Inspection report on compliance with HTA licensing standards
Inspection date: **21 January 2025**

LifeArc

HTA licensing number 12634

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
LifeArc (The Accelerator Building, Stevenage Bioscience Catalyst)	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.

LifeArc ('the establishment') was found to have met all of the HTA standards.

Advice

The HTA advises the DI to consider the following to further improve practices:

Number	Standard	Advice
1.	GQ1(a)	All staff are required to read standard operating procedures (SOPs) before they commence working with human tissue. To strengthen assurance, the DI should consider keeping a record of all staff that have read the relevant SOPs.
2.	GQ1(d)	Although brief notes of what was discussed at governance meetings are kept, these lack sufficient detail. To strengthen this further, the DI should consider including more detailed note-keeping for key discussions held and specific actions agreed during meetings to ensure that there is a more complete record.
3.	GQ2(b)	Actions arising from audits are documented on the 'Audit Record' form; however, it is unclear when an action is still pending or if it has been completed. Although this information can be retrieved, the DI should consider developing a centralised system to record audit actions and due dates respectively so that this information be retrieved easily.
4.	GQ2(a)	The establishment carries out regular traceability audits. The DI should consider extending the scope of audits, to include process audits, which could include – for example - sample receipt through to disposal. This may help the establishment identify whether procedures reflect actual practices.

5.	PFE1(c)	The procedure for cleaning and decontamination is documented within risk assessments and other procedures. The DI is advised to consider having this information in one procedural document so that staff can access it easily.
6.	PFE2(c)	The establishment has a temperature monitoring system in place which notifies staff of excursions that occur both within hours and out-of-hours. The DI should consider introducing a regular challenge of the alarm system to ensure it is operating as expected.
7.	PFE2(d)	The establishment has a comprehensive storage contingency procedure in place. The DI should consider keeping a copy of this in the cryostore to ensure that staff dealing with a failure can access the procedure readily.

Background

Life Arc is a self-funded life sciences charity. The establishment has a strong focus on global health and rare diseases such as childhood cancers. The establishment stores human tissue samples which are purchased from HTA-licensed establishments or imported from outside of the UK. Before researchers can use human tissue they must apply to the establishment's human tissue committee.

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

Of the 47 HTA standards 38 were assessed (standards published 3 April 2017). Standards, C1(a),(b),(d),(e) and (f) and C2(a), (b) and (c) were not applicable as the establishment does not seek consent. PFE2(b) is not applicable as the establishment does not store material for research from the deceased.

Review of governance documentation

A number of documents were reviewed during the assessment which included, but were not limited to, standard operating procedures for licensable activities, key policies, traceability audits, meeting minutes, staff training records, incident reports and agreements.

Visual inspection

There was no visual inspection of the premises; however, a meeting took place with relevant staff members to discuss the PFE standards. A number of photographs of areas where licensable storage takes place were shared.

Audit of records

No traceability audit was carried out; however, a review of recently conducted audits was undertaken as part of the assessment.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff which included the, DI, Senior Scientist and Health and Safety Officer.

Report sent to DI for factual accuracy: 21 February 2025

Report returned from DI: 14 March 2025

Final report issued: 14 March 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.