ETHICS COMMITTEE CERTIFICATE OF APPROVAL

This is to certify that

Project No: 399/23 (HREC/100,081-Alfred-2023)

Project Title: A Single-center, Randomized, Double-blind, Placebo- and Positive-controlled Phase I Study to Evaluate the Safety, Tolerability, and Immunogenicity of Recombinant Zoster Vaccine (CHO) in Healthy Adults

Principal Researcher: Dr Kristi McLendon

*was considered by the Ethics Committee under National Mutual Acceptance (NMA) on **27-Jul-2023**, meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED** on **31-Jul-2023***

It is the Principal Researcher's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

The Principal Researcher is required to notify the Secretary of the Ethics Committee, via amendment or progress report, of

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Researcher to continue in that role, or any other change in research personnel involved in the project;
- Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

Additionally, the Principal Researcher is required to submit

- A Progress Report on the anniversary of approval and on completion of the project.

The Ethics Committee may conduct an audit at any time.

All research subject to the Alfred Hospital Ethics Committee review must be conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007).

The Alfred Hospital Ethics Committee is a properly constituted Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Human Research (2007).

SPECIAL CONDITIONS

1. **All research projects approved by the Alfred Hospital Ethics Committee are subject to, and must be carried out in compliance with, the most recent applicable COVID-19 government and relevant institution's restrictions.**
2. **Continuous insurance coverage needs to be maintained throughout the period of the clinical trial (ie until the final report has been submitted to the Ethics Committee for acknowledgement). Therefore, once the policy expires it is expected that it will be renewed under the same terms.**
3. **Provide the Trial Registration Number when available.**
4. **Provide the TGA Acknowledgement of CTN when available.**

APPROVED DOCUMENTS

Document	*Version*	*Date*
Protocol: TVAX-006-01	1.0	28-Apr-2023
Master Participant Information Sheet & Consent Form	1.0	20-Jul-2023
Master Participant Information Sheet & Consent Form – Pregnancy follow-up	1.0	20-Jul-2023
Wallet Card	1	20-Jul-2023
Participant Adverse Event Diary (Post Injection Day 1 - 8)	1.0	30-Jun-2023
Participant Contact Card Diary (Post Injection Day 8 - 31)	1.0	01-Jul-2023
Consumer Medicine Information (CMI) - SHINGRIX	6.0	May-2022
Advertising Social Media	1	12-Jul-2023

Documents Acknowledged	*Edition*	*Date*
Investigator's Brochure: Recombinant Herpes Zoster Vaccine (CHO Cells)	1.0	26-Jun-2023
Insurance Certificate: (13-Aug-2023 to 12-Aug-2024)	-	04-Jul-2023

APPROVED SITES

Approval is given for this research project to be conducted at the following sites and campuses:

Q-Pharm Pty Ltd (Nucleus Network Pty Ltd) – Qld, PI: Dr Kristi McLendon

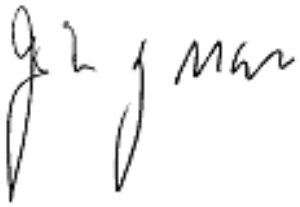
The Alfred Hospital Ethics Committee has approved the study but does not take responsibility for research governance processes at the participating sites. It is the responsibility of each participating site to create and implement research governance practices to adequately authorise, monitor and oversee the conduct of the study at their site.

Site-Specific Assessment (SSA)
SSA authorisation is required at all sites participating in the study. SSA must be authorised at a site before the research project can commence.

The completed Site-Specific Assessment Form and a copy of this ethics approval letter must be submitted to the Research Governance Officer for authorisation by the Chief Executive or delegate. This applies to each site participating in the research.

The HREC wishes you and your colleagues every success in your research.

SIGNED:



Professor John J. McNeil
Chair, Ethics Committee

Please quote project number and title in all correspondence