



129 Glen Osmond Rd
Eastwood SA 5063
Phone: 08 8361 3222
Fax: 08 8361 3322

26-Mar-19

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

Dear Dr. Briskey

Re: Application No: 2017-05-397-A-3

Study Title: PEA-HED17, A double-blind randomised controlled study to evaluate the effectiveness of orally-dosed Palmitoylethanolamide (PEA) compared to ibuprofen for reducing pain severity and duration of headaches in healthy participants aged 18 years and older.

Type of Application: Amendment/Investigator Brochure Form

Name of the Documents Submitted and Approved:

Attachments

PEAHED-18 Thank You and Consent email V1_08-03-19_clean
PEAHED-18 WEBSITE ADVERT TEXT_V2_01-03-19_clean
PEAHED-18 FACEBOOK ADVERT TEXT_V2_08-03-19_clean
PEAHED17_PICF_FINAL V9_01.03.19_clean
PEAHED17_Protocol_V7_01.03.19_clean

Date of Approval: 26-Mar-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

A handwritten signature in black ink, appearing to read 'Annette Braunack-Mayer'.

Annette Braunack-Mayer



**129 Glen Osmond Rd
Eastwood SA 5063
Phone: 08 8361 3222
Fax: 08 8361 3322**

**Chair, Committee F, HREC TGA Code EC00455
BELLBERRY HUMAN RESEARCH ETHICS COMMITTEE**

e-protocol

This page is the manifestation of an electronic signature certifying that I have reviewed the electronic copy of this document and certify that it is an exact copy having all of the same attributes and information as the original document.

Document Name: PEAHED Amendment 3 - Version 26th March 2019

Document ID: 807

No. Pages: 2

Study: Gencor - PEA for Headache Pain and Severity - PEAHED-19

Electronic Signature for: Carly Tribe

Electronically Signed by: ctribe

Date & Time: 01/APR/2019 11:18 AM AEST

IP Address: 1.128.109.66