Licence application assessment report on compliance with HTA licensing standards
Assessment date: **17June 2025**

IMU Biosciences

Proposed HTA licensing number 12804

Application to be licensed under the Human Tissue Act 2004

Activities

Premises/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
IMU Biosciences	Application made	Application not made

Summary of findings

The HTA found the proposed Designated Individual (DI) and the proposed Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that IMU Biosciences ('the establishment') had met the majority of the HTA's standards, five minor shortfalls were found against standards for Governance and quality systems, and Premises, facilities and equipment.

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 assessment.

Compliance with HTA standards

Minor Shortfalls

Standard	Assessment 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		
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.	Ratified, documented, and up-to-date Standard Operating Procedures (SOPs) were in place but did not cover all licensable activities. There was no SOP in place for staff to follow in order to minimise the likelihood of theft, damage, or loss of HTA relevant material during transport. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

Standard	Assessment findings	Level of shortfall
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities.	A comprehensive schedule of audits was in place but did not include auditing of consent records. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.	Risk assessments were in place but were incomplete. There was no documented risk assessment in place for potential incorrect disposal of HTA relevant material. Additionally, current risk assessments only indicate the level of risk collectively and not for each hazard identified. Although specific controls are in place, the remaining residual risks have not been assessed. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

Standard	Assessment findings	Level of shortfall
PFE1 The premises are secure and fit for purpose		
a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.	The premises were clean, secure, and well maintained. However, there was no evidence that an assessment of the premises had been carried out. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue		
d) There are documented contingency plans in place in case of failure in storage area.	An SOP is in place detailing emergency procedures for cold storage failure. However, emergency procedures rely on alternative storage on the same premises. There is no contingency arrangement in place should there be an emergency situation such as potential power failure, that might render the premises unusable for storage of human tissue. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

Advice

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

Number	Standard	Advice
1.	C1(b)	The establishment conducts on-site studies on healthy volunteers whose samples are used for internal quality control and calibration purposes. The consent forms for these studies allude to the use of participant samples for 'future research' but these do not involve the use of relevant material. The proposed DI is advised to amend the consent form for the healthy volunteer studies to clarify the reference to 'future research' to ensure accurate reflection of the activities involved.
2.	T1(c)	The establishment will be working with collaborators on recognised Research Ethics Committee (REC) - approved projects. They aim to undertake and complete the research work within the REC approval validity period. To achieve this, the proposed DI is advised to have a system in place to track REC approval expiry dates.
3.	T2(b)	Sample disposal is currently documented on the Laboratory Inventory Management System (LIMS). The date of disposal is automatically captured by the electronic system, but the method and reason of sample disposal are currently being documented in free text in the comments box of the inventory. As the method and reason of disposal are not mandatory information in this platform, the proposed DI is advised to ensure the Disposal SOP mandates the documentation of method and reason of sample disposal in the relevant sections of the database.
4.	PFE2(c)	Appropriate temperature monitoring, alarm, and call out system is in place to monitor critical storage conditions. The proposed DI is advised to put arrangements in place for temperature alarms to be regularly tested and manually challenged periodically, to ensure that they are operating as expected.
5.	PFE2(c)	The proposed DI is advised to consider labelling equipment used to store relevant material to ensure staff are aware of the necessity to maintain the quality, safety and security of such material and prevent mix-ups with

		other tissues. The proposed DI is also advised to consider adding signage defining alarm set points of minimum and maximum temperatures to ensure staff are visually reminded of the acceptable temperature ranges.
6.	PFE2(c)	Out-of-hours alarms are currently covered by the core members of the team including the DI, the Director of Laboratory Operations, and the Laboratory Manager. However, there is no defined allocation of responsibility for responding to alarm calls taking place outside working hours. The proposed DI is advised to consider establishing a roster of respondents for out-of-hours temperature excursions to ensure clear responsibility for alarm response and management.

Background

IMU Biosciences is a biotech company founded in 2021. The establishment focuses on developing immune data platforms with clinical applications to improve health outcomes in various disease areas. The establishment will be conducting their own clinical trials, receiving samples for storage and processing, from clinical sites across the UK and from abroad. They will also be working on external research projects in collaboration with their UK-based partners.

Description of activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during a desk-based assessment and site visit:

Standards assessed

Of the 47 HTA licensing standards that were covered during the assessment (standards published 3 April 2017), 41 were assessed. C1(e) and (f) and C2(a), (b), and (c) were not applicable as the establishment is not involved in seeking consent for research within the scope of the Human Tissue Act 2004. PFE2(b) is not applicable as the establishment will not be storing material from the deceased.

Review of governance documentation

Local policies and procedural documents relating to licensed activities, template transfer agreements, equipment service records, audit plans, risk assessments, meeting minutes, temperature monitoring systems for the storage units, and staff training records were reviewed.

Visual inspection

The visual inspection comprised of reviewing the laboratory, sample storage areas, ‘goods in’ area, and post room. A discussion took place on the sample journey and the responsibilities of staff receiving samples.

Meetings with establishment staff

A roundtable meeting was held with the proposed DI and Persons Designated (PDs) supporting the application process.

Report sent to proposed DI for factual accuracy: 09 July 2025

Report returned from proposed DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 21 July 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, and;
- 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, or;
   - 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 site visit.

   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, or;
- 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.