Inspection report on compliance with HTA licensing standards
Inspection date: **1 July (remote) and 3 & 4 July (site visits) 2024**

University of Liverpool

HTA licensing number 12020

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 University of Liverpool Main campus	Licensed	Not licensed
Satellite site University of Liverpool CH64 7TE	Licensed	Not licensed
Satellite site Alder Hey Children's Hospital	Licensed	Not licensed

Satellite site Liverpool Women's Hospital	Licensed	Not licensed
Satellite site Aintree University 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 University of Liverpool ('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 standards.

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

GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
e) There is a system for managing complaints.	The establishment did not have system in place for managing complaints. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail		
b) A register of donated material, and the associated products where relevant, is maintained.	During the inspection, it was noted that there were several boxes of diagnostic FFPE samples in the storage area that had not yet been double-checked for research consent or labelled in accordance with expected procedures. The consent documents were stored in a different room. As these samples were not secured in a safe or fireproof cabinet, and the consent forms were not kept in the same location, there was a risk of losing traceability as the samples were not registered in the system.	**Minor**

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.	During the inspection at the main hub, it was found that two FFPE block samples were not recorded in the tracking system. This indicated an incomplete audit trail, specifically regarding the storage locations of samples.	**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.	C2(a)	Clinical staff currently obtain consent for research work at the establishment. In the future, the establishment plans to recruit healthy volunteers for research and obtain consent through researchers. The DI is advised to develop equivalent consent training for the researchers to that received by the clinical staff who seek consent.
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.	PFE1 (c)	The establishment has documented cleaning and decontamination procedures; however, there were typographical errors in the pertaining document. The DI is advised to review and correct these errors to ensure clarity and accuracy.
4.	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.
5.	PFE2 (c)	The establishment currently 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.
6.	PFE2 (c)	The DI is advised to implement a process to regularly test and periodically manually challenge fridge and freezer temperature alarms to provide an assurance that they are operating as expected.

Background

University of Liverpool stores a range of tissues and bodily fluids for use for the scheduled purpose of ‘research in connection with disorders, or the functioning, of the human body. The establishment is also functioning as a Research Tissue Bank (RTB) with recognised Research Ethics Committee approval. University of Liverpool has been licensed by the HTA since 2007. This was the third inspection of the establishment; the most recent previous inspection took place in March 2019.

Since the previous inspection, the establishment has appointed a new DI and two new Persons Designated (PDs).

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
All 47 HTA licensing standards were covered during the inspection (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 two satellite sites (Alder Hey Children's Hospital and Liverpool Women's Hospital). The visual inspection included a review of the areas where material is stored in freezers and at room temperature (RT).

Audit of records
During the visual inspection, records for 17 samples in storage were reviewed. These samples comprised samples in -80°C freezers (sample to record), stored at RT (sample to record). Two samples at RT 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 Human Material Governance Team members, Human Material Oversight Committee members, BioBank Managers and representatives of the different research groups working under the licence at the hub and satellite sites.

Report sent to DI for factual accuracy: 25 July 2024

Report returned from DI: 30 July 2024

Final report issued: 30 July 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: 4 December 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.