Inspection report on compliance with HTA licensing standards
Inspection date: **15 June 2022**

RxCelerate
HTA licensing number 12665

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
Rxcelerate	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.

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

Compliance with HTA standards

All applicable 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.	C1(d)	The establishment has comprehensive information sheets and consent forms. As most blood samples collected from healthy volunteers tend to be used up during the research work, the DI may wish to include this detail in relevant information sheets. This may help to improve transparency, clarifying to the participant that no residual samples may remain should they decide to withdraw their consent to be involved in the research.
2.	GQ2(a)	Every six months, the establishment undertakes a thorough HTA audit. To improve clarity on coverage, the DI should consider setting out the HTA standards relevant to each aspect audited.
3.	GQ2(a)	To improve the range and scope of auditing, the DI is advised to consider including observational audits of staff (new starters or more experienced staff) undertaking activities covered by documented procedures.
4.	GQ2(b)	Staff at the establishment conduct thorough and regular audits, relevant to their HTA-licensed activities. The DI may wish to consider ensuring that all audit actions that are completed are documented on the proforma itself or ensuring that the evidence of each completed action can easily be traced back to the audit itself. This should help to improve clarity about the completion of audit actions.

5.	GQ5(a)	The establishment has a detailed SOP for reporting incidents involving human tissue. This SOP includes the following statement, in a table which highlights the risk grading for each incident category: 'Untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or lifethreatening, disabling, or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity.' The DI is advised to consider reviewing and revising (or removing) this wording, if it is not relevant to the establishment's remit, as it appears to apply to activities relevant to the Human Application sector rather than the Research sector.
6.	PFE2(c)	The Laboratory Manager reviews the critical storage conditions data, that is managed using a web-based system for trend analysis. This trend analysis is not documented at present; therefore, the DI is advised to consider formalising this process.
7.	PFE2(c)	Critical storage conditions are appropriately monitored and alarmed, with notifications sent out should a qualifying temperature excursion arise. The alarms are not tested at present, as the establishment relies upon the notifications from routine excursions that may take place to provide the assurances that the system is working as expected. To strengthen this assurance, the DI is advised to consider how this approach can be evidenced and to consider regular alarm system testing.

Background

The establishment is a private company that delivers pre-clinical drug development programs on behalf of pharmaceutical companies and stores blood samples collected from healthy volunteers by consent-trained phlebotomists.

The establishment has been licensed since 2017 and this was the first inspection of the licence. Since the licence application assessment visit, there have been no significant changes to the licence arrangements, or the activities carried out under the licence. The only change has been an increase in the number of volunteers that the establishment may collect samples from.

There is an Health Research Authority (HRA)-approved biobank at the establishment that stores samples with consent which have been collected previously from ethically approved research projects. The Biobank is for internal use only, if required, and does not operate as a research tissue bank. The samples are not released and not are any samples being collected for storage in the bank. As serum and plasma are the only samples types stored, the Biobank was not covered under the scope of this inspection.

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

45 standards were assessed (standards published 3 April 2017). T1(g) and PFE2(b) were not applicable.

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, study audits including an audit against HTA standards, meeting minutes, staff training records, traceability records and incidents.

Visual inspection

There was no visual inspection of the premises; however, a meeting took place with relevant staff members to discuss the PFE standards.

Audit of records

No traceability audits were carried out; however, a review of the establishment's audits was undertaken as part of the assessment. The establishment carries out extensive audits against the HTA standards. The Inspector had no concerns with the reports presented during the assessment.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff and included the DI, PD, Laboratory Manager and Project Manager of the In vitro team involved with licensed activities.

Report sent to DI for factual accuracy: 5 July 2022

Report returned from DI: 13 July 2022

Final report issued: 14 July 2022

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.