

Inspection report on compliance with HTA licensing standards
Inspection date: **2 October (remote) and 4 October (site visits) 2024**



Liverpool School of Tropical Medicine

HTA licensing number 12548

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
Hub site Liverpool School of Tropical Medicine	Licensed	Not licensed
Satellite site Liverpool Life Sciences Accelerator	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 Liverpool School of Tropical Medicine ('the establishment') had met the majority of the HTA's standards, three minor shortfalls were found against standards for Governance and quality systems, and Traceability. The shortfalls related to audit findings, risk assessment and traceability of samples.

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
GQ2 There is a documented system of audit		
b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these	The establishment did not have a Corrective and Preventive Action (CAPA) plan approach in place that specifies responsible parties for follow-up actions and outlines timeframes for completing these actions. <i>The establishment submitted sufficient evidence to address this shortfall before the report was finalised.</i>	Minor

T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail		
<p>c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom</p>	<p>During the inspection at the satellite and hub sites, it was found that two samples held under the HTA licence in two freezers were not recorded in the tracking system.</p> <p><i>The establishment submitted sufficient evidence to address this shortfall before the report was finalised</i></p>	<p>Minor</p>

PFE1 The premises are secure and fit for purpose		
<p>a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.</p>	<p>An overarching risk assessment was in draft format. The establishment had not yet completed an appropriate evaluation of the premises.</p> <p><i>The establishment submitted sufficient evidence to address this shortfall before the report was finalised</i></p>	<p>Minor</p>

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(b)	The establishment manages document control manually, reviewing each document to track changes and check for upcoming review dates. Given the high volume of activities, the DI is advised to consider transitioning to a digital document control system. This would improve efficiency and provide better oversight of document changes and review schedules, ultimately supporting timely updates and strengthening overall governance.
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 refrigerators where relevant materials are kept. Displaying the defined temperature range for storage on refrigerators is beneficial for other users as it ensures clear and immediate access to important information. This practice can support the maintenance of proper storage conditions, thereby preserving the integrity and viability of the stored materials.

4.	PFE2(c)	The DI is advised to implement a process to regularly test and periodically manually challenge fridges and freezers temperature alarms to provide an assurance that they are operating as expected.
5.	PFE2(c)	The establishment downloads monthly data from the remote monitoring system to observe trends; however, they do not document these trends. The DI is advised consider how best to document temperature trends to support record-keeping and analysis.

Background

Liverpool School of Tropical Medicine is licensed for the storage of relevant material which has come from a human body for use in a scheduled purpose, under the Human Tissue Act 2004 (HT Act). The institution conducts a broad spectrum of studies pertaining to tropical diseases. Additionally, it maintains a Research Tissue Bank (RTB), which holds generic ethical approval from a recognised Research Ethics Committee (REC). Liverpool School of Tropical Medicine has been licensed by the HTA since 2009. This was the third inspection of the establishment involving site visit components. A previous site visit inspection took place in December 2018 and an Evaluated Self Assessment (ESA) was undertaken in July 2023. Since the 2018 inspection, the establishment has appointed a new CLH name contact and DI.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during the inspection:

Standards assessed against during inspection

There are 47 standards in the Research sector, of which 46 were assessed. Standard PFE2(b) could not be assessed as the establishment does not store bodies or body parts (standards published 3 April 2017).

Review of governance documentation

The assessment included a review of documentation relevant to the establishment's licensed activities. This included policies and

procedural documents relating to licensed activities, agreements with suppliers, equipment maintenance records, risk assessments, arrangements for temperature monitoring for the storage units, staff training records, a review of the sample tracking spreadsheets and databases used to record and track relevant material, audits, and incidents.

Visual inspection

The site visit included a visual inspection of areas where samples were stored, at the hub site and the satellite site. The visual inspection at the hub site included a review of the areas where RTB material is stored in freezers, at room temperature (RT), and in Liquid Nitrogen tanks (LN2).

Audit of records

During the visual inspection, records for 4 samples in storage were reviewed. These samples comprised samples in -80°C freezers (sample to record). Two group's samples in -80°C could not be located in the traceability system (see shortfall against HTA standard T1(c))

Meetings with establishment staff

The inspection included discussions with the DI, PDs and other staff working under the licence. This included the Head of Research.

Report sent to DI for factual accuracy: 30 October 2024

Report returned from DI: 6 November 2024

Final report issued: 7 November 2024

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.