Inspection report on compliance with HTA licensing standards
Inspection date: **21-22 February 2023**

Basingstoke and North Hampshire Hospital

HTA licensing number 12362

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 **Basingstoke and North Hampshire Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	*Carried out*	*Carried out*
A&E	-	*Carried out*	-
Satellite site **Royal Hampshire**	Licensed	Licensed	Licensed

Hospital			
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	*Carried out*	*Carried out*
A&E	-	*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 Basingstoke and North Hampshire Hospital ('the establishment') had met the majority of the HTA's standards, ten major and three minor shortfalls were found against standards for consent, 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 shortfalls identified during the inspection.

Major shortfalls

Standard	Inspection findings	Level of shortfall
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.	Whilst policies and Standard Operating Procedures (SOPs) cover mortuary procedures, there is a lack of consistency in the level of detail in SOPs. Key steps are included but these do not specify the individual actions that need to be undertaken to accomplish each step. These include, but are not limited to, SOPs detailing the process for: • Internal transfers within the hospital and between sites. • Transfers and checks for transfer of bodies to the freezer. • Details on unique identifiers when completing identification checks. • Royal College of Pathologists (RCPath) guidance on pathologists completing external post mortem examinations before evisceration. This is not an exhaustive list of the SOPs requiring amendment. To fully address this shortfall the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate and contain sufficient detail to reflect current practice. This was identified as a shortfall at the last HTA inspection, and whilst addressed at the time, the updated SOPS lack consistency.	**Major**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	At the time of the inspection an updated audit schedule was not submitted. The audit schedule from 2022 did not contain completion dates for mortuary specific audits.	**Major (Cumulative)**
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	Audit templates reviewed do not contain responsible persons or time frames for completion of actions.	**Major (Cumulative)**

c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	At the time of inspection audits for retained and archived tissue were not submitted, the inspection team are therefore not assured that staff are fully aware of what is held and why.	**Major (Cumulative)**
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	Risk assessments for procedures related to the licensed activities are not reviewed on a regular basis. This was identified as a shortfall at the last HTA inspection, and whilst risks were assessed as part of the corrective action plan in 2018, these have not been reviewed since.	**Major (Cumulative)**
b) 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	Risk assessments contain risk scoring but do not include further mitigations, who is responsible for completing actions or a timeframe for completion. Furthermore, risk assessments do not contain sufficient detail, or cover all risks associated with regulated activities, such as: • Viewing of the wrong body • Post mortem of the wrong body. This is not an exhaustive list of the risk assessments requiring amendment. To fully address this shortfall the establishment should review all HTA reportable incidents and ensure they are risk assessed with sufficient detail to mitigate risk.	**Major (Cumulative)**
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 viewing process on both sites does not include checking three points of identification of the deceased when meeting visitors to ensure the correct body has been prepared. The inspection team were also not assured that the three points of identification provided by funeral services were always the identifiers that could be compared against the wristband. This increases the risk of the wrong body being viewed or released.	**Major**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The inspection team were not assured that tissue taken at post mortem was fully traceable. Tissue is transferred between sites, and there is currently no amalgamated system in place to record details of tissue traceability. The inspection team identified three cases where blocks were on a different site to the slides, and whilst all accounted for, no member of staff had oversight of its exact location, or when they would be reunited. This increases the risk of loss of post mortem tissue.	**Major**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete	The tissue audit at Basingstoke and North Hampshire Hospital identified a case where the Coroner's jurisdiction had ended in October 2022 and the tissue was still being retained with no details of the families wishes on file. The tissue audit in Royal Hampshire Hospital identified a case where a family had not specified their wishes for the tissue, and it has been retained since 2019. In both cases, there was no documented evidence that these were being followed up by staff and was contrary to the department's policy of disposing tissue after one month if no family wishes were received. Therefore, tissue is not disposed of in a timely manner and there is a risk that it is being retained against the families' wishes.	**Major (Cumulative)**

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 system in place for contacting the Coroner's office and ensuring the families wishes have been received when the Coroner's jurisdiction has finished. This has resulted in tissue being kept longer than necessary. This was a shortfall at the last inspection, and whilst corrective actions were put in place at the time, the inspection team were not assured that the new processes had been implemented.	**Major (Cumulative)**
c) Disposal is in line with the wishes of the deceased's family	Families' wishes had not been received or followed up for two cases identified in the tissue audits. This poses a risk of the disposal method not being in line with the families' wishes.	**Major (Cumulative)**
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 age and subsequent deterioration of some areas means that they cannot be maintained, cleaned and decontaminated effectively. Examples include: • Limescale build up on post mortem room sinks and benches. • Damaged wooden door frames and untreated wooden window frames. • Deterioration and damage to ceiling tiles.	**Major**
c) There are documented cleaning and decontamination procedures and a schedule of cleaning.	Although the mortuary premises are subject to regular cleaning, this is not documented or evidenced.	**Major**

d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	The viewing room at Basingstoke and North Hampshire Hospital is currently being used for a temporary fridge unit. The inspection team identified that this area was not secure due to a broken window latch. This area is not covered by CCTV. The establishment put in remedial actions to secure the area before the inspection team left the site.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
d) Fridge and freezer units are in good working condition and well maintained	The fridge floors and internal racking at Royal Hampshire Hospital are showing signs of limescale build up and rust. The flooring of the fridge units is constructed of embossed patterned metal, this along with the rusting, means there is a risk that the fridges cannot be cleaned or decontaminated effectively.	**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		
b) Records demonstrate up-to-date staff training	Individual staff members explained they had received recent training for taking consent. However, a documented list of consent takers, with training dates of completion was unavailable.	**Minor**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Persons designate (PDs) from maternity wards and A&E do not receive invites to the HTA governance meetings or receive minutes. This poses a risk to the DI not having sufficient oversight of regulated activities in these areas.	**Minor**
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	The main mortuary fridges are alarmed and tested regularly; however, the inspection team identified a single freezer within the Royal Hampshire Hospital post mortem room that was in use, and not connected to an alarm system. Furthermore, the single unit maternity fridges on both sites were not connected to an alarm system.	**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(e)	The establishment gives the option to families for retention of post mortem material for research. Currently the establishment does not conduct research. The DI is advised to consider providing this information to families to set expectations and ensure that informed consent is obtained.
2.	GQ6a	The DI is advised to monitor the ambient temperature in the fridge room and adjacent offices at Basingstoke and North Hampshire Hospital mortuary. This will assist with the risk assessments for

		equipment breakdown and working conditions for staff.
3.	GQ6a	The DI is advised to audit the lone working arrangements to ensure the mitigations to risk already in place are suitable and in use.
4.	T1d	The DI and mortuary manager are advised to audit the process of identifying same and similar names, as slight discrepancies were identified in the register. These were not sufficient to amount to a shortfall.
5.	PFE1d	The DI is advised to assess the document management for the mortuary key traceability sheets in the porter's lodge, to ensure oversight and ease of completing access audits.
6.	PFE3a	The DI is advised to monitor very minor rust to the mortuary trolleys to ensure it does not deteriorate further as this could result in a shortfall of HTA standard PFE3(a).
7.	PFE3e	Chemicals for preservation of tissue samples are currently not stored in ventilated areas and transferred to the post mortem room when required. The DI is advised to strengthen procedures to ensure staff are aware that these chemicals should always be opened and used in ventilated areas.
8.	N/A	The mortuary in Basingstoke and North Hampshire Hospital is storing a small number of organs in display cases for teaching purposes. Whilst these are '***existing holdings'*** and predate the Human Tissue Act 2004 the DI is advised that these are fully catalogued and the good practice guidance, set out in the HTA's codes of practice, is followed.

Background

Basingstoke and North Hampshire Hospital has been licensed by the HTA since August 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in August 2018.

Since the previous inspection, there has been a change to the designated individual and mortuary management. Royal Hampshire County hospital has become a satellite site on this licence and was included as part of this 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 included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and training records for staff.

Visual inspection
The inspection included a visual assessment of both Basingstoke & North Hampshire Hospital and Royal Hampshire Hospital. This included the mortuary fridge rooms, post mortem rooms, viewing areas, laboratory and maternity storage areas. The inspection teams observed the processes for admission, release and viewing of bodies within the mortuaries.

Audit of records

Basingstoke and North Hampshire Hospital (Hub site)
Audits were conducted for four bodies from refrigerated storage and one from freezer storage. Identification details on bodies were crosschecked against the information recorded in the mortuary register and associated paperwork. No discrepancies were found.

Audits of traceability were conducted for tissue blocks and slides from three coroners consented cases. These included audits of the consent documentation for the retention of these tissues and the subsequent storage at the satellite site. The inspection team identified one case from 2022 where families wishes had not been received for its continuous retention. *See shortfall T2(b)*

Royal Hampshire Hospital (Satellite site)

Audits were conducted for three bodies from refrigerated storage. Identification details on bodies were crosschecked against the information recorded in the mortuary register and associated paperwork. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides from five coroners consented cases. These included audits of the consent documentation for the retention of these tissues. The inspection team identified one case from 2019 where families wishes had not been received for its continuous retention. *See shortfall T2(b)*

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, mortuary manager, lead APTs, pathologists, mortuary porters, bereavement officers and bereavement midwifes.

Report sent to DI for factual accuracy: 22 March 2023

Report returned from DI: 04 April 2023

Final report issued: 18 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: 7 August 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.