Site visit inspection report on compliance with HTA licensing standards
Inspection date: **16 – 17 October 2019**

University Hospital of North Durham

HTA licensing number 12461

Licensed under the Human Tissue Act 2004

Licensed activities

Hub and satellite site rows denote whether the site is licensed to carry out an activity; the rows below the hub and satellite rows denote whether or not the activity is currently carried out in that area.

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 **University Hospital of North Durham**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology laboratory	-	-	*Carried out*
Maternity department	-	*Carried out*	*Carried out*

Accident and Emergency (A&E) department	-	*Carried out*	-
Satellite site **Darlington Memorial Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Maternity department	-	*Carried out*	*Carried out*
A&E department	-	*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 the University of North Durham (the establishment) had met the majority of the HTA's standards, seven major and six 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		
e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained	The inspection team's tissue traceability audit found that tissue blocks are occasionally used for laboratory quality assurance purposes without appropriate consent. Use for quality assurance is not listed on the hospital post-mortem examination (PM) consent form, the Coroner's consent forms or in the information provided to those giving consent.	**Major**
g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided	The consent form for adult PM examination does not reflect the requirements of the HT Act and the HTA codes of practice. It is not clear how the wishes for fate of tissue taken at PM examination should be recorded on the consent form.	**Major**
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.	Some standard operating procedures (SOPs) do not include sufficient details of procedures. • The SOPs for viewings and release of bodies from the mortuary do not describe the minimum number of identifiers of the deceased that should be used and how identification checks should be performed. • The mortuary SOP for temperature monitoring does not state the alarm trigger points for the permanent body store units at the hub and satellite sites.	**Major**

b) Procedures on evisceration ensure that this is not undertaken by an APT unless the body has first been examined by the pathologist who has instructed the APT to proceed	Anatomical Pathology Technologists (APT) undertake evisceration before external examination of the body by the pathologist. The SOP for PM examination describes that evisceration can be undertaken by an APT without the body first being examined by a pathologist.	**Major**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records)	At Darlington Memorial Hospital, the prefix of the mortuary identification number assigned to the body upon arrival at the mortuary is not recorded in the mortuary register correctly. This means that the identification number recorded in the mortuary register does not match the other documentation or records associated with the body. It also means that the identification number recorded in the mortuary register is not unique.	**Major**
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	Procedures for identification of bodies do not always use a minimum of three identifiers of the deceased. • Identification of bodies for release from the mortuary to funeral directors may be performed using only one or two identifiers provided by the funeral directors. • For bodies admitted to the mortuary from the hospital, identification for PM examination may be performed using only two identifiers. • Identification of bodies for viewings may be based on only one identifier of the deceased (full name) provided by the family at the time of arranging a viewing and upon arrival at the mortuary.	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		

a) The premises are clean and well maintained	The mortuary at University Hospital of North Durham is not adequately cleaned or maintained. • At the time of the inspection, there was tissue debris on the surfaces of the PM tables and the dissection unit. • There are areas of damage to the floor and walls in the body storage area.	**Major**

Minor shortfalls

Standard	Inspection findings	Level of shortfall
GQ4 There is a systematic and planned approach to the management of records		
b) There are documented SOPs for record management which include how errors in written records should be corrected	The inspection team found some minor amendments to written mortuary records which were difficult to read. The SOP for record management does not detail how errors in written records should be corrected.	**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	During a review of previous incidents, the inspection team found one near miss incident that should have been reported to the HTA. The DI is required to retrospectively report this incident to the HTA. *The establishment has reported this near miss incident to the HTA following the inspection.*	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The inspection team's tissue traceability audit identified discrepancies in three cases. The number of tissue blocks recorded at the time of the PM examination was not consistent with the number of tissue blocks received in the Pathology laboratory.	**Minor**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		

e) Security arrangements protect against unauthorised access and ensure oversight of visitors and contractors who have a legitimate right of access	The establishment have identified a risk of unauthorised access to the mortuary at University Hospital of North Durham through the rear door of the mortuary. The inspection team witnessed this door being left open whilst body transfers were in progress. This practice risks unauthorised access to the mortuary.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The establishment does not know what the temperature alarm trigger points are for the main mortuary fridges and freezer. This means the establishment cannot provide assurance that the alarms will trigger when storage temperatures deviate from ranges that will optimally maintain the condition of bodies.	**Minor**
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	The temperature alarms for the fridges and freezers are not tested regularly to ensure that they will trigger when temperatures deviate from set ranges.	**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 advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	C1(c)	The DI is advised to review the written information provided for those giving consent for adult PM examination. The information form contains sections to record the relatives' wishes. This information is also recorded on the PM consent form. This could lead to confusion and transcription errors.
2.	C1(g)	The DI is advised to consider using the HTA model consent form for adult PM examination. This will help ensure that informed consent is sought for PM examination and the options for the fate of tissues are accurately recorded. The DI is advised to liaise with the Coroner's office to ensure that the family wishes forms accurately reflect the purposes for which retained tissue may be used.

3.	GQ1(a)	The DI is advised to review governance documents relating to licensed activities to ensure that references to the HTA codes of practice are up to date.
4.	T1(a)	The DI is advised to consider adding the mortuary identification number allocated upon receipt of bodies to the mortuary to the identification bands attached to the body. This may help to further strengthen the procedures for traceability of bodies.
5.	PFE2(e)	The DI is advised to ensure that the contingency refrigerated storage units are connected to the remote temperature alarm system when they are in use.

Background

The University Hospital of North Durham has been licensed by the HTA since April 2007. This was the fourth site visit inspection of the establishment; the most recent previous inspection took place in March 2016.

Since the previous inspection, the number of bodies admitted to the mortuary and the number of PM examinations undertaken at University Hospital of North Durham has reduced. The mortuary at Darlington Memorial Hospital is a new facility since the last inspection.

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

All 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

The inspection team undertook a review of policies and procedural documents relating to licensed activities, cleaning records for the mortuary and PM rooms, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, incident reports, staff training records and consent training information.

Visual inspection
The inspection team carried out visual inspection of the body storage areas, PM rooms, viewing rooms, the maternity departments at both sites and the Pathology laboratory tissue storage area at the hub site.

Audit of records
The inspection team undertook audits of traceability for four bodies in storage at the hub site and four bodies at the satellite site. Traceability details were crosschecked between the identification band on the body, information on the door of the storage unit (hub site), mortuary whiteboard, mortuary register and paperwork. For one body, there was a minor discrepancy in the surname written on the mortuary whiteboard compared to all of the other information. At the satellite site, the prefix of the mortuary identification number assigned to bodies is not recorded correctly in the mortuary register.

Audits were conducted of tissue taken at PM examination for four cases at the hub site and four cases at the satellite site. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, laboratory database, and tissue blocks being stored. One of the cases reviewed confirmed that disposal of tissue had been completed in line with the wishes of the family. Full traceability of tissues was demonstrated for all eight cases. However, discrepancies were found for three cases between the number of tissue blocks taken at PM examination and received in the Pathology laboratory. In addition, the inspection team found that the laboratory had used PM tissue for a scheduled purpose for which consent had not been given.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence, including mortuary staff, portering staff, laboratory staff and individuals involved in the consent seeking process. Telephone interviews were conducted with staff involved in the Sudden Unexpected Death in Infancy and Childhood (SUDIC) protocol.

Materials held for the police
Under section 39 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, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings stored in a designated area in the PM room were reviewed by the HTA during the inspection.

Any findings in relation to 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.

Report sent to DI for factual accuracy: 13 November 2019

Report returned from DI: 09 December 2019

Final report issued: 09 December 2019

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: 20 February 2020

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 the 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.