Inspection report on compliance with HTA licensing standards
Inspection date: **04 March 2025**

Great Ormond Street Hospital

HTA licensing number 12654

Licensed under the Human Tissue Act 2004

Licensed activities

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose	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
Great Ormond Street Hospital	Licensed	Not licensed

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 ('the establishment') had met the majority of the HTA's standards, one minor shortfall was found against standards for Governance and quality systems.

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

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.	During the inspection, it was noted that some of the establishment's Standard Operating Procedures (SOPs) were not reviewed and updated in accordance with their policy. This was also the case for the incident reporting form. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised*	**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 practices:

Number	Standard	Advice
1.	GQ1(a)	The establishment has a policy in place to review SOPs and other documents on a two- or three-year cycle. The DI is advised to ensure that the next review date is clearly indicated on each SOP to help track the review dateand prevent any missed reviews.
2.	T1(c)	Several research groups working on the licensed premises routinely work with material held under project-specific approvals from recognised Research Ethics Committees (RECs). To improve awareness and oversight of storage requirements for all material held on the licensed premises, the DI is advised to implement a system to record and track the expiry dates of REC approvals. This will allow the DI to be aware of any material coming to the end of its approval so that it can be transferred to the governance of the HTA licence, transferred elsewhere, or disposed of.
3.	PFE2(c)	The DI is advised to display the defined temperature range for storage on fridges and freezers where relevant material is stored. This would provide staff with ready access to important information, supporting the maintenance of storage conditions to preserve the integrity and viability of the stored material.
4.	PFE2(c)	Several groups are working under the HTA licence, with each group managing out-of-hours responses to storage area alarms independently. However, the overarching contingency SOP does not include a procedure for managing out-of-hours responses. The DI is advised to update the SOP to include out-of-hours alarm response, ensuring a consistent approach across all groups.

Background

Great Ormond Street Hospital stores human tissue for research under its HTA Research sector licence. The establishment also maintains a research tissue bank that has approval from a recognised research ethics committee (REC), where samples from living donors are stored.

Great Ormond Street Hospital has been licensed by the HTA since April 2017. This was the second inspection of the establishment; an evaluated self-assessment took place in December 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

Of the 47 HTA standards 46 were assessed (standards published 3 April 2017). PFE2(b) is not applicable as the establishment does not store human tissue from deceased donors.

Review of governance documentation

A number of documents were reviewed during the assessment which included policies, SOPs, consent forms and Participant Information Sheets, traceability audits, risk assessments, meeting agendas, temperature monitoring reports, and calibration records for the storage units.

Visual inspection

There was no visual inspection of the premises; however, a meeting took place with relevant staff members to discuss thenm Premises, facilities and equipment (PFE) standards. Fridges, freezers, and Liquid Nitrogen storage facilities were assessed remotely through a live video tour.

Audit of records

No traceability audit was carried out; however, a review of recent audits conducted for some research groups was undertaken as part of the assessment.

Meetings with establishment staff

Roundtable discussions were carried out with establishment staff which included the DI, Person Designated (PD), Lead Quality Risk Manager for the Laboratories Medicine and Head of Research and Development, and Chief of Medicine.

Report sent to DI for factual accuracy: 20 March 2025

Report returned from DI: 04 April 2025

Final report issued: 04 April 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 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 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.