

## 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.

<b>Project Number:</b>	12090			
<b>Project Title:</b>	Tocotrienol-rich Vitamin E from Palm oil (Tocovid) and its effects in Diabetes and Diabetic Nephropathy			
Chief Investigator: Professor Khalid Kadir				
<b>Approval Date:</b>	12/02/2018			
Expiry Date:	12/02/2023			

## 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 MHUREC.
- 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.

Thank you for your assistance.

Professor Nip Thomson

Chair, MUHREC

CC: Ms Badariah Ahmad, Ms Suzanne Tan, Ms Yilynn Chiew

## List of approved documents:

Document Type	File Name	Date	Version
Explanatory Statement	English Explanatory Statement (Suzanne)	02/01/2018	1
Explanatory Statement	Malay Explanatory Statement (Suzanne)	02/01/2018	1
Supporting Documentation	Interview Template (suzanne)	02/01/2018	1
Supporting Documentation	Examination Template (Suzanne)	02/01/2018	1
Supporting Documentation	Table of Baseline and Screening Tests (Suzanne)	02/01/2018	1
Clinical Trial Detail Form	CTD (Suzanne)	02/01/2018	1
Consent Form	English Explanatory Statement (Suzanne) V2	05/02/2018	2
Consent Form	Malay Explanatory Statement (Suzanne) V2	05/02/2018	2