Inspection report on compliance with HTA licensing standards
Inspection date: **09 August 2024**

Immunocore Ltd

HTA licensing number 12643

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 Building 92, OX14 4RY	Licensed	Not licensed
Satellite site Buildings 93 and 96, OX14 4RZ	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 Immunocore Ltd ('the establishment') had met the majority of the HTA's standards, two minor shortfalls were found against standards for Governance and quality systems and Premises, facilities and equipment. These related to complaints management and documented procedures for cleaning and decontamination.

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

Standard	**Inspection findings**	**Level of shortfall**
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 a documented system for managing complaints. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

PFE1 The premises are secure and fit for purpose		
c) There are documented cleaning and decontamination procedures	The establishment did not have documented cleaning and decontamination procedures. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, wi thin 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(c)	While the establishment has a process for notifying staff of changes to SOPs or processes, the DI is advised to implement a system to ensure that staff maintain competence in both new and existing procedures. For example, SOPs could be shared with staff during the review process, even when no changes are made. Similar approaches can help to reinforce adherence to established processes and provide opportunities for staff to refresh their understanding and maintain consistent application across the establishment. Regular reinforcement may help to ensure staff remain competent and aware of both new updates and existing practices.

Background

Immunocore Ltd is licensed for the storage of relevant material that has come from a human body for use for a scheduled purpose, under the Human Tissue Act 2004 (HT Act). Human samples are stored for use for the scheduled purpose of 'research in connection with disorders, or the functioning, of the human body'. The establishment is a biotechnology company focusing on the development of therapeutics for a range of diseases. Relevant material is obtained from clinical trials, internal volunteers, third party providers or purchased from commercial suppliers. Samples stored under the licence are from living and deceased donors, who may be healthy or have a disease. Samples mainly include blood, blood components and tissue. As well as relevant material stored under the licence, the establishment also stores human samples for research projects that have project-specific approval from recognised research ethics committees (RECs).

The establishment has been licensed by the HTA since January 2016. This was the third inspection of the establishment; the most recent inspection took place in April 2019. Since the previous inspection, there have been changes to the DI and one new Person Designated hasbeen added; the establishment has also added a satelite site to their licence.

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

39 out of 47 HTA licensing standards were covered during the assessment (standards published 3 April 2017). Some standards relating to consent procedures (C1(a), C1(d), C1(e), and C1(f)) and standards relating to consent training (C2(a), C2(b) and C2(c)) were not applicable as the establishment does not directly seek consent from donors and PFE2(b) could not be assessed as the establishment does not store bodies or body parts.

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 including risk assessments, arrangements for temperature monitoring for the storage units, staff training records, a review of the sample tracking system and databases used to record and track relevant material, agreements, audits, and incidents.

Visual inspection
No site visit was undertaken as part of this inspection. The establishment provided images of the storage facilities that allowed for assessment of security measures and the signage on the individual units.

Audit of records
There were no sample audits carried out. A number of audits carried out by the establishment staff, which included audits covering processes and traceability of specimens, were reviewed.

Meetings with establishment staff
The inspection included discussions with the DI, Manager Research Compliance, Biological Sample Specialist, Senior Scientist and Senior Laboratory Technician.

Report sent to DI for factual accuracy: 30 August 2024

Report returned from DI: 17 September 2024

Final report issued: 30 September 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.