

04-Aug-17

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

Dear Dr. Briskey

Re: Application No: 2016-11-832-A-1

Study Title: A double-blind, randomised, placebo-controlled interventional study to evaluate the effect of orally-dosed herbal extract, Gynostemma pentaphyllum extract (ActivAMP®) capsules on body composition in overweight men and women aged over 18 years.

Type of Application: Amendment/Investigator Brochure Form

Name of the Documents Submitted and Approved:

Attachments

AMPBOD17_V5_FinalProtocol_17July17_untrackedchanges

AMPBOD17_V5_PICF_17July17_untracked changes

Activamp advertising V5_untrackedchanges

Includes:

AMP-BOD17 fully signed updated Title Standard Indemnity received and HREC Indemnity received (2/8/17)

The following sites are included in this approval:

RDC GLOBAL PTY LTD
3B/76 Doggett St, Newstead, QLD 4006

and

The University of Queensland, School of Human Movement and Nutrition Sciences, St Lucia.

The PI will travel between sites as required and supervise at each site.

Date of Approval: 02-Aug-17

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.



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

Yours sincerely

A handwritten signature in black ink, appearing to read 'J. Karrasch', written in a cursive style.

Jeffrey Karrasch
Chair, Committee E (TGA HREC Code EC00450)
BELLBERRY HUMAN RESEARCH ETHICS COMMITTEE