Inspection report on compliance with HTA licensing standards
Inspection date: **19 and 20 March 2024**

Addenbrooke's Hospital

HTA licensing number 12318

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 Addenbrooke's Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	-	*Carried out*
A&E	-	*Carried out*	-
Cambridge Brain Bank	-	-	*Carried out*
Theatres	-	*Carried out*	-
Tissue Museum	-	-	*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 Addenbrooke's ('the establishment') had met the majority of the HTA's standards, 7 major and 3 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.

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	Whilst there is guidance in place for staff to follow when seeking consent. It does not detail the length of time given to those giving consent to change their mind. Furthermore, there is no information for staff relating to consent training and competency and how often this should be refreshed.	**Major**
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	Records do not demonstrate up to date training in HTA requirements when seeking consent. There are no records available to review indicating which staff have received training in obtaining consent for adult hospital consented PMs. *(as a result, standard C2(c) cannot be assessed)*	**Major (cumulative)**
d) Competency is assessed and maintained	There are no documents available for review assessing staff as competent with the HTA requirements when seeking consent for adult hospital consented PMs.	
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 an audit schedule is in place and audits of tissue have been completed, there has not been an audit carried out of holdings in the histology 80°C freezer for at least three years. The use of paper traceability slips in tissue storage drawers is not audited. This poses the risk of loss of tissue traceability when tissue is removed for further analysis or transferred to the offsite archive. Furthermore, the audits of tissue holdings do not contain a sufficient sample size for the establishment to assure themselves that any non-conformances are identified, and robust follow-up actions are completed in a timely way.	**Major**
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	Whilst staff know how to identify and report incidents, the inspection team identified one incident and three near misses which met the threshold for reporting to the HTA which had not been reported.	**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	There are significant areas of damage to the structure of the building and equipment in use. These include but are not limited to: • The PM suite has areas of exposed plaster to the walls. • There are breaches in the wall tiles which could lead to water ingress, posing an increased risk of ineffective decontamination. • The floor in the PM room is reaching the end of its natural life, showing signs of significant wear. Increasing the risk of porosity which may prevent effective decontamination. • The porcelain PM tables are chipped in places which poses the risk of ineffective decontamination. Furthermore, they cannot be effectively load tested and are not height adjustable which could increase the risk of accidental damage to a body during transfer, and staff sustaining a musculoskeletal injury. • The drain in the PM room appears to be insufficient and is not suitably covered. • The floor in the contingency storage unit is showing signs of wear and has areas of superficial water staining. This poses the risk of ineffective decontamination.	**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)	Whilst the external and contingency storage units have an audible intruder alarm in place, the alarm for the external storage unit only sounds in the mortuary. It is not clear if this alerts the security team out of hours. This poses the risk of any unauthorised access to the external body store, used by porters, not being acted upon out of hours.	**Major (cumulative)**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Security audits are undertaken every three months. However, this audit does not capture information relating to the use of a key stored in the porters lodge for access to the external body store. The storage unit is located in an area accessible by the public. Whilst the unit is monitored by CCTV, the use of the key is not audited for the length of time it is booked out against staff duty rosters and CCTV feed. This poses the risk of unauthorised access to the body store not being identified and acted upon in a timely way.	
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	The trays used to store bodies in the contingency storage unit are constructed from coated wood. These are difficult to manoeuvre due to their weight and are not compatible for use with the hydraulic trolleys. This poses the risk of accidental damage to a body during transfer, and staff sustaining musculoskeletal injury. Furthermore, the ventilation ducts are located in a position that poses the risk of staff sustaining a head injury.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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	Whilst porters undertake a competency assessment as part of their annual training, this is not documented.	**Minor**
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)	There is no system in place for the confirmation of receipt of perinatal losses transferred from the maternity unit at The Rosie Hospital and third party establishments. This poses the risk of loss of traceability.	**Minor**
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 histology 80°C freezer used to store tissue has a build-up of ice and during the inspection staff had difficulty accessing the tissue being stored. This poses the risk of a reportable incident occurring involving equipment failure or loss of traceability.	**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 information leaflet for coronial perinatal and paediatric post mortem examinations does not reflect current establishment practice. The DI should expedite the current review of these documents to ensure the information given accurately reflects the location the PM will be carried out.
2.	GQ1(h)	Whilst meetings to discuss HTA activities are undertaken, these have taken place annually for the last two years. The DI is advised to resume the frequency of these meetings to twice yearly, to enable persons designate to receive information and feedback relating to HTA business within the establishment.

3.	GQ5(a)	Whilst porters receive training relating to HTA reportable incidents, the DI is advised to display a list of HTA reportable incidents in the porters lodge as a visual reminder.
4.	T1(b)	The DI is advised to consider discontinuing the use of the paper mortuary registers as there is an electronic system in place and the use of more than one mortuary tracking system increases the risk of a transcription error.
5.	PFE2(e)	The DI is advised to add alarm testing of fridges out of hours to the existing fridge temperature testing schedule to ensure the system works as expected during times when the mortuary is closed.

Background

Addenbrooke's Hospital has been licensed by the HTA since 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in March 2020.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence. There are plans in place for the Cambridge Brain Bank to be added to the establishment's existing HTA research licence and the tissue museum is currently being dismantled with sensitive disposal of the existing tissue holdings.

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, cleaning records for the mortuary, records of servicing of equipment, audits, risk assessments, meeting minutes, reported incidents and training records for mortuary staff.

Visual inspection
The inspection included a visual assessment of the establishment including the post mortem suite, body storage areas and viewing rooms. Areas outside the mortuary carrying out licensed activity were also visited this included the maternity ward at the Rosie Hospital, Histopathology, The Cambridge Brain Bank and the tissue museum. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records
Audits were conducted onsite of four bodies in refrigerated storage and one body in long term frozen storage. The release of one body into the care of the Funeral Director was observed. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork in addition to information held electronically. No discrepancies were identified.
Audits of traceability were conducted for 10 cases of histology samples, a further three cases from frozen storage, and four for whole organs, removed at post mortem. The inspection team identified 31 tissue slides which had not been booked out or returned to the tissue store in line with the SOP, these were in an office within the pathology department. (see shortfall against GQ2(c) for further information).
Audits of traceability were conducted for one brain stored in the Cambridge Brain Bank, in addition to all the traceability records held, no discrepancies were identified.

Meetings with establishment staff
Staff carrying out processes under the license were interviewed including the DI, Mortuary Manager, Senior APT, Tissue Co-ordinator, Quality Manager, Mortuary Apprentice, Bereavement Midwife, Perinatal/Paediatric Consent Seeker, Adult and Paediatric Pathologist and Adult Consent Seeker.

Report sent to DI for factual accuracy: 28/03/2024

Report returned from DI: 04/04/2024

Final report issued: 05/04/2024

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 January 2025

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.