Licence application assessment report on compliance with HTA licensing standards
Site visit date: **28 November 2023**

Colibri Scientific Ltd

Proposed HTA licensing number 12766

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
Colibri Scientific Ltd	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.

Colibri Scientific Ltd (the establishment) was found to have met all HTA standards.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

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.	GQ1(a)	The proposed DI is advised to amend CS_SOP_006 to include the process step of recording the relevant material disposal date within the tissue tracking database to ensure a clear and accurate representation of the procedure.
2.	GQ1(a)	The proposed DI is advised to amend the scope of CS_SOP_030 Handling Client Complaints to include clients storing relevant material under the establishment's licence as well as those involved in clinical trials to ensure the document captures the governance expectations and complaint procedure for all samples stored at the establishment.
3.	GQ1(b)	There was a document control system in place ensuring documents were regularly reviewed. The proposed DI is advised to consider adding review dates to governance documentation so all staff may easily identify when a document is due for review and to provide additional assurance that review dates are not overlooked.
4.	GQ2(a)	The proposed DI is advised to audit against HTA standards to demonstrate compliance with HTA licensing requirements.
5.	GQ2(b)	Corrective and preventative actions (CAPAs) identified from audit non-compliance findings are added to a deviation log. The proposed DI is advised to include timeframes for completing CAPA actions to ensure they are resolved in a timely manner.
6.	GQ3(b)	The proposed DI is advised to expand the new starter induction programme to include training on:

		• The HTA licensing framework • Risk assessments • Material Transfer Agreements (MTA) to ensure all staff are fully trained on all policies and procedures relevant to their work.
7.	GQ5(a)	Staff were instructed in how to use incident reporting systems. However, the proposed DI is advised to further assist staff by providing relevant examples of adverse events within the Quality Manual so reporting and investigation can take place as expected.
8.	PFE2(d)	The establishment has documented and comprehensive site storage contingency arrangements. Should offsite storage be required, the establishment has a formalised agreement to transfer relevant material stored with recognised research ethics committee (REC) approval to another HTA-licensed establishment. To ensure that all relevant material is covered, the proposed DI is advised to amend the agreement to also include the transfer of relevant material stored under the proposed licensing arrangements.

Background

Colibri Scientific Ltd project manages sample operations for clinical trials and stores samples on behalf of clients.

Description of activities undertaken

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

Standards assessed against during visit

46 out of 47 HTA licensing standards were covered during the inspection (standards published 3 April 2017). One standard was not applicable as the establishment does not intend to store bodies or body parts [standard PFE2(b)].

Review of governance documentation
The assessment included a review of documentation relevant to the establishment's proposed licensable activities. This included policies and procedural documents, risk assessments, adverse event reporting, training requirements, temperature monitoring for the refrigerated and ultra low freezer units, equipment servicing records and a review of the HTA tissue tracking database that will be used to record and track relevant material.

Visual inspection
The visit included a visual inspection of the areas where the establishment proposes to undertake the licensable activity. This included the areas where relevant material will be received into the establishment and stored.

Meetings with establishment staff
The assessment included meetings and discussions with the proposed DI, Quality Consultant, Sample Manager and Document Manager.

Report sent to proposed DI for factual accuracy: 15 December 2023

Report returned from proposed DI: 18 December 2023

Final report issued: 2 January 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.