Inspection report on compliance with HTA licensing standards
Inspection date(s): **16 and 17 February 2023**

Royal Stoke University Hospital

HTA licensing number 12224

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 **Royal Stoke University Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Accident and emergency department	-	*Carried out*	-
Maternity department	-	*Carried out*	*Carried out*
Pathology	-	-	*Carried out*

Satellite County Hospital	-	Licensed	Licensed
Mortuary	-	*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 Royal Stoke University Hospital ('the establishment') had met the majority of the HTA's standards, two major and three minor shortfalls were found against the standards for Governance and quality systems, 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 shortfall identified during the inspection.

Compliance with HTA standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
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 number of slides that are cut from PM blocks are not always recorded on the establishment's electronic system. During the HTA traceability audit the records for two cases did not accurately reflect the number of slides in storage. Furthermore, there is not a system in place to ensure that PM slides taken by pathologists are then returned to the histology department in a timely manner.	**Major**

	During the HTA audit, the inspection team identified one case from 2017 where the location of slides was not recorded.	
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's Codes of Practice		
(b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary.	There is no procedure for following up with the Coroner to determine when the Coroner's authority has ended. This means that the establishment staff cannot assure themselves that tissue is not kept for longer than necessary. During the site visit, the inspection team carried out an audit of tissue taken during PM. Two of the cases selected for review had been stored since 2018 and 2020 and there was no documented evidence that these cases had been followed up with the Coroner to establish the families' wishes.	**Major**

Minor shortfalls

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
(d) competency is assessed and maintained.	Although staff receive consent training from the establishment for which perinatal PMs are referred there are no competency assessments.	**Minor**
GQ2 There is a documented system of audit		
(a) There is a documented schedule of audits.	The PM blocks and slides stored by the establishment are scheduled to be audited annually however due to resources this has not been carried out for approximately three years.	**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 unauthorized access and ensure oversight	CCTV covers the entrance and exits of the mortuary at County Hospital however access to the body store is via key coded locks. Although CCTV provides oversight of people accessing the mortuary, and is audited for this purpose, there	**Minor**

of visitors and contractors who have a legitimate right of access.	is no controlled-access system which poses a risk of unauthorized access.	

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfall 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(b)	The establishment do not carry out perinatal PMs, however they take consent using the referring hospital's consent documentation. There is an SOP for this however the ratification and approval of the document has been delayed. The DI is advised to get the reviewed document published and distributed to staff as soon as possible to ensure that knowledge of processes is kept up to date.
2.	C2(b)	Staff are trained in consent seeking for perinatal PMs by the establishment for which they are referred. Although staff had up to date training there are no centralised records. The DI may wish to consider developing a database of consent trained individuals in order to ensure training is kept up-to-date and is auditable.
3.	GQ6(a)	There are some duplications of hazards in the establishment's risk assessments relating to licensable activity. The DI may wish to review these and amalgamate some which overlap. This will help to streamline documentation and also reduce the time taken for staff to review the documents.
4.	GQ6(b)	The risk of a security breach is covered in the establishment's suite of risk assessments however not all mitigations in place to lower the risk have been documented. The DI is advised to document the robust security audit procedures which are in place as a further mitigation within this assessment.
5.	PFE3(f)	Key items of equipment are subject to regular maintenance however records are not kept within the mortuary and only available upon request. The DI is advised to request copies of all maintenance, servicing and repair reports so that they are easily accessible to the Mortuary Manager for review and monitoring purposes.

Background

Royal Stoke University Hospital has been licensed by the HTA since May 2007. This was the fourth inspection of the establishment; the most recent inspection took place in April 2017.

Since the previous inspection, there have been some significant changes to the licence arrangements including the change of Designated Individual (DI) in January 2018, and a change in Corporate Licence Holder contact (CLHc) in November 2021.

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 reviewed the establishment's self-assessment document provided by the DI. Policies and procedural documents relating to licensed activities were reviewed. This included standard operating procedures, risk assessments, audits, incidents, meeting minutes, equipment servicing reports, and training and competency assessment documents. Consent seeking procedures and information for families giving consent for hospital and perinatal PMs were also reviewed.

Visual inspection

The inspection team undertook a site visit inspection of the two sites including the mortuary body storage area, the PM suite, the Maternity Department and histology filing room at Royal Stoke University Hospital, and the mortuary body storage area at County Hospital.

Audit of records

The inspection team undertook audits of traceability for five bodies in storage at the Hub site, this included hospital cases in the fridge and freezer. Traceability details were crosschecked between the identification band on the body and information on the electronic and paper records. No discrepancies were identified.

The inspection team undertook audits of traceability for four bodies in storage at the Satellite site, this included hospital cases in the fridge. Traceability details were crosschecked between the identification band on the body and information on the electronic records. No discrepancies were identified.

Audits were conducted of stored tissue taken at PM examination for eight cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, the electronic database, and tissue being stored. The establishment could not provide documented evidence that they had consent to retain the samples from two cases from 2018 and 2020 as the family wishes form had not been obtained from the Coroner. For one case from 2017, slides could not be located. For two cases, the number of slides had not been recorded accurately on the electronic system.

Meetings with establishment staff
The assessment team met with staff carrying out activities under the licence, including an Anatomical Pathology Technologist (APT), Mortuary Manager, a Porter and the Bereavement Midwives involved in the perinatal PM consent seeking process.

Report sent to DI for factual accuracy: 08 March 2023

Report returned from DI: 03 April 2023

Final report issued: 13 April 2023

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: 19 June 2023

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 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 inspection.

   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 inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

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