Inspection report on compliance with HTA licensing standards
Inspection date: **12 September 2022**

Imanova Limited

HTA licensing number 12587

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
Imanova Limited	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.

Imanova Limited ('the establishment') was found to have the met majority of HTA's standards; however, one minor shortfall was identified against one standard for Governance and quality systems (risk assessments).

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 shortfall identified during the assessment.

Compliance with HTA standards

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded, and monitored		
GQ6(a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.	There are documented health and safety risk assessments but there are no risk assessments for practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice. "The establishment submitted sufficient evidence to address this shortfall before the report was finalised."	**Minor**

Advice

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

Number	**Standard**	**Advice**
1.	C1(d)	To strengthen assurance on consent provided by donors for their samples to be stored and used for research, the DI is advised to include a specific option on the template consent form, alongside the other options for interventions for which donors provide their written consent.
2.	GQ5(b)	The establishment has a documented procedure that sets out the steps to be taken by staff if there is a deviation from existing protocols and procedures. The DI is advised to also include examples of adverse events so staff are clear of the types of events that are expected to be managed using the deviation procedure.
3.	PFE2(c)	The DI is advised to test the temperature alarm system periodically, to ensure that the systems for call-out and management of notifications are working as expected.

Background

The establishment is contract research organisation that holds a HTA licence to cover research activities. The establishment has two arms of work: pre-clinical research and clinical research involving studies under HRA (Health Research Authority) approval (studies which have received ethical approval from recognised Research Ethics Committees). Tissue purchased for pre-clinical research is stored under the governance of the HTA licence.

The establishment stores blood, urine and plasma for clinical research and brain tissue for pre-clinical research. This was the establishment's second HTA inspection; there had been no significant changes since the last inspection, which took place in 2014.

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 standards were assessed (standards published 3 April 2017).

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, staff competency records and records relating to traceability.

Visual inspection

There was no visual inspection of the premises; however, the establishment shared a visual presentation that included photographs of licensed storage areas. This was followed up by a meeting 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 traceability audits was undertaken as part of the assessment. The Regulation Manager had no concerns with the audits presented during the assessment.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff, which included the CLHc (Corporate Licence Holder contact), DI and PD (Person Designated).

Report sent to DI for factual accuracy: 28 September 2022

Report returned from DI: 10 October 2022 (no comments)

Final report issued: 18 October 2022

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 Virtual Regulatory Assessment Report.

Date: 18 October 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.