Inspection report on compliance with HTA licensing standards
Inspection date: **16-17 November 2022**

East Suffolk and North Essex NHS Foundation Trust
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
Accident and Emergency Department	-	Carried out	-
Maternity	-	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 Ipswich Hospital ('the establishment') had met the majority of the HTA's standards, twelve major and thirteen 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, Standard Operating Procedures (SOPs), audits, risk assessments, identity checking, security arrangements, temperature monitoring and alerts.

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	At the time of inspection, the inspection team had not seen evidence of a documented SOP consent seeking for perinatal post mortem examination.	**Major**

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice	At the time of the inspection the establishment could not provide training records for staff seeking consent for perinatal post mortem examination.	**Cumulative Major**
b) Records demonstrate up-to-date staff training	At the time of the inspection the establishment could not provide up-to-date staff training records for staff seeking consent for perinatal post mortem examination.	
d) Competency is assessed and maintained	Competency has not been assessed for those seeking consent for perinatal post mortem examination.	

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 the Royal College of Pathologists.	Whilst documented policies and SOPs covering all mortuary and laboratory procedures are in place, the current versions are out of date and lack sufficient detail and clarity. These include but are not limited to: • Receipt of deceased into the mortuary • Releasing patients to undertakers • Procedures for handling and transfer of Products of Conception, Non-Viable Fetuses, early neonatal and stillbirth deaths This is not an exhaustive list of the SOPs requiring update, and amendment. To address this shortfall the establishment should review all SOPs relating to mortuary activities, ensuring that they are up to date, accurate, cross referenced to the appropriate codes of practice and guidance, and contain sufficient and clear detail of all procedures. *This was identified as an area on which advice and guidance was given at the previous HTA inspection.* *Please see advice item 5*	**Major**
f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity	During both the staff interviews and site visit, the inspection team noted that the mortuary staff are deviating from documented procedures, for example release of a body and the use of wristbands to identify deceased with same and similar names; however, any deviations that occur are not recorded by staff or monitored via a scheduled audit. *See shortfall against standard GQ2(a)* *Please see advice item 11*	**Major**

g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	The establishment's current governance framework does not incorporate all areas where HTA regulated activities are undertaken, for example both the Accident and Emergency and Maternity Departments. The DI cannot be assured that staff are carrying out activities in accordance with the HTA licence conditions.	**Major**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	At the time of the inspection the establishment did not have a documented schedule of audits in place and could not provide evidence of audit activity undertaken in the last 2 years. As the establishment does not have an audit schedule, it has not been possible to verify that staff are routinely following the procedures that govern their work. *As a result, the inspection team have been unable to assess the establishment against standard* GQ2(b)	**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	Staff undertaking HTA regulated activities, including porters and the maternity team, are not aware of HTA Reportable Incident (HTARI) categories and how to report these incidents. Trust and externally contracted staff undertaking HTA regulated activities use different, non-interlinked, systems to report incidents and incident data is not subsequently shared. This presents the risk that the establishment does not have oversight of all HTA related incidents. The inspection team identified several incidents which occurred during 2022 which should have been, but were not, reported to the HTA. They were however reported on the establishment's internal incident system and the DI was aware of them. *Following the inspection, these incidents have been reported to the HTA for assessment and will be managed accordingly.*	**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	The establishment's risk assessments relating to licensed activities have not been reviewed for at least two years. In addition, the inspection team identified that the following had not been risk assessed: • Risks to the security and safety of staff whilst lone working. • The establishment has installed a transparent glass "wall" and glass doors at the Funeral Directors entrance. This presents a risk of oversight of transfers of the deceased. In addition, access to the body store from the Funeral Directors' entrance is via 2 sets of plastic, push through/non-secured, semi-transparent "doors". The risk of unauthorised/unsupervised access to the body store area (for persons already present within the mortuary) as well as unintentional oversight into activities undertaken in the body store area have not been risk assessed. *Please see advice item 10* *Lone working was identified as an area on which advice and guidance was given at the previous HTA inspection.*	**Major**
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	The establishment's risk assessments lack sufficient detail in relation to what control measures have been implemented to reduce the risk, and how, after implementation, they have reduced the risk.	**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	The establishment does not consistently use three identifiers to identify bodies and tissues related to HTA licensable activity; this includes the documentation Funeral Directors are required to provide to facilitate release of the deceased. This presents a risk of releasing the wrong body. *This was identified as an area on which advice and guidance was given at the previous HTA inspection.*	**Cumulative Major**
h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements	The establishment does not have a documented procedure for the transportation of both bodies and tissue to anywhere outside the mortuary.	
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The establishment is not currently ensuring full traceability of tissue and organs sent off site. No confirmation of receipt is received which also includes the transfer of babies for post mortem examination.	

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)	The inspection team identified the following risks to the security arrangements of the mortuary. • The access doors into the mortuary for both hospital staff and visitors do not have systems in place for staff to view who is requesting access to the department prior to opening these entrance doors. This may pose a risk of visitors accessing the rest of the mortuary if staff security is compromised. This potential risk is compounded by the location of these access points in a windowless, enclosed corridor, without CCTV coverage creating a blind spot between the mortuary access doors and the main hospital corridor. • The establishment does not have a process in place to ensure the DI has oversight of all staff with authorised access to the mortuary. This does not facilitate robust controlled access to the department and may pose a risk to security.	**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 establishment's fridge and freezer units are alarmed. However, the alarms are not tested regularly, both in and out of hours, to ensure they trigger at the set temperatures ranges and that the call out procedure in place is effective. *This was identified as an area on which advice and guidance was given at the previous HTA inspection.*	**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		
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 establishment's consent policy for adult post-mortem examination and the retention of tissue does not reflect the requirements of the HT Act and the HTA's Codes of Practice. For example, it contains references to the 2009 version of the HTA code of practice relating to consent, the current code was published in 2020. It also includes references to Next of Kin, HTA training programmes which are not available and hyperlinks which are no longer in use	**Minor**
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	The documentation used during the consent seeking process for adult post mortem examination does not include information on withdrawal of consent. During the staff interviews the inspection team noted that this was covered verbally when the seeking consent.	**Minor**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
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	The documented SOPs and policies reviewed by the inspection team did not demonstrate that the author and authoriser where different members of staff. The inspection team identified several SOPs which contained conflicting information in the title, header, and footer sections.	**Minor**

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Governance meetings covering licensed activity and including staff from relevant areas, Persons Designate, and the DI are not undertaken.	**Minor**
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 a controlled document for competency assessment after staff training, however the training schedule has not been adhered to for the newest member of staff.	**Minor**
c) Staff are assessed as competent for the tasks they perform	Whilst competency assessments covering all mortuary and laboratory procedures are in place, at the time of the site visit, the inspection team noted that they do not demonstrate how competency is assessed and did not consistently document who had conducted the assessment.	**Minor**
f) There is a documented induction and training programme for new mortuary staff	There is an induction checklist used for new members of staff however this is a generic Trust document which does not include specific training and induction in mortuary activities. *This was identified as an area on which advice and guidance was given at the previous HTA inspection.*	**Minor**
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	There is no induction or training programme in place for visiting and external staff e.g., independent pathologists. This presents a risk of staff not following the establishment's processes for key mortuary activities.	**Minor**

GQ4 There is a systematic and planned approach to the management of records		
b) There are documented SOPs for record management which include how errors in written records should be corrected	There is a controlled document covering record management however it does not include how errors in written records should be corrected. During the site visit the inspection team noted that amendments in written registers complied with HTA requirements.	**Minor**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
c) The incident reporting system ensures that follow up actions are identified (i.e., corrective, and preventative actions) and completed	The establishment's incident reporting system is not used to identify follow up actions and ensure completion of them.	**Minor**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	There is no demarcation of a transitional area between the PM room, the body store, or the changing room, making it difficult for staff and visitors to determine clean areas from dirty areas of the mortuary. During the site visit the inspection team noted robust procedures in place to prevent cross contamination.	**Minor**

c) There are documented cleaning and decontamination procedures and a schedule of cleaning	There is not a comprehensive SOP covering cleaning and decontamination. An up-to-date cleaning checklist, documenting completed cleaning tasks, was not made available during the inspection. *This was identified as an area on which advice and guidance was given at the previous HTA inspection and has not yet been sufficiently addressed by the establishment.*	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
f) Temperatures of fridges and freezers are monitored on a regular basis	Whilst the establishment has electronic temperature recording in place for refrigeration and freezer storage, temperature records are not reviewed. *This was identified as an area on which advice and guidance was given at the previous HTA inspection.*	**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)	Documents used in the consent seeking process reference “Next of Kin”. The DI is advised to review and update these documents.

2.	C1(d)	There is no written information for staff on how to handle retained tissue if the establishment do not receive instructions from the consent giver in relation to the future use, storage, and disposal. The DI is advised to review and update these documents with appropriate information.
3.	C1(e)	The hospital post mortem consent form includes the option for tissue to be used for research purposes, however research is not undertaken by the establishment. The DI is advised to consider providing this information to consent givers at the time of seeking consent.
4.	C1(g)	The establishment uses an agreed and ratified consent form to document consent was given and information provided, however the DI is advised to contact Addenbrookes Hospital to ensure the establishment are using the most up to date version of this form.
5.	GQ1(b)	The post mortem SOP does not stipulate that evisceration must take place only after the external examination has been completed by the pathologist. The DI is advised, when reviewing the SOP, to ensure this process is clearly documented.
6.	GQ1(c)	The establishment has body condition checks in place; however, the DI is advised to ensure these are consistently recorded on the electronic database. The DI is further advised that relevant SOPs, competency assessments and future body audits reflect this process.
7.	GQ2(a)	The DI is advised, when compiling the audit schedule, to include audits of tissue in storage and the consent in place.
8.	GQ3(d)	The establishment has up-to-date annual appraisals and personal development plans; however, the DI is advised to ensure all current records are agreed and signed off.
9.	GQ5(d)	Staff reporting incidents via the Trust incident system only receive feedback if it is requested at the time of reporting. The DI is advised to put a process in place to ensure information and learning from incidents is shared with appropriate staff.
10.	GQ6(a)	The establishment has installed a transparent glass “wall” and glass doors at the Funeral Directors entrance. The DI is advised to consider modification works which create an opaque finish, preventing oversight of Mortuary activity.

11.	T1(d)	The establishment has a system for identifying deceased with same and similar names, however when conducting the body traceability audit the inspection team found two deceased with same and similar names located in adjacent trays in the same fridge. Whilst this is not a deviation from the SOP it presents the risk of a release of the wrong body. The DI is advised to review the storage procedure for same and similar name bodies, avoiding co-location and to update the SOP and training accordingly.
12.	T1(e)	Identity checks are in place each time a body is moved; however, the DI is advised to ensure the process prevents cross contamination to the documentation used during this process.
13.	PFE1(a)	The inspection team noted minor areas of rust to the drain in the body store, the DI is advised to complete an audit of the premises, facilities and equipment and ensure works are completed.
14.	PFE2(d)	The inspection team noted minor areas of rust to some of the fridges, the DI is advised to complete an audit of the premises, facilities and equipment and ensure works are completed.
15.	PFE2(i)	The DI is advised to include the contingency plans for power failure and insufficient storage in the relevant SOPs.
16.	PFE3(a)	The inspection team noted minor areas of rust to some of the hydraulic trolleys, the DI is advised to complete an audit of the premises, facilities and equipment and ensure works are completed.

Background

Ipswich Hospital has been licensed by the HTA since 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in October 2017.

Since the previous inspection, there has been a number of modifications to this licence, there has been the addition of a 116-space body storage facility and changes of the personnel holding the positions of Designated Individual 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. SOPs, risk assessments, staff training and competency records, meeting minutes, incidents, consent seeking procedures, including completed consent forms and information for relatives giving consent was also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the premises which included the mortuary body storage area, the post mortem room, the external storage unit, viewing room, histopathology department.

Audit of records
The inspection team undertook audits of traceability for five bodies in storage. This included bodies with same/similar names, a neonatal case and long stay body in frozen storage.
Traceability details were crosschecked between the identification band on the body, the mortuary electronic database and associated paperwork. One discrepancy was found with same/similar name wristbands.

Audits were conducted of tissue taken at post mortem examination for 4 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. All 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 DI, Senior Anatomical Pathology Technician, consent seekers for both adult and perinatal hospital post mortem examinations, bereavement midwife, porter, laboratory staff and pathologist.

Report sent to DI for factual accuracy: 15th December 2022

Report returned from DI: 28th December 2022

Final report issued: 3rd February 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.