

Evaluation report on compliance with HTA licensing standards

Report date: **22 March 2024**



Sygnature Discovery Ltd
HTA licensing number 12614

Licensed under the Human Tissue Act 2004

Licensed activities

Hub site

Sygnature Discovery Ltd, Nottingham

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

Satellite site

Sygnature Discovery Ltd, Alderley Park

- 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 12614) 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.

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 and in particular there is a risk assessment for the receiving and/or storing specimens without appropriate consent documentation.

T1(c) – An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.

T2(b) – The date, reason for disposal and the method used are documented.

[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.

Final report issued: 22 March 2024