

**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:** 26262  
**Project Title:** Elucidating the Effects of Tocotrienol rich Vitamin E in a Prediabetes Population of different ethnicities in Malaysia.  
**Chief Investigator:** Dr Badariah Ahmad  
**Approval Date:** 18/06/2021  
**Expiry Date:** 18/06/2026

**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: Ms Siti Mokhtar, Professor Khalid Kadir, Assoc Professor umadevi palanisamy, Ms Siti Mokhtar

**List of approved documents:**

Document Type	File Name	Date	Version
Questionnaires / Surveys	findrisc form	08/09/2020	1.0
Supporting Documentation	EmailScript_PrediabetesStudy_FINAL	12/11/2020	1.0
Supporting Documentation	Study Protocol_muhrec	18/12/2020	final
Supporting Documentation	MUHREC_PREDIABETES FLYER_VERSION 2	24/12/2020	2
Supporting Documentation	TelephoneScript_PrediabetesStudy_VERSION 2	24/12/2020	2
Consent Form	English_Informed Consent_FINAL	24/12/2020	2
Explanatory Statement	EXPLANATORY STATEMENT_version2	25/12/2020	version 2
Supporting Documentation	Investigational Product	28/12/2020	1
Supporting Documentation	findrisc form	23/02/2021	1
Supporting Documentation	EmailScript_PrediabetesStudy_VERSION 3	23/02/2021	3
Supporting Documentation	MUHREC_PREDIABETES FLYER_VERSION 3	23/02/2021	3
Supporting Documentation	TelephoneScript_PrediabetesStudy_VERSION 3	23/02/2021	3
Explanatory Statement	ENGLISH_EXPLANATORY STATEMENT_VERSION 3	23/02/2021	3

Consent Form	English_Informed Consent_VERSION 3	23/02/2021	3
Supporting Documentation	Product Info Placebo_000003	24/02/2021	2
Supporting Documentation	Research Plan_PreDiabetes Study_MUHREC	24/02/2021	1
Supporting Documentation	TelephoneScript_PrediabetesStudy_VERSION 4	07/04/2021	4
Supporting Documentation	EmailScript_PrediabetesStudy_VERSION 4	07/04/2021	4
Supporting Documentation	MUHREC_PREDIABETES FLYER_VERSION 4	07/04/2021	4
Supporting Documentation	Research Plan_PreDiabetes Study_MUHREC_version2	07/04/2021	2
Explanatory Statement	ENGLISH_EXPLANATORY STATEMENT_VERSION 4	07/04/2021	4
Supporting Documentation	Product Info Placebo_simedarby	26/04/2021	2
Supporting Documentation	EmailScript_PrediabetesStudy_VERSION 5	07/05/2021	5
Explanatory Statement	ENGLISH_EXPLANATORY STATEMENT_VERSION 5	07/05/2021	5
Supporting Documentation	ENGLISH_EXPLANATORY STATEMENT_VERSION 6	01/06/2021	6
Supporting Documentation	Tocotrienol_Vitamin E 100mg	09/06/2021	2
Supporting Documentation	Placebo_palm superolein 300mg	09/06/2021	2