Licence application assessment report on compliance with HTA licensing standards
Assessment dates: **26 January 2023** (remote) and **6 February 2023** (site visit)

CN Bio Innovations

Proposed HTA licensing number 12752

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
CN Bio Innovations	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 CN Bio Innovations (the 'establishment') had met all of the HTA's licensing standards.

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

Advice

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

Number	Standard	Advice
1.	GQ2(a)	The establishment has a quarterly audit schedule detailed within a policy. The proposed DI is advised to add specific dates and audit types within the schedule to ensure that they are carried out in accordance with the intended purpose and timelines.
2.	GQ5(a)	The establishment has a detailed SOP outlining the process for incident reporting. To improve staff awareness and understanding, the proposed DI is advised to give examples of what types of incidents are to be reported that relate to licensed activities, such as specimen loss, incorrect documentation and loss of traceability (this is not an exhaustive list).
3.	PFE1(a)	To ensure that staff are aware of the necessity to maintain sample quality, safety and security, the proposed DI is advised to consider improving signs on the fridges, freezers and liquid nitrogen tank, highlighting that human samples are contained within.
4.	PFE2(c)	Although they can be stored at much higher temperatures, fixed cells are stored in a refrigerated unit that is not monitored or alarmed. The storage is not critical and risks have been assessed. In the future, if storage failure could compromise the samples in any way, the proposed DI is advised to again consider remote temperature monitoring and an alarm call-out system similar to what is in place for the freezers.
5.	PFE2(d)	The establishment has sufficient storage capacity. There is an informal arrangement in place for the hire of a Liquid Nitrogen dewar should there be an issue with their own. The proposed DI is advised to consider formalising this arrangement or obtaining an ‘emergency’ dewar should the need arise.

Background

CN Bio Innovations is a biotechnology company that develops bioengineered drug discovery tools to assist pharmaceutical and other biotechnology companies develop novel therapies. The establishment has applied for a HTA licence for the storage of relevant material, which has come from a human body, for use for the scheduled purpose of 'research in connection with disorders, or the functioning, of the human body'.

At the time of inspection, the establishment was storing relevant material for the purpose of research that would require a HTA licence to be in place.

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

39 out of 47 HTA licensing standards were covered during the assessment (standards published 3 April 2017).
Some standards relating to consent were not applicable as the establishment does not intend to seek consent from donors (C1(b), C1(d), C1(e), C1(f), C2(a), C2(b) and C2(c)). Furthermore, the standard relating to the dignity of the deceased (PFE2(b)) was not applicable.

Review of governance documentation

Policies and procedural documents relating to all licensable activities including overarching policies, standard operating procedures and risk assessments were assessed. Documents detailing the plans for staff training, incident management, governance meetings and audits were reviewed. The establishments tracking systems were also assessed.

Audit of records

As relevant material was being stored on site, audits were conducted for three cell types in -80^{o}C freezer storage. The labelled aliquots were audited from location, to sample storage maps, tracking documentation, supplier approval documentation, consent forms and project plans. No discrepancies were identified.

Visual inspection

The Regulation Manager undertook a visual inspection of the premises which included the main office area, laboratories and liquid nitrogen tank storage area.

Meetings with establishment staff

The Regulation Manager met with staff carrying out activities under the licence, including Lead Scientists, the Laboratory Manager, the General Counsel and the proposed DI.

Report sent to proposed DI for factual accuracy: 13 February 2023

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

Final report issued: 16 February 2023

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.