Inspection report on compliance with HTA licensing standards
Inspection date: **05 November 2024**

Christie Pathology Partnership
HTA licensing number 30003

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
Christie Pathology Partnership	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*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 Christie Pathology Partnership (‘the establishment’) had met the majority of the HTA’s standards, two major shortfalls were found against standards for Governance and quality systems and Premises, facilities and equipment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Compliance with HTA standards

Major shortfalls

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.	Although self-identified prior to the arrival of the inspection team, Christie Pathology Partnership currently has no security SOP in place. (*see advice items 1 and 2)*	**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	Although outside of the subset of standards assessed during this focused inspection, the inspection team noted that the floor in the body store has a large crack, which poses the risk of ineffective cleaning and decontamination.	**Major**

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.	GQ1 a)	The DI is advised to incorporate the opening and closing down process of the mortuary into the security SOP. This will ensure there is sufficient written guidance for staff.
2.	PFE1 e)	The DI is advised to investigate and follow up on failed attempts to access the mortuary which have been identified prior to, or during security audits. Furthermore, the DI is advised to change the codes to the mortuary alarm system and keypad locks on a regular basis. Written guidance on the trigger points for code changes should also be included in the security SOP.

Background

Christie Pathology Partnership has been licensed by the HTA since May 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in April 2023.

Since the previous inspection, there have 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
The Inspection focused on areas of concerns identified following an Evidential Compliance Assessment (ECA) submitted by the establishment at the HTAs request against a subset of standards relevant to security. 5 out of the HTA's 72 standards were covered during the focused inspection (standards published 3 April 2017). Standards covered at this inspection are listed in Appendix 3. The remaining 52 standards will be assessed during the next routine inspection of the establishment.

Review of governance documentation
The inspection team reviewed policies and procedural documents relating to licensed activities. This included standard operating

procedures, risk assessments, audits and training assessment documents.

Visual inspection
The inspection team undertook a site visit inspection which included reviewing security systems in place in the mortuary body storage areas, the viewing room and the Post mortem suite.

Meetings with establishment staff
The assessment team met with staff carrying out activities under the licence, including the establishment's DI.

Report sent to DI for factual accuracy: 15 November 2024

Report returned from DI: 29 November 2024

Final report issued: 12 December 2024

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 26 February 2025

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as ‘Critical’, ‘Major’ or ‘Minor’. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the Human Tissue Act 2004 (HT Act) or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the HT Act or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   - A notice of proposal being issued to revoke the licence
   - Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or

- indicates a breach of the relevant Codes of Practice, the HT Act and other relevant professional and statutory guidelines, or
- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

   This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

   In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. Establishments must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.

Appendix 3: Standards Assessed during onsite Inspection

Governance and quality systems
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. These include: i. post-mortem examination, including the responsibilities of Anatomical Pathology Technologists (APTs) and Pathologists and the management of cases where there is increased risk; ii. practices relating to the storage of bodies, including long term storage and when bodies should be moved into frozen storage; iii. practices relating to evisceration and reconstruction of bodies; iv. systems of traceability of bodies and tissue samples; v. record keeping; vi. receipt and release of bodies, which reflect out of hours arrangements; vii. lone working in the mortuary; viii. viewing of bodies, including those in long-term storage, by family members and others such as the police; ix. transfer of bodies internally, for example, for MRI scanning; x. transfer of bodies and tissue (including blocks and slides) off site or to other establishments; xi. movement of multiple bodies from the mortuary to other premises, for example, in the event that capacity is reached; xii. disposal of tissue (including blocks and slides), which ensures disposal in line with the wishes of the deceased person's family; xiii. access to the mortuary by non-mortuary staff, contractors and visitors; xiv. contingency storage arrangements.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits.
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.

Premises, facilities and equipment
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).
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.