



129 Glen Osmond Rd  
Eastwood SA 5063  
Phone: 08 8361 3222  
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18-Dec-18

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

**Dear Dr. Briskey**

**Re: Application No:** 2017-05-397-A-1

**Study Title:** A double-blind randomised placebo-controlled study to evaluate the effectiveness of orally-dosed Palmitoylethanolamide (PEA) to reduce 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**

PEAHED17\_Protocol\_V5\_clean\_07.11.18  
PEAHED17\_PICF\_FINAL V7\_clean\_29.11.18  
PEA Advert\_V3\_clean\_13.11.18  
PEAHED-18 FACEBOOK ADVERT TEXT\_V1\_14-11-18  
PEAHED-18 General Recruitment Email for RDC database V1\_14-11-18  
PEAHED-18 RADIO TEXT\_V1\_14-11-18  
PEAHED-18 Thank You email for enquiries V1\_14-11-18  
PEAHED-18 WEBSITE ADVERT TEXT\_V1\_14-11-18

Includes:

The Committee note the removal of Casey Dick as Co-Investigator and that an updated Standard Indemnity and HREC Indemnity were submitted to reflect the updated Protocol Study Title.

**Date of Approval:** 18-Dec-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



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*Annette Braunack-Mayer*

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**Chair, Committee F**  
**BELLBERRY HUMAN RESEARCH ETHICS COMMITTEE**

e-protocol

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**Document Name:** PEAHED Amendment 1 - Version 18th December 2018

**Document ID:** 805

**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 11:17 AM AEST

**IP Address:** 1.128.109.66