Inspection report on compliance with HTA licensing standards
Inspection date: **22 July and 13, 14 September 2022**

John Radcliffe Hospital
HTA licensing number 12052

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 **John Radcliffe Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	*Carried out*	*Carried out*
A&E	-	*Carried out*	-
Satellite site **Churchill Hospital**	Licensed/Not licensed	Licensed/Not licensed	Licensed/Not licensed

Mortuary	-	*Carried out*	*Carried out*
Radiology	-	*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 John Radcliffe Hospital ('the establishment') had met the majority of the HTA's standards, 10 major and 11 minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment. These related to consent seeking training and competency assessment of staff, record keeping, body storage capacity, the use of three identifiers of the deceased in relevant procedures, measures for identifying same or similar name bodies, mortuary maintenance and security.

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
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	Whilst doctors seeking consent for perinatal post mortem (PM) examination have completed some training as part of their national medical qualifications which addresses the requirements of the HT Act, this training does not incorporate local policy or procedures for the seeking of consent as required in the HTA codes of practice.	**Major (Cumulative)**
b) Records demonstrate up-to-date staff training	Some staff involved in seeking consent for adult and perinatal PM examination do not have up-to-date training.	
d) Competency is assessed and maintained	Competency of staff seeking consent is not assessed or maintained.	
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: • Condition checking of bodies – whilst a system has been developed to complete this regularly, it is not documented in a SOP. • PM02 – Release of the deceased: This SOP does not sufficiently detail the identification procedure in place at the point of release of a body. • H205 - Retention and disposal of post mortem material: This SOP does not sufficiently detail how relevant material is identified as the correct material for return at a later date, repatriation to the body or disposal. 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**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	The establishment have identified a significant risk to the delivery of mortuary services due to the current mortuary staffing levels. Whilst this risk has been placed on the Trust risk register, HTA oversight of actions in place to address this risk is required.	**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 inspection team identified the following issues in relation to the use of three identifiers of the deceased: • Viewing of the deceased does not incorporate the requirement for three identifiers of the deceased to be provided by visitors at the time of arrival which are then checked against information on the body. This is to ensure the correct visitors have arrived to view the correct body. • Specimens arriving to the laboratories from the mortuary are not routinely labelled with three points of identification of the deceased.	**Major**
d) There is a system for flagging up same or similar names of the deceased	The system to flag up bodies with a same or similar name is not robust. The inspection team identified two bodies in storage with the same or similar name that had not been flagged either on paperwork in the patient files, on the body itself or on the body store whiteboards.	**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	Whilst the interior of the premises were clean at the time of the inspection, the inspection team identified the following areas which require maintenance: • The body store at the hub site has some areas of damage, including cracks to walls exposing porous plaster and areas where the seal between the floor and wall is damaged. These areas would be difficult to effectively disinfect and decontaminate. • The PM room floor is showing signs of wear in several areas meaning the floor may no longer be effectively sealed in these areas. • The body store at the satellite site has some areas of damage to walls exposing porous plaster and damage to the main wooden mortuary doors. These areas would be difficult to effectively disinfect and decontaminate. • The roof in close proximity to the viewing room entrance at the satellite site has areas of damaged and crumbling concrete which could pose a risk to staff and visitors should this worsen. Furthermore, the area outside the visitor entrance is not well kept or maintained. • The exterior of the satellite site is considerably overgrown with bushes and weeds including to the rear of the building where the external fridge condenser units are held, this poses a risk to these units becoming damaged by debris.	**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 mortuary at the satellite site was secure at the time of the inspection, the inspection team identified a number of potential security risks: • The wooden gates to the rear yard area of the mortuary are kept closed out-of-hours, however, they are not routinely locked. This area is however, monitored by CCTV. • The external doors to the body store do not appear to be fully robust due to age of the doors. The wood in areas is damaged and worn. • The visitor entrance has a number of windows that can be opened fully in the waiting area. Whilst access to the rest of the mortuary is restricted, there is a risk of unauthorised access to the visitor area if the windows are not locked and secured fully before staff leave the building. Furthermore, this entrance is not monitored with the use of CCTV and is housed behind a small, gated area. • The external components of the fridge units at the satellite site are accessible outside of the mortuary. This leaves a risk of the external components being tampered with.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	The establishment does not have sufficient refrigerated storage capacity. At the time of the inspection, two external temporary body storage units were in operation, with a further three temporary storage units erected within the PM rooms – two housed in the main PM room which are blocking pass through fridge doors and a third in the high-risk PM room which means this room cannot be used for its designed purpose. The risk relating to the lack of refrigerated storage capacity is currently on the Trust risk register and the establishment have identified actions to address this risk. Had this not been the case, this shortfall would have resulted in a critical finding.	**Major**

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The establishment does not have sufficient freezer storage to meet needs. At the time of inspection, all freezer spaces were fully occupied. Whilst the establishment has contingency plans in place to move bodies requiring frozen storage to another HTA licensed establishment when all freezers are occupied, the inspection team identified a number of bodies which had been held in refrigerated storage longer than the recommended 30 days which were beginning to show signs of deterioration. Furthermore, the establishment do not have bariatric freezer storage. The risk relating to the lack of freezer storage is currently on the Trust risk register and actions have been identified to address this risk.	**Major**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The ventilation system in the main PM room failed the most recent inspection meaning it is not achieving the required air change rates. This room is currently being used to perform high risk PM examinations as the dedicated high-risk PM room is housing a temporary body storage unit.	**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 the patient information leaflet provides information on who to contact if a family wishes to withdraw or amend their consent, this information should also be written on the consent form. The inspection team identified one consent form which had not been completed fully to include the relevant detail for the family.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Whilst the establishment has a documented schedule of audits, which includes auditing of body traceability records, there are no audits undertaken on bodies in storage.	**Minor**
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	The mortuary audits completed do not always include sufficient detail of how audits were completed or sufficiently detail follow up actions that have been taken and completed.	**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	The mortuary at the hub site is holding a substantial amount of historical paper-based PM and mortuary records. The records are located on several shelving units placed along the access corridor from the porter entrance to the body store. Due to the location, there is no restriction in place for who has access to these records, furthermore, the records are not backed up electronically due to the age and type of records held which means there is currently a risk of loss or damage.	**Minor**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		

b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents	The HTARI reporting SOP does not detail that incidents are required to be reported to the HTA within five days of an incident occurring or being discovered. Furthermore, the SOP contains outdated and now broken links to the HTA website which means that staff do not have access to relevant information on HTARI reporting or follow up investigation requirements.	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
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	Mortuary risk assessments do not sufficiently detail how identified risks are mitigated. Furthermore, not all risk assessments consider risks to the deceased in procedures undertaken. Whilst a rare occurrence, a risk assessment is required in relation to the movement of super bariatric bodies into the PM room. This is to ensure any risks to the deceased have been fully mitigated.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The procedure undertaken for returning tissue or organs to the body prior to release of the deceased does not include detail of identification checks performed to ensure correct repatriation.	**Minor**
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	During the tissue traceability audit, the inspection team identified that there is no agreed procedure for where in the mortuary electronic database relevant information of material retained at PM is captured prior to it being sent to the laboratory. Although all information was present, the location of the information in the database differed from case-to-case making traceability auditing difficult.	**Minor**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		

c) There are documented cleaning and decontamination procedures and a schedule of cleaning	Whilst the premises were clean at the time of the inspection, and there are documented cleaning and decontamination procedures in place, establishment staff do not document the cleaning undertaken for the satellite site or the PM rooms at the hub site as part of the cleaning schedule.	**Minor**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The establishment has a visitor log to the mortuary in operation at the hub site. The inspection team identified that in some instances visitors were not ensuring the time out of the department is recorded upon departure. Furthermore, whilst there are regular audits of access undertaken, there is no visitor log in operation at the satellite site.	**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 temperatures of fridges are routinely monitored at the satellite site and in the maternity department, and records are kept of the daily checks, the actual temperature of these units is not recorded to allow trend analysis to be completed. This poses a risk to fluctuating temperatures outside of optimal range not being identified in order for action to be taken to prevent a unit failure.	**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(a)	The DI is advised to add further detailed information to the consent policy on actions to be taken to inform the mortuary if there is a change to, or withdrawal of consent.
2.	C1(g)	The DI is advised to review and update the perinatal PM consent form in use to reference the latest HTA Codes of Practice.
3.	GQ1(g)	The DI is advised to display the HTA removal licence in the CT scanning area as removal of relevant material may be undertaken as part of the PMCT.
4.	GQ3(a)	Whilst porters who have not been trained in relevant mortuary duties are supervised by trained individuals, the DI is advised to ensure the ongoing training of all porters is completed as soon as possible. This will prevent the risk of untrained individuals being left without appropriate supervision if the number of trained individuals decreases.
5.	GQ4(a)	The DI is advised to review the following RCPath guidance when addressing the shortfall under this standard: The retention and storage of pathological records and specimens (5th edition).
6.	GQ4(b)	The DI is advised to audit how mistakes in written records are corrected in the mortuary register. The inspection team identified a few instances of very minor changes to this record in which the corrections made the information difficult to interpret.
7.	GQ5(a)	The DI is advised to place visual Human Tissue Authority reportable incident (HTARI) guidance in the areas in which licensed activity takes place. This will assist staff working in such areas to understand the types of incidents which require reporting to the HTA. Details of who should be informed of an incident within the establishment both in, and out-of-hours so timely HTARI reporting can be completed should also be included.

8.	T1(b)	The DI is advised to audit the completeness of the mortuary register on a more regular basis. There were some recent, although infrequent examples, of funeral directors not signing the register to indicate they had collected a body.
9.	T1(c)	Three identifiers of the deceased are obtained from funeral directors at the point of collection of a body on a hospital body release form. This form is then compared to the internal mortuary paperwork and agreed with the funeral director. The internal paperwork is then crosschecked against the identification band of the body and agreed. The DI is advised to ensure that the hospital release form brought by the funeral director is also crosschecked against the information on the body at the same time to strengthen this procedure and further mitigate the risk of a release of a wrong body.
10.	PFE1(a)	Pest control boxes are in use in the viewing room and waiting area at the satellite site. The DI is advised to find a solution to house these discreetly and securely to avoid any risk of visitors coming into contact with them.
11.	PFE1(d)	Whilst wall alarms are in place in the mortuary viewing rooms for staff to raise an alarm for assistance if required, the DI is advised to further consider the security arrangements in place for staff. This is particularly important as staff undertake lone working (to include out-of-hours) across both sites for various tasks of which others external to the mortuary may be unaware, such as the security department. Furthermore, the DI is advised to regularly test the wall alarms in place to ensure they work as expected.
12.	PFE1(d)	Whilst regular review of the mortuary CCTV footage is currently undertaken, the inspection team were advised the newly appointed mortuary manager would soon be overseeing the future review once granted permissions to access the CCTV data. The DI is advised to oversee this handover to ensure the regular reviews continue as expected. It is further advisable to check the current practice in regard to the review of CCTV against the updated HTA standards and guidance, page 20 (published September 2022) to ensure the review is being undertaken in a manner that complies with the guidance issued.
13.	PFE1(e)	Several doors which allow access to the PM room at the hub site rely on the use of manual key locks. The keys are currently housed in the mortuary office out-of-hours which is locked. The DI is advised to review the security procedures of use of the keys and consider whether alternative security measures may prevent unauthorised access to secure areas should keys be left in locks mistakenly.

14.	PFE1(e)	The DI is advised to place signage on the fire door in the viewing gallery of the PM room to inform visitors to this area it is not to be used as a routine exit from the building and is for emergency exit only.
15.	PFE2(e)	Whilst regular fridge alarm tests take place, the DI is advised to test the procedure out-of-hours. This would help ensure that the system in place for alarm response by staff working out-of-hours functions as expected.

Background

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

Since the previous inspection, the following changes have been made to the licensing arrangements: the current Corporate Licence Holder contact (CLHc) was approved in 2022, the current DI was approved in 2021 and Persons Designated (PDs) were added to the licence in 2019,2020 and 2022.

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 was 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 PM room, the temporary body storage units, and the viewing room. The area within the maternity department for the storage of bodies was inspected as well as the storage arrangements for relevant material held within the pathology and neuropathology departments. The CT scanning area was also visited as removal of relevant material may occur in this area. The inspection team also undertook a visual inspection of the satellite site which included the body storage area and the viewing room.

Audit of records
The inspection team undertook audits of traceability for four bodies in storage at the hub site. This included bodies with same / similar names and a body housed in the temporary storage unit and a body in frozen storage. Traceability details were crosschecked between the identification band on the body, information on the mortuary whiteboard, the mortuary register, the electronic mortuary database, and associated paperwork. Whilst no discrepancies with traceability were identified, it was noted that the bodies with a same or similar name had not been flagged according to procedure.

Traceability audits were undertaken for three bodies at the satellite site, with no discrepancies identified.

Audits were conducted of tissue taken at PM examination for four cases which had been sent to histology. Information was crosschecked between consent forms, information on the laboratory database and tissue blocks and slides being stored. One case reviewed demonstrated disposal of tissue had been completed in line with the wishes of the family. The further three cases demonstrated they were being held with appropriate consent for a scheduled purpose. Whilst no discrepancies were identified, the inspection team noted the electronic database in the mortuary does not have a dedicated field for capturing the information in a consistent manner.

Audits of three cases sent to neuropathology were conducted, whilst no discrepancies with traceability were identified, the inspection team noted that specimens may arrive to the department with less than three identifiers of the deceased on specimen containers and the form used to check specimens back out of neuropathology only contains a check of two identifiers of the deceased.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence, including the newly appointed mortuary manager and members of mortuary staff, laboratory staff in both histology and neuropathology, members of the portering staff and team, staff involved in the consent seeking process for adult and perinatal PM examination, a pathologist who undertakes PM examination and the DI.

Report sent to DI for factual accuracy: 25 October 2022

Report returned from DI: 11 November 2022

Final report issued: 21 November 2022

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: 11 April 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.