

26-Feb-19

Dr. David Briskey
RDC Global
3B/76 Doggett Street
Newstead QLD 4006

Dear Dr. Briskey

Re: Application No: 2017-12-916-A-4

Study Title: A double-blind, randomised, placebo-controlled interventional study to evaluate the effect of orally-dosed Almega PL on cardio-metabolic parameters and inflammatory markers in men and women.

Type of Application: Amendment/Investigator Brochure Form

Name of the Documents Submitted and Approved:

Attachments

ALMCVH18_ADVERT_FINAL_V5_06.12.18_clean
ALMCVH_FacebookText
ALMCVH_Thank_You_Email_1_Feb_2019
Radio Ad 4 RDC Clinical_1_Feb_2019
ALMCVH18_PICF_FINAL_V6_05.02.19_clean
ALMCVH18_PROTOCOL_FINAL_V7_05.02.19_clean

Includes:

An updated HREC Indemnity was also submitted as part of this amendment to reflect the updated study title.

Date of Approval: 21-Feb-19

Thank you for submitting the above mentioned application.

The Bellberry Human Research Ethics committee (HREC) has scientifically and ethically reviewed this study.

This Bellberry HREC is constituted and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (2007, incorporating all updates as at 2018) (National Statement).

I wish to advise that the Bellberry Human Research Ethics Committee has ethically approved these documents/changes.

Details of Ethics Committee:

It is the process of the Bellberry Human Research Ethics Committee not to disclose personal details of its reviewing members. This Project was considered by a Committee that fulfilled the requirements of the National Statement (2007) section 5.1.29 & 5.1.30. Please note that the Principal Investigator and Co-Investigators are not members of the Bellberry Human Research Ethics Committees and were not involved in the review of this study.

Please do not hesitate to contact me if further clarification is required.

Yours sincerely





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Brian Stoffell
Chair, Committee A, TGA Code: EC00372
BELLBERRY HUMAN RESEARCH ETHICS COMMITTEE

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