Inspection report on compliance with HTA licensing standards
Inspection date: **25-27 October 2022**

Stoke Mandeville Hospital

HTA licensing number 12245

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 **Soke Mandeville Hospital**	Licensed	Licensed	Licensed
Mortuary	Carried out	Carried out	Carried out
A&E	-	Carried out	-
Maternity	-	-	Carried out
Satellite Site **Wycombe Hospital**	Licensed	Licensed	Licensed
Mortuary	-	-	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 Stoke Mandeville Hospital ('the establishment') had met the majority of the HTA's standards, two major and five minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment. These related to staff training and competencies, SOPs, audits, identity checking, security arrangements, temperature monitoring and alerts at Stoke Mandeville Hospital.

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
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.	Standard Operating Procedures (SOPs) do not always include sufficient detail of procedures or reflect current practice. These include but are not limited to: • Post-mortem examination, including the responsibilities of the APT's and Pathologists. • Practices relating to the evisceration and reconstruction of bodies. • Viewing of bodies, including identification checking. • Transfer of bodies and tissue off site or to other establishments. To fully address this shortfall the establishment should review all SOPs to ensure they contain sufficient detail, are reflective of current practice and cover all mortuary and laboratory procedures relevant to licensed activity.	**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	Three identifiers are not used to identify bodies for the following procedures: • Preparing the body for viewing using information taken at the time of booking the appointment. • A second check for viewings with identifiers being provided by the family prior to entry to the viewing room. This poses the risk of the wrong body being viewed.	**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		
f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds	Whilst families are given a timeframe to change their minds, this varies across documentation. Some consent guidelines state 24 hours whilst others state 48. This poses a risk to a post mortem being completed before the cooling off period is over.	**Minor**
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
d) Competency is assessed and maintained	There is no process to ensure staff are assessed as competent to take consent following their initial training.	**Minor**
GQ2 There is a documented system of audit		
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	Whilst the establishment audits families wishes against monthly communication with the Coroner's office, no audits are scheduled for archived tissue.	**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 of visitors and contractors who have a legitimate right of access	There are two locks which prevent access to restricted areas from the viewing room. There is no documented process for securing this area and the inspection team were not assured that current arrangements for using the washing facilities, within the viewing room, allows for the area to be fully secured.	**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 fridge within the maternity department does not have remote monitoring and alarm systems. This is not sufficient to alert staff if the storage temperature deviates from an acceptable range.	**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(b)	Consent documents contain reference to ‘next of kin’ and out of date hyperlinks. The DI is advised to review and update all documentation used in the consent seeking process and ensure consistence.

2.	C1(e)	The establishment gives the option to families for retention of post mortem material for future use including education, training, and research. The establishment does not carry out research. The DI is advised to consider providing this information to families to set expectations and to ensure that any consent given by families for tissue to be retained is suitably informed.
3.	T2(c)	The DI is advised to liaise with the coroner's office and update the consent documentation to ensure relatives are given sufficient information to make informed decisions on the repatriation of microscopic tissue on glass slides.

Background

Stoke Mandeville Hospital has been licensed by the HTA since 2017. This was the fourth inspection of the establishment; the most recent previous inspection took place in September 2017.

Since the previous inspection, there have been a number of modifications to this licence. These changes include the Hub and Satellite sites being swapped (Wycombe Hospital was previously the Hub) with the satellite now only licenced for storage activity. There is also an additional body storage facility now situated at the hub site with capacity for 400 bodies as well as changes to personnel holding the positions of Corporate Licence Holder and Persons Designate.

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 in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. Traceability audits, risk assessments, staff training

and competency records, meeting minutes, cleaning logs and schedules, alarm testing records, incidents, consent seeking procedures(including completed consent forms and information for relatives giving consent) were also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the premises at the hub site which included the mortuary body storage area, the post mortem room, the external storage units, viewing room, and storage on the maternity ward. The inspection team also undertook a visual inspection of the satellite site which included the body storage area and the Pathology department where consent and relevant tissue is handled and stored.

Audit of records
The inspection team undertook audits of traceability for six bodies in storage at the hub site. These included bodies with same / similar names, a long-stay body, a perinatal case and two bodies stored in the external storage facility including a body in frozen storage.

Traceability details were crosschecked between the identification band on the body, information on the mortuary whiteboard, the mortuary register and associated paperwork. No discrepancies were identified.

Traceability audits were not undertaken at the satellite site, as at the time of inspection there were no deceased in storage.

Audits were conducted of tissue taken at post mortem examination for five cases which had been sent to histology. Information was crosschecked between consent forms, information on the laboratory database, HTA spreadsheet and tissue blocks and slides being stored. Four cases demonstrated tissue had been handled in compliance with the wishes of the family.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence, including the mortuary manager and mortuary team (staff work across both sites), laboratory staff in histology, members of the portering staff, consent seekers, pathologist and the DI.

Report sent to DI for factual accuracy: 25 November 2022

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 28 December 2022

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.