

Monash University Human Research Ethics Committee
Approval Certificate

This is to certify that the project below was considered by the Monash University Human Research Ethics Committee. The Committee was satisfied that the proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research* and has granted approval.

Project ID: 30401
Project Title: Immune modulation mechanisms in healthy human volunteers following influenza vaccination and daily supplementation palm tocotrienol-rich fraction
Chief Investigator: Professor Dr Ammu Radhakrishnan
Approval Date: 27/01/2022
Expiry Date: 27/01/2027

Terms of approval - failure to comply with the terms below is in breach of your approval and the *Australian Code for the Responsible Conduct of Research*.

1. The Chief Investigator is responsible for ensuring that permission letters are obtained, if relevant, before any data collection can occur at the specified organisation.
2. Approval is only valid whilst you hold a position at Monash University.
3. It is responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash letterhead and the Monash University complaints clause must include your project number.
6. Amendments to approved projects including changes to personnel must not commence without written approval from MUHREC.
7. Annual Report - continued approval of this project is dependent on the submission of an Annual Report.
8. Final Report - should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected completion date.
9. Monitoring - project may be subject to an audit or any other form of monitoring by MUHREC at any time.
10. Retention and storage of data - The Chief Investigator is responsible for the storage and retention of the original data pertaining to the project for a minimum period of five years.

Kind Regards,

Professor Nip Thomson

Chair, MUHREC

CC: Professor umadevi palanisamy, Professor Khalid Kadir, Dr Badariah Ahmad

List of approved documents:

Document Type	File Name	Date	Version
Consent Form	Informed Consent Immunity and TRF - English	08/11/2021	1
Supporting Documentation	Investigational Medicinal Product_Tocovid 200 mg and Plaebo	09/11/2021	1
Supporting Documentation	Tocovid (WITOC26-0)_Uhl_e_low	09/11/2021	1
Supporting Documentation	Vaxigrip Tetra Influenza vaccine	09/11/2021	1
Supporting Documentation	Informed Consent Immunity and TRF - English	09/11/2021	1
Explanatory Statement	Explanatory Statement Immunity and TRF - English 16102021 Ver 2	16/12/2021	2
Supporting Documentation	Explanatory Statement Immunity and TRF - English 16102021 Ver 2	16/12/2021	2
Supporting Documentation	Additional Notes	16/12/2021	1
Supporting Documentation	MUHREC flyer Immunity and TRF 16122021 Ver 3	05/01/2022	3
Supporting Documentation	Telephone Script Immunity and TRF Ver 3	05/01/2022	3