Inspection report on compliance with HTA licensing standards
Inspection date(s): **11 April 2023**

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, one major and three minor shortfalls were found against the 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 shortfall identified during the inspection.

Compliance with HTA standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
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.	Some Standard Operating Procedures (SOPs) lack detail and are incomplete. This includes the SOPs for: ○ The viewing SOP finishes at the preparation of the body and omits details of what to do when the family arrive. ○ The release SOP does not detail the 'release form' which is an important part of the identification checking procedure. ○ The release out of hours SOP does not detail identification procedures. ○ The security SOP does not detail the audits that are carried out. ○ The storage SOP does not detail that the mortuary manager is called out in an emergency and alludes to estates dealing with problems and informing staff the next day. This is not an exhaustive list of the SOPs requiring amendment. To fully address this shortfall, the establishment should review all SOPs relating to mortuary activities where there is a requirement for checking the identity of bodies to ensure they are accurate and contain sufficient detail to reflect current practice.	**Major**

Minor shortfalls

Standard	Inspection findings	Level of shortfall

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	Not all practices and processes relating to licensed activity are included in the establishment's risk assessments. The risk assessments and register do not cover risks relating to consent, security and dignity and integrity of bodies.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue		
(a) Storage arrangements ensure the dignity of the deceased	Although there are condition checks that take place, there are no formalised and documented condition checking procedures.	**Minor**
(g) Bodies are shrouded or in body bags whilst in storage.	During the visual inspection some bodies were not fully shrouded. The sheets loosely covered the bodies and, in some cases, areas of the deceased were exposed. This poses a risk to the dignity of the deceased.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfall 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(b)	There is a 24 hour 'cooling-off' period that is given to families requesting a hospital PM in case they wish to change their mind. Although it is always given, this is not detailed in the consent SOP. The DI is advised to include this level of information.
2.	C2(a)	There is a consent training PowerPoint that is delivered by the DI to persons involved in the consent seeking process for hospital PMs. The presentation details the Human Tissue Act 2018 which is incorrect. The DI is advised to update the reference to the Human Tissue Act 2004.
3.	C2(a)	Consent training is in place for all consent seekers involved in adult hospital PMs however this training is not detailed within the establishment's consent policy and consent SOP. The DI is advised to detail what training is in place to ensure all staff understand the requirements prior to involvement in the process.
4.	GQ6(a)	There are some duplication of hazards in the establishment's risk assessments relating to licensable activity. The DI may wish to review these and amalgamate those which overlap. This will help to streamline documentation and also reduce the time taken for staff to review the documents.

Background

Christie Pathology Partnership has been licensed by the HTA since May 2007. This was the fourth inspection of the establishment; the most recent inspection took place in March 2018.

Since the previous inspection, there have been some significant changes to the licence arrangements including the change of Designated Individual (DI) in September 2021, and a change in Corporate Licence Holder contact (CLHc) in February 2020 and January 2021.

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. Policies and procedural documents relating to licensed activities were reviewed. This included standard operating procedures, risk assessments, audits, incidents, meeting minutes, equipment servicing reports, and training and competency assessment documents. Consent seeking procedures and information for families giving consent for hospital PM's were also reviewed.

Visual inspection
The inspection team undertook a site visit inspection including the mortuary body storage area and the PM suite.

Audit of records
The inspection team undertook audits of traceability for three bodies in storage. Traceability details were crosschecked between the identification band on the body and information on the electronic and paper records. No discrepancies were identified.

Audits were conducted of stored tissue taken at PM examination for the two most recent hospital PM's. Information was crosschecked between the mortuary documentation, consent for PM documents, family wishes forms, the electronic database, and tissue being stored. No discrepancies were identified.

Meetings with establishment staff
The assessment team met with staff carrying out activities under the licence, including a Bereavement Advisor, Quality and Governance Manager, an Anatomical Pathology Technologist (APT), the Mortuary Manager who is the establishment's DI and a member of mortuary staff involved in the adult PM consent seeking process.

Report sent to DI for factual accuracy: 28 April 2023

Report returned from DI: 12 May 2023

Final report issued: 16 May 2023

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: 21 June 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.