

01-Aug-18

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

Dear Dr. Briskey

Re: Application No: 2017-11-841-A-2

Study Title: A double-blind, randomised, placebo-controlled study to evaluate the effect of orally-dosed LipiSpense curcumin and/or palmitoylethanolamide (PEA) on exercise recovery in healthy males.

Type of Application: Amendment/Investigator Brochure Form

Name of the Documents Submitted and Approved:

Attachments

CURREC_WebAd
CURREC_Thank_You_Email
RDC_General_Email
Facebook Plan
Curcumin & PEAAadvert_V4_Final_untrackedchanges_26.07.18

Includes:

The Committee notes that RDC submitted a protocol violation report for using unapproved advertisements, and that this Amendment is to submit the correct advertisements to be used for Approval.

Date of Approval: 30-Jul-18

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 May 2015) (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 5.1.29-30. 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

Michael James



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Michael James
Chair, Committee C (TGA HREC Code EC00430)
BELLBERRY HUMAN RESEARCH ETHICS COMMITTEE

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