Inspection report on compliance with HTA licensing standards
Inspection date: **22 June 2023**

Synairgen Research Ltd

HTA licensing number 12532

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
Synairgen Research Ltd	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.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

Number	Standard	Advice
1.	C2(c)	The DI is advised to consider regular refresher training for consent-seekers to support knowledge and up-to-date regulatory and governance requirements.
2.	GQ1(a)	Donor consent is usually sought 'in person' but has, on occasion, been obtained electronically. SOP-CLIN-51 Obtaining Informed Consent covers electronic written consent but focuses on the identification of the donor. The DI is advised to clarify the step-by-step process for obtaining electronic consent within the standard operating procedure for a clear and accurate representation of the process.
3.	GQ1(c)	The establishment's internal audit findings identified some members of staff had not read and acknowledged new and amended standard operating procedures following their publication. The DI is advised to include an escalation mechanism to ensure standard operating procedures are read and acknowledged by staff in a timely manner to provide assurance up-to-date procedures are being followed.
4.	GQ2(a)	Scheduled audits were undertaken at a regular frequency. The DI is advised to consider including a regular audit against HTA standards to demonstrate compliance with HTA licensing requirements.
5.	GQ2(b)	A new procedure was recently introduced to record audit non-compliances and track corrective and preventative actions (CAPAs). However, past audits still had CAPAs outstanding and although they were verbally confirmed as resolved, the DI is advised to formally document the closure of these CAPAs after review of confirmatory evidence.

6.	GQ5(b)	Adverse events are investigated and corrective and preventative action taken where necessary. The DI is advised to consider implementing timeframes for completing CAPAs to ensure action is taken to resolve and / or prevent a recurrence in a timely manner.
7.	PFE2(c)	Slides containing relevant material were stored at ambient temperature. The DI is advised to formalise temperature monitoring of this storage area to ensure the integrity of tissue and cells is maintained.
8.	PFE2(d)	The Non Clinical Quality Manual contains the risk assessments associated with practices requiring compliance with the Human Tissue Act 2004. It states that if an emergency situation renders the premises unsuitable for the storage of samples then consideration could be given to storing samples in an accredited, secure, off-site biorepository facility. The DI is advised to consider identifying an appropriate HTA-licensed establishment capable of storing relevant material on behalf of Synaigen Research Ltd in an emergency situation and formalising the arrangement. Any arrangements made could be documented in L096 Freezer and Liquid Nitrogen Alarm System and Contingency Planning to ensure correct procedures are followed if an emergency situation arises.

Background

Synairgen Research Limited is a commercial company providing clinical and non-clinical operations focused on the development of novel therapies for respiratory disease. They have developed a biobank of samples obtained from recruited volunteers.

Synairgen Research Ltd has been licensed by the HTA since November 2008. This was the second inspection of the establishment; the most recent previous inspection took place in October 2014.

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
46 out of 47 HTA licensing standards were covered during the inspection (standards published 3 April 2017). One standard was not applicable as the establishment did not store bodies or body parts [standard PFE2(b)] under the research licence.

Review of governance documentation
The inspection comprised a review of documentation relevant to the establishment's licensed activities including; policies and procedural documents, equipment servicing records, material transfer agreements, risk assessments, minutes of meetings, a review of the tissue traceability database, staff training records, temperature monitoring for the storage units and audits.

Visual inspection
No site visit was undertaken as part of this inspection. However, the establishment provided photographs of the relevant material storage areas and the security measures in place at the establishment.

Audit of records
The establishment's traceability database was reviewed and checked with samples against consent, and storage location through to use or disposal.

Meetings with establishment staff
The inspection included virtual meetings with the following staff: the Designated Individual (DI), two Persons Designated (PD), a clinical research nurse, two members of the Quality Management Team and the named Corporate Licence Holder representative. The meetings covered: consent, quality management, traceability, and premises, facilities and equipment.

Report sent to DI for factual accuracy: 7 July 2023

Report returned from DI: 10 July 2023

Final report issued: 11 July 2023

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.