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13/08/2018

Dear Professor Ralph Martins,

Reference No:5201833483834

Title: 3348 Examine the effect of CocoMCT® on clinical factors related to health, cognition, quality of life and Alzheimer's disease (AD) - Tolerance Study

Thank you for submitting the above application for ethical and scientific review. Macquarie University Human Research Ethics Committee HREC Medical Sciences Committee considered your application.

I am pleased to advise that ethical and scientific approval has been granted for this project to be conducted by Professor Ralph Martins and other personnel:Associate Professor Edward Barin, Dr Ann Bacsi, Associate Professor Hamid Sohrabi, Dr Pratishtha Chatterjee, Dr Tejal Shah, Dr Cintia Botelho Dias, Ms Kathryn Goozee, Dr Mitra Elmi, Miss Shani Lauf.

Approval Date:

This research meets the requirements set out in the *National Statement on Ethical Conduct in Human Research* (2007, updated July 2018) (the *National Statement*).

Standard Conditions of Approval:

- 1. Continuing compliance with the requirements of the *National Statement*, which is available at the following website: http://www.nhmrc.gov.au/book/national-statement-ethical-conduct-human-research
- 2. This approval is valid for five (5) years, subject to the submission of annual reports. Please submit your reports on the anniversary of the approval for this protocol.
- 3. All adverse events, including events which might affect the continued ethical and scientific acceptability of the project, must be reported to the HREC within 72 hours.
- 4. Proposed changes to the protocol and associated documents must be submitted to the Committee for approval before implementation.

It is the responsibility of the Chief investigator to retain a copy of all documentation related to this project and to forward a copy of this approval letter to all personnel listed on the project.

Should you have any queries regarding your project, please contact the Ethics Secretariat on 9850 4194 or by email ethics.secretariat@mg.edu.au

The HREC Medical Sciences Committee Terms of Reference and Standard Operating Procedures are available from the Research Office website at: https://www.mq.edu.au/research/ethics-integrity-and-policies/ethics/human-ethics

The HREC Medical Sciences Committee wishes you every success in your research.

Yours sincerely,

Professor Anthony Eyers

Chair, HREC Medical Sciences Committee

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC)National Statement on Ethical Conduct in Human Research (2007, updated July 2018) and the CPMP/ICH Note for Guidance on Good Clinical Practice