Site visit inspection report on compliance with HTA licensing standards
Inspection date: **1 October 2019**

Great Ormond Street Hospital for Children NHS Foundation Trust

HTA licensing number 30001

Licensed under the Human Tissue Act 2004

Licensed activities

Rows denote whether the site is licensed to carry out an activity; the rows below denote whether or not the activity is currently carried out in that area.

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
Great Ormond Street Hospital for Children NHS Foundation Trust	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Histopathology laboratory	-	-	*Carried out*
Paediatric and Neonatal Intensive Care Unit (PICU/NICU)	-	*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 Great Ormond Street Hospital for Children NHS Trust (the establishment) had met the majority of the HTA's standards, four minor shortfalls were found against the standards for Consent, 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

Minor Shortfalls

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	The establishment does not have a process to identify which staff have received consent training and when refresher training is due.	**Minor**
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.	The SOP for viewings of bodies lacks detail of how identification checks are performed and what information is obtained from the family prior to a viewing. The lack of documentation of this process poses a risk of misidentification of the body for viewing.	**Minor**

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	Some staff undertaking licensed activities in the mortuary were unable to demonstrate an awareness of the reporting requirements for HTA Reportable Incidents (HTARIs) and the establishment's procedures for reporting HTARIs to the HTA.	**Minor**
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	At the time of the inspection, the establishment could not provide records to evidence that the ventilation system for the post mortem (PM) suite had been serviced regularly and met the minimum number of required air changes per hour. ***Prior to the final report being issued the DI submitted evidence of the actions taken in relation to this shortfall. The HTA has assessed this evidence as satisfactory and considers this standard to be met.***	**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(d)	The DI is advised to consider updating the information leaflet provided to families to clarify that tissue that has been consented to be retained for research may be disposed of if it is not used.

2.	T1(c)	In order to strengthen the process for release of bodies from the mortuary, the establishment is advised to: • Inform funeral directors of the requirement to bring a minimum of three identifiers of the deceased to be crosschecked with identification bands on the body; • Document the process to be followed if funeral directors arrive at the mortuary with fewer than three identifiers of the deceased, and to ensure that all mortuary staff understand procedures; and • Update the 'Transfer of Care Form' to specify the identifiers of the deceased that may be used for identification checks.
3.	PFE2(c)	The DI is advised to keep under review the contingency arrangements for freezer storage and the process for transferring bodies to other establishments for freezer storage. This would provide assurance that the arrangements are sufficient to meet the needs of the service.
4.	PFE2(f)	The DI is advised to consider implementing a formal system for trending of the fridge temperatures to identify any issues, such as an increase or decrease in temperature over several months, which may indicate a potential failure of the refrigerator units before it occurs.
5.	T1(d)	The DI is advised to consider including examples in the SOP describing the process to label bodies in the mortuary with same or similar names. This may help to ensure that staff understand the procedure and follow the process consistently.

Background

Great Ormond Street Hospital for Children NHS Trust is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased, and relevant material, for use for scheduled purposes. The establishment accepts referrals from other hospitals for perinatal and paediatric PM examinations.

The establishment has been licensed by the HTA since May 2007. This was the third site visit inspection of the establishment; the most recent previous inspection took place in December 2015.

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

All 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

The inspection included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records for the mortuary and PM suite, contracts for servicing of equipment and records of servicing, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, incidents and staff training records.

Visual inspection

The inspection included a visual inspection for the mortuary body store, PM suite, viewing room and histopathology laboratory.

Audit of records

Audits were conducted for three bodies in refrigerated storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and relevant documentation.

Audits of traceability were conducted for tissue blocks taken from four PM cases, including audits of the consent documentation for the retention of tissues. Information was crosschecked against paper and electronic records. The storage locations of the tissue blocks were followed up in the histopathology laboratory. No discrepancies in the traceability of these tissues were found.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the mortuary manager, a trainee Anatomical Pathology Technologist, a consultant pathologist, the clinical practitioner who admits bodies into the mortuary, consent seekers for paediatric and perinatal PM examinations, and the DI.

Materials held for the police

Under section 39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings stored in a designated area in the PM suite were reviewed by the HTA during the inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

Report sent to DI for factual accuracy: 29 October 2019

Report returned from DI: 6 November 2019

Final report issued: 8 November 2019

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 March 2020

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 site visit 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 site visit.

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

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