HTA since 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in January 2016.

Since the previous inspection, there have been significant changes to the licence. Since July 2018, the UHNT and James Cook University Hospital mortuary services have been working collaboratively; this change was led by HM Coroner and is part of a wider pathology collaboration. Adult post mortem examinations are performed at James Cook University Hospital, with UHNT post mortem suite designated for contingency purposes. A joint mortuary manager is in post to oversee the licensable activities and other staff are employed with letters of access to work at both sites, although currently no James Cook University Hospital staff are working at UHNT.

**Description of inspection activities undertaken**

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

*Standards assessed against during inspection*

Standards GQ1b, T2b and PFE3e were not assessed as they are not applicable to the activities undertaken. Standards PFE1b, PFE2d and PFE3a are applicable but were not assessed. The remaining 66 HTA licensing standards (standards published 3 April 2017) were assessed.

*Review of governance documentation*

The inspection included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records for the mortuary, records of equipment servicing, audits, risk assessments, meeting minutes and reported incidents.

*Visual inspection*

There was no site visit inspection as part of this assessment.

*Meetings with establishment staff*

Staff carrying out processes under the licence were interviewed including the DI, mortuary assistant, a pathologist, portering staff, maternity consent seeker representative, adult consent seeker and A&E SUDIC representative.

**Report sent to DI for factual accuracy: 28 June 2021**

**Report returned from DI: 6 July 2021**

**Final report issued: 12 July 2021**

## 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 Virtual Regulatory Assessment Report.

## Date: 21 December 2021

## Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the DI 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.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

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. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, 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 provided.

HTA inspection reports are published on the HTA's website.

**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 Human Tissue Act 2004 (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 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:

   - A notice of proposal being issued to revoke the licence
   - 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.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - 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 Codes of Practice, 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 review or at the time of the next 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. Establishments 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 routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.