Licence application assessment report on compliance with HTA licensing standards
Site visit date: **29 January 2024**

Nucleome Therapeutics

Proposed HTA licensing number 12771

Application for a licence under the Human Tissue Act 2004

Activities applied to be licensed

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
Nucleome Therapeutics, Oxford Science Park	Applied to be licensed	Not applied to be licensed

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.

The HTA found that Nucleome Therapeutics (the establishment) had met all HTA standards.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

Number	Standard	Advice
1.	GQ2(a)	The establishment plans to have a robust schedule of audits, with the use of an external auditor to carry out annual auditing against HTA standards. The proposed DI is also advised to consider how the establishment may gain optimal benefit from auditing, perhaps widening the types of audits to provide assurance across a range of activities that will take place under the licence.
2.	GQ3(b)	Appropriate training is available for new starters who will be working with human tissue. To strengthen induction of new staff the proposed DI should consider developing a documented process for competency assessment to evidence that members of staff have reached training and performance expectations in particular aspects of their work.
3.	GQ6(a)	The establishment has developed assessments which cover the risks relating to activities to be licensed. To assist with ongoing risk management, the proposed DI is advised to consider the adoption of a conventional risk matrix approach.
4.	PFE2(c)	The proposed DI is advised to schedule periodic testing of the critical storage alarm system to ensure it is working as expected.

5.	PFE2(d)	The proposed DI is advised to consider keeping a controlled copy of the contingency plan in critical storage areas. This should help to ensure staff have ready access to the plan in an emergency, and are aware of actions to take as a result of critical storage failure.

Background

The establishment is a small biotechnology company that sources blood samples from commercial suppliers to extract DNA and RNA. The establishment does not plan to seek consent directly from participants, which will be sought by allied health professionals. They will store blood samples from living donors only.

Description of activities undertaken during the assessment

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during the assessment:

Standards assessed

Of the 47 HTA licensing standards that could apply, 46 were assessed (standards published 3 April 2017). PFE3(c) was not applicable as the establishment does not intend to store the deceased.

Review of governance documentation

A review of policies and procedural documents relating to licensed activities, contracts for servicing of equipment and records of servicing, audit procedures, risk assessments, incident reporting, meeting minutes, temperature monitoring for the storage units and staff training records was undertaken.

Visual inspection

A visual inspection was carried out of the laboratory where tissue would be received and the storage areas which accommodate fridges/freezers (including storage at -20^{0}C, -80^{0}Cand -150^{o}C) and liquid nitrogen storage.

Meetings with establishment staff

A roundtable meeting was held with the proposed DI and Persons Designated (PDs) as well as other members of staff who would be working with human tissue.

Report sent to proposed DI for factual accuracy: 12 February 2024

Report returned from proposed DI: 20 February 2024 (No comments)

Final report issued: 21 February 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 site visit 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 site visit inspection;
- a request for information that shows completion of actions;
- monitoring of the action plan completion, or;
- follow up at next routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.