Licence application assessment report on compliance with HTA licensing standards
Assessment date: **7 January 2026**

ReNewVax Ltd

Proposed HTA licensing number 12819

Application for a licence under the Human Tissue Act 2004

Activities

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
ReNewVax Ltd	Application made	Application not made

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.

ReNewVax Ltd 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.	C1(a)	The establishment does not plan to seek consent directly from donors and intends to use commercial suppliers. There are, however, consent standard operating procedures (SOPs), Patient Information Sheet templates, consent form templates and consent takers checklists within the establishment's Human Material Governance documentation. For clarity, the proposed DI is advised to archive any non-applicable documents until such a time they may be required.
2.	GQ1(a)	The proposed DI, proposed Corporate LH contact, Person Designated and members of the Human Material Governance Committee (HMGC) are all named throughout the SOPs and policies. If staff members change, it will be a significant undertaking to update all of the documents to keep them correct and up-to-date. The proposed DI is advised to consider referencing the role and not the individual's name in documents, to simplify document management.
3.	GQ2(a)	The audit schedule details the establishment's plans to undertake project audits annually and a full HTA compliance audit every two years. The proposed DI is advised to add specific dates within the schedule to ensure that planned audits are carried out in accordance with the intended timelines.
4.	GQ5(a)	The 'Incidents, Adverse Events and CAPA SOP' (RNV.HTA_SOP007) references the requirement to report incidents to the HTA. There is no requirement for incidents to be reported in the Research sector and the proposed DI is advised to update this section in the document. Although there is currently no requirement for establishments in the Research sector to report adverse incidents to the HTA, if a DI has concerns about an adverse event, they are encouraged to contact us for further advice.
5.	GQ6(a)	The establishment's 'Human Material Risk Assessment' (RNV_HTA005) details that it covers *'the licensed building and approved satellite rooms'*. The establishment has not applied for any satellite premises and therefore the proposed DI is advised to review and amend this reference.
6.	PFE3(a)	There is a 'Daily Storage Checklist', which the proposed DI confirmed would not be completed daily. The proposed DI is advised to rename the form and make it clear to the establishment staff how often the checklist should be completed.

7.	N/A	To ensure that staff are aware of the necessity to maintain sample quality, safety and security, the proposed DI is advised to consider putting a sign on the cryostores to highlight that human samples are contained within.

Background

ReNewVax ('the establishment') is a biotechnology company with a focus on the research of bacterial diseases and the development of human vaccines. 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'.

Description of activities undertaken during assessment

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

Standards assessed

38 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 directly from donors (C1(a), C1(b), C1(d), C1(e), C1(f), C2(a), C2(b) and C2(c)). Furthermore, PFE2(b) was not relevant as the establishment does not intend to store the deceased.

Review of governance documentation

Policies and procedural documents relating to all licensable activities including an overarching quality manual, standard operating procedures and risk assessments were assessed. Documents detailing the plans for staff training, incident management, governance meetings and audits were reviewed. The establishment's plans for the traceability of material were also assessed.

Visual inspection

The Regulation Manager undertook a visual inspection of the premises which included one laboratory and office area. The security arrangements and the suitability of the storage area was assessed.

Meetings with establishment staff

The Regulation Manager met with staff involved in the proposed licensed activities including the Head of Research who is the proposed DI, a Senior Scientist who is a proposed Person Designated (PD), and the Chief Executive Officer who is the proposed Corporate Licence Holder contact (CLHc).

Report sent to proposed DI for factual accuracy: 15 January 2026

Report returned from proposed DI: 20 January 2026

Final report issued: 20 January 2026

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.