

Evaluation report on compliance with HTA licensing standards
Report date: **14 February 2025**



Empyrean Therapeutics Ltd
HTA licensing number 12681

Licensed under the Human Tissue Act 2004

Licensed activities

Empyrean Therapeutics Ltd

- Storage of relevant material which has come from a human body for use for a scheduled purpose

Evaluation summary

At the HTA's request, the establishment submitted a self-assessment for evaluation of compliance against the HTA's licensing standards.

Evaluated self-assessments are intended to be proportionate and risk-based. They are one of several tools that the HTA uses to maintain regulatory oversight. The regulatory framework places responsibility for compliance with those undertaking regulated activities. Designated Individuals are responsible for the accuracy of self-assessments.

As part of this process, the Designated Individual (DI) reported the establishment (HTA licensing number 12681) was substantially compliant with HTA's licensing standards. Based on the assurances provided, the HTA takes overall compliance to be satisfactory.

The HTA advises the DI to review the following areas against published HTA guidance to ensure they are meeting regulatory expectations and all statutory obligations:

Documented risk assessments for all practices and procedures, including receiving and/or storing specimens without appropriate consent documentation (HTA licensing standard GQ6(a)). Further information about meeting standard GQ6(a) can be found in the Research Standards and Guidance document on the HTA website

[Research Standards and Guidance \(hta.gov.uk\)](https://www.hta.gov.uk/research-standards-and-guidance)

The HTA cannot provide any guarantees or endorsements of licensed establishments, or their activities, based on self-assessments.

The frequency and format of future assessments of compliance will be determined by the HTA according to evaluated risk.

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