Inspection report on compliance with HTA licensing standards
Inspection date: **09 July 2025**

Ipswich Hospital
HTA licensing number 30017

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
Ipswich Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
A&E	-	*Carried out*	-

Summary of inspection findings

Following the inspection the establishment submitted an application to replace the current DI which was approved by the HTA. The HTA found the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Ipswich Hospital (‘the establishment’) had met the majority of the HTA’s standards, six cumulative major, six major and seven minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment. Shortfalls were identified against a number of the same standards for the inspection in 2022. Following that inspection, evidence was provided by the establishment to demonstrate these shortfalls had been addressed, however compliance has not been maintained (see shortfalls detailed below).

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		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice	The Trust policy 'Seeking consent for post mortem (PM) examination on an adult' requires updating to address the following: • Include Medical Examiner's Officers (MEOs) are trained and competency assessed to seek consent for PM examination. • The correct information to reflect the hierarchy of qualifying relationships outlined in the HT Act and HTA's Codes of Practice. • Include up to date references to the HTA's standards and Codes of Practice In addition, the policy refers to an annual audit of the process by the Divisional Compliance Manager, however, there is no evidence to confirm this audit is carried out. *Part of this shortfall was identified at the last HTA inspection.*	**Major (cumulative)**
b) There is a documented standard operating procedure (SOP) detailing the consent process	Although there is a process in place for seeking consent for PM examination on an adult, this is not documented in a Standard Operating Procedure (SOP).	

c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice	The current information booklet given to relatives does not contain sufficient information to demonstrate the requirements of the HT Act or the HTA's Codes of Practice are being met. For example: • The information does not include the hierarchy of qualifying relationships so it is clear who can give consent. • What relatives should do if they wish to change their minds and the time frame they have to do this. • It is not clear that tissue blocks and slides require consent to be kept as part of the medical record. *See advice item 1*	

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.	To fully address this shortfall the establishment is required to review all SOPs to ensure they reflect current practice and contain sufficient detail. Examples include but not limited to: • HCM46 Tracking and disposal of tissue Ipswich and SOP M16 Management of toxicology samples refers to only using two identifiers of the deceased for tissue for disposal and dispatch of toxicology, respectively. • HCM46 Tracking and disposal of tissue Ipswich does not include the procedure to follow should a receipt for tissue sent off site not be received back. • SOP MOR0013 Mortuary security is not clear that where access is granted to the mortuary by staff other than mortuary staff, for example, porters giving access to estates staff, they are accompanied at all times. • SOP MOR056 Deviation from an SOP refers to a Quality Management System that is not currently in use. • SOP M11 Relatives, visitors and viewing of the deceased in the mortuary does not include a requirement to check a minimum of three identifiers on the deceased immediately prior to relatives viewing. This is also reflective of current practice. The procedure for returning foetuses and babies to the maternity ward for viewings, in and out of hours, is not included in an SOP. • SOP M20 Transfer of foetal cases is not clear that a minimum of three identifiers for foetuses should be brought by the contracted funeral director when transferring them for PM examination. • SOP M25 Use of additional capacity refers to two additional storage units when there is only one and does not include a requirement to	**Major (cumulative)**

	check a minimum of three points of identification when bodies are transferred in to the unit. Where SOPs refer to checking identification of bodies and tissue, they do not always state a minimum of three points of identification should be checked and what these identifiers could be. There are no documented procedures for: • the management of bodies admitted to the mortuary with unknown identities. • on-call and lone working arrangements specifically for mortuary staff. • condition checking of bodies. • long-term storage of bodies. Although there is a system for identifying bodies with same or similar names, this is not documented in relevant SOPs. *Part of this shortfall was identified at the last HTA inspection.*	
d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	Document control for SOPs is inconsistent and they have not been reviewed in-line with the establishment's own review cycle. Some SOPs show tracked changes indicating these are not final versions but are in use. *This shortfall was identified at the last HTA inspection.*	
e) There is a system for recording that staff have read and understood the latest versions of these documents	The current system for ensuring staff confirm they have read and acknowledged SOPs which govern their work is not robust. The spreadsheet in use for staff to record the date they have read and acknowledged SOPs does not include the SOP versions.	

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Formal mortuary staff meetings have not been regularly undertaken. The monthly HTA Mortuary and Bereavement governance meetings have not taken place since January 2025. This poses a risk that HTA matters are not being regularly reviewed, which may have impacted compliance and oversight.	**Major**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	There is a documented schedule of audits for the mortuary, however, no audits have been completed, including robust security audits (see shortfall against PFE1(e)). *Lack of audits was identified as a shortfall at the last HTA inspection.* *Following the site visit the establishment submitted an updated schedule of audits with associated audit templates.* As a result of this shortfall, standard GQ2(b) could not be assessed.	**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	No tissue traceability audits have been completed in the mortuary for the transfer of tissue to the histopathology department or for specimens sent off site. The tissue traceability audit conducted on site identified two cases with discrepancies between the laboratory information system (LIMS), the mortuary electronic record and tissue in storage. Another case had nine tissue slides in storage when the relatives wishes were for them to be disposed of. *The mortuary staff are currently completing a full audit of PM tissue blocks and slides from 2006 which were transferred from the histopathology laboratory for storage in summer 2024. See advice item 10.*	
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		

a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	There is no documented training records for staff working in the mortuary. *Following the site visit the establishment submitted training records to demonstrate some progress has already been made to address this shortfall.* Refresher training for the porter supervisor responsible for cascading training of mortuary activities to the wider portering team has lapsed. Not all porters have undertaken their formal two yearly refresher training.	**Major (Cumulative)**
c) Staff are assessed as competent for the tasks they perform	There is no documented competency records for staff working in the mortuary. *Following the site visit the establishment submitted competency records to demonstrate some progress has already been made to address this shortfall.* The competency assessment for the porter supervisor responsible for assessing competency of the wider portering team has lapsed. Not all porters have undertaken their formal two yearly competency assessment.	
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	Review of the establishment's incident log identified a serious security breach incident and a near-miss accidental damage incident that should have been reported to the HTA. *This shortfall was identified at the last HTA inspection.*	**Major**

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	Although the establishment has a range of risk assessments, the document control is inconsistent and the content is not always accurate. Examples include but not limited to: • MOR RA016 Use of temporary mortuary facility has control measures in place not relevant to the external body store at Ipswich Hospital. • MOR RA005 Manual Handling does not state that the assessment is for Ipswich Hospital mortuary. The 'risk register' spreadsheet does not fully correspond to the individual risk assessment documents submitted by the establishment and does not state all the risk ratings for the risks detailed in the spreadsheet. Risk assessments have not been reviewed in-line with the establishment's own review cycle. To fully address this shortfall the establishment are required to review all risk assessments to ensure they are relevant to the activities carried out at the mortuary at the establishment. *See advice item 6.* *Part of this shortfall was identified at the last HTA inspection.*	**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 are not distributed to staff to read and acknowledge to help ensure they are aware of the risks associated with their work.	

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	Mortuary staff do not routinely check a minimum of three identifiers on the deceased with details provided by relatives immediately before a viewing takes place. This poses a risk of viewing of a wrong body.	**Major**
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 sytems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	The inspection team identified two specimens in the freezer which had been stored for approximately a year and the bodies had been released. It was unclear if any follow-up of these specimens has occurred.	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		

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)	Although there is CCTV coverage to monitor access to the mortuary, there is no out of hours CCTV monitoring of the external door used by funeral directors. Mortuary staff are unable to visually verify who is requesting access to the mortuary via the main internal hospital door. This poses a risk to staff and a potential risk to the security of the mortuary. *Part of this shortfall was identified at the last HTA inspection.*	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Although a review of CCTV is carried out each working day, documented regular audits of CCTV footage against swipe card access and visitor logs have not taken place. By not completing these audits, the establishment cannot be assured that there is appropriate access to the mortuary. *See advice item 5.* It is not clear if swipe card access lists for the mortuary are being regularly reviewed to ensure those staff who have access remain authorised to do so. The relatives reception area for viewings is next to the mortuary office which is usually secured during viewings. However, if staff feel they may require support from other staff during a viewing, the office door is left open potentially giving access to the mortuary body store via the mortuary office. The panic alarms in the viewing room and relatives reception area are not routinely tested. *See advice item 9.*	**Major**
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 current fridge alarm testing schedule for the body store fridges does not include testing the lower alarm trigger point. Staff are not aware of what the upper and lower alarm trigger points for the fridges and freezers are, therefore cannot be assured they are set at appropriate temperatures to trigger the alarm. When the external refrigerated body storage unit is in use its operation is overseen by the estates department. The mortuary staff are not aware of what the upper and lower alarm trigger points are, or if the alarm is tested to provide assurance it will work in the event of a failure.	**Major (Cumulative)**
f) Temperatures of fridges and freezers are monitored on a regular basis	When the external refrigerated body storage unit is in use temperature monitoring is overseen by the estates department. The mortuary staff are not aware if the normal temperature range for this body store is the same as the main body store, therefore cannot be assured it is operating at appropriate temperatures.	

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	Training records demonstrated that training is not up to date for all staff who can seek consent for PM examinations on adults.	**Minor**
d) Competency is assessed and maintained	Competency records demonstrated that competency assessments are not all up to date for staff who can seek consent for PM examinations on adults.	**Minor**

GQ4 There is a systematic and planned approach to the management of records		
a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record	There is no evidence to demonstrate there is a system for the management of records.	**Minor**
b) There are documented SOPs for record management which include how errors in written records should be corrected	The SOP M23 Control of process and quality records which could contain this information is incomplete.	**Minor**
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 inspection team identified the following areas that require attention: • Patches of flaking paint and exposed plaster in the body store and the internal corridor from the hospital entrance used by the porters. • Damage to wall corner casings. • Floor seals have deteriorated in places and floor edges have chipped in some areas along the body store drain. • The drains in the body store are showing some areas of rust and have rusty screws and require cleaning. *This was identified as an area on which advice and guidance was given at the previous HTA inspection.* Areas with damage or inadequate sealing mean they cannot be adequately cleaned and disinfected.	**Minor**

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 inspection team identified the following that require attention: • Damage to fridge doors. • Patches of rust on mortuary trolleys and clinical waste bins. *Rust on mortuary trolleys was identified as an area on which advice and guidance was given at the previous HTA inspection.* *See advice items 13 and 14.*	**Minor**
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	The establishment do not have have access to or copies of the servicing and maintenance records for mortuary equipment, therefore these could not be provided to the inspection team for review.	**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 use the information in the HTA's Code A 'Guiding principles and the fundamental principle of consent' and the HTA's model consent form to help produce the information given to relatives for adult consented PM examinations.

2.	C2(b)	The DI is advised to assess the effectiveness of the current system for managing training compliance, to ensure that all staff receive refresher training at appropriate intervals, in line with regulatory guidance.
3.	GQ1(g)	The DI is advised to formally appoint a PD in the Emergency Department and in the mortuary as a specific point of contact for oversight of activity in that area.
4.	GQ2(a)	The DI is advise to ensure the ongoing audit of PM tissue now being stored in the mortuary is completed and the tissue is dealt with in accordance with the relatives wishes.
5.	GQ2(a)	The DI is advised to ensure: • Regular security audits are recorded and conducted in-line with the length of time CCTV footage is retained for. • CCTV footage is compared against swipe card access and the visitor log. • Audits focus on out of hours access events ensuring these correspond with legitimate purposes to access the mortuary. • Follow-up of unusual patterns, times of entry and failed access attempts.
6.	GQ6(a)	As part of the review of all risk assessments, the DI is advised to include (when completed) the ongoing refresher training and re-competency assessments of staff as a control measure in relevant risk assessments.
7.	T1(g)	The DI is advised to ensure staff in the mortuary are aware that SUDIC cases admitted to the mortuary may have a specimen with them for transfer to the establishment where the PM examination takes place. Traceability of the specimen should be recorded for future reference, if needed.
8.	PFE1(d)	To improve oversight and security of the viewing room reception area and corridor leading to the viewing room, the DI is advised to install CCTV in these areas.
9.	PFE1(e)	To improve lone working measures and reduce risks to staff, the DI is advised to implement the use of lone worker devices, which has been discussed at the establishment for some time.

10.	PFE2(b)	The mortuary is now storing PM tissue blocks and slides following analysis. The DI is advised to ensure the staff have appropriate storage shelving and boxes for the tissue. This will help ensure the tissue is stored appropriately and can be effectively audited.
11.	PFE2(c)	The DI is advised to ensure that the condition of bodies is recorded on release.
12.	PFE2(f)	The DI is advised to ensure that staff receive support and training to use the existing temperature monitoring system for the body store fridges and freezers.
13.	PFE3(a)	If the plans to remove the storage cupboard in the body store and replace it with a fridge for paediatric/perinatal cases does not go ahead, the damage to the cupboard requires repairing so it can be adequately cleaned and disinfected.
14.	PFE3(a)	The establishment use sets of instruments which are colour-coded using tape. Over time this tape has become worn and started to peel off. The DI is advised to consider alternative methods for colour coding as the worn tape prevents effective cleaning and disinfection of the instruments. The DI is advised to liaise with the estates team to address the loud volume of the bell to alert staff to someone wishing to access the mortuary. The current volume level could startle staff while working, posing a health and safety risk. Staff reported the bell also disturbs relatives during viewings.

Background

Ipswich Hospital has been licensed by the HTA since July 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in November 2022.

Since the previous inspection, the DI has recently changed but there has been no significant changes to the licence arrangements or the activities carried out under the licence.

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 policies and procedural documents relating to licensed activities for the mortuary. This included SOPs, risk assessments, audits (see shortfall against GQ2(a) and (c)), incidents, meeting minutes, training records and competency assessment documents (see shortfall against GQ3(a) and (c)). Consent seeking procedures and information for families giving consent for adult and perinatal PM examinations (see shortfall against C1(c)). Servicing and maintenance records for mortuary equipment were not reviewed as these were not provided for review (see shortfall against PFE3(f)) .

Visual inspection
The inspection team undertook a visual inspection of the premises which included the mortuary access points, body storage areas, including the external body storage unit adjacent to the mortuary, the viewing room, PM room and the area in the mortuary being used to store PM tissue blocks and slides. *See Advice item 10.*

Audit of records
The inspection team undertook audits of traceability for four bodies in storage, including a perinatal case. Bodies with same/similar names and a body in long term storage were not included as none were being stored at the time of the inspection. Traceability details were crosschecked between the identification bands on the bodies, information in mortuary paperwork and the mortuary electronic record. No discrepancies were identified.

Audits were conducted of stored tissue taken at PM examination for seven cases. Information was crosschecked between the mortuary documentation, relatives wishes forms and the laboratory electronic records and tissue being stored. Discrepancies were identified with three cases (see shortfall against GQ2(c)).

Meetings with establishment staff
The assessment team met with staff carrying out activities under the licence, including mortuary staff, histopathology staff, a portering staff member, a pathologist, staff involved in the consent seeking processes for PM examinations and staff who are involved in the removal of relevant material in the Emergency Department.

Report sent to DI for factual accuracy: 26 August 2025

Report returned from DI: 10 September 2025

Final report issued: 15 September 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.

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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.