Bellberry Limited supporting research and ethics

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

**06-Mar-19**

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

**Dear** Dr. Briskey,
**Re: Application No:** 2018-08-668
**Study Title:** Effect of LEVAGEN CWD palmitoylethanolamide (PEA) supplement on sleep quality/quantity in a healthy adult population: A double-blind randomized placebo-controlled interventional study
**Application Type:** NEW
**Type of Review:** FULLBOARD

**Name of the Documents Submitted & Approved: Attachments**

PEA Sleep Facebook Ads
PEA Sleep General Recruitment Email for RDC database
Image selection for ads
Facebook Plan Sleep
SLEPEA18_AdText_V3_29.11.18_clean
SLEPEA18_WebsiteText_V2_13-12-18_clean
The Sleep Inertia Questionnaire
SF36 general health questionnaire
Pittsburgh_Sleep_Quality_Index
PROMIS Sleep Disturbance
DASS-21
ESS PDF 1990-97
Final-CSD-Morning-only-with-instructions
HAM-D
SLEPEA18_PICF_V4_07.01.19_clean
Pharmako.18.19.cofc to 300919
1A - Aciute Oral Toxicity Study
1B - Repeat Dose 14 Day Oral Toxicity Study
1C - Repeat Dose 90 Day Oral Toxicity Study
1D - Ames Study
1E - In-Vitro Micronucleus Test
1F - Nestmann-2016-Food_Science_&_Nutrition PEA
1G - GRAS dossier -PEA
1H - Palmitic Acid Mono Ethanolamide GRAS - Final
Investigators Brochure Palmitoethanolamide_V2_10.10.18_clean
Research Paper - 'Entourage' effects of N-palmitoylethanolamide and N-oleoylethanolamide on vasorelaxation to anandamide

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occur through TRPV1 receptors
SLEPEA18_PROTOCOL__V4_07.01.19_clean
Product Specification - Code - 900633
Lot 20180615_07, Levagen+, COA, GCWDLEV90-180227

**Date of Meeting:** 19-Sep-18
**Date of Approval:** 05-Mar-19
**Period of Approval:** 05-Mar-19 - 05-Mar-21

Thank you for submitting the above mentioned application.

The Bellberry Human Research Ethics Committee (HREC) reviewed this study 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) on the above meeting date.

This Bellberry HREC is constituted and operates in accordance with the National Statement.

I wish to advise that the Bellberry Human Research Ethics Committee has approved this project and that the application meets the requirements of the National Statement subject to the conditions mentioned below.

**CONDITIONS:-**

- **THAT YOU ACKNOWLEDGE YOUR AGREEMENT TO THE UNDER MENTIONED CONDITIONS BY SIGNING AND RETURNING A COPY OF THIS LETTER, PRIOR TO THE COMMENCEMENT OF THE RESEARCH. THE SIGNED LETTER CAN BE EMAILED TO BELLBERRY@BELLBERRY.COM.AU OR POSTED TO THE ABOVE ADDRESS**.
- The data collected for the purpose of this research project cannot be used for any other purpose without the approval of the Bellberry Human Research Ethics Committee. Requests to use this data for other purposes must be made in the form of a formal research proposal.
- All research data, including electronic data is to be stored by the Principal Investigator for 15 years after the research has been completed or after the last contact, whichever is the later. Data must be recorded in a durable and appropriately referenced form and comply with relevant privacy protocols.
- That copies of all completed consent forms and any other data used in this research may be inspected at any time by representatives of the Bellberry Human Research Ethics Committee.
- That a report on the progress of the research will be made to the Bellberry Human Research Ethics Committee on **05-Mar-20** or on completion of the trial (if sooner) and then annually for the duration of the trial. This report is to indicate whether any ethical problems or complications have arisen, particularly side effects of drugs used or any other factor which may result in the investigation not producing any result as distinct from the anticipated result.
- That you will notify the Bellberry Human Research Ethics Committee of any changes that may be required within the research proposal.
- Bellberry Human Research Ethics Committee approval is conditional upon your meeting any statutory obligations that you may have in relation to this project.
- Adverse Event reporting should be reported to the Bellberry Human Research Ethics Committee as per the monitoring guidelines posted on the website www.bellberry.com.au.
- Any extension to the initial approval period is to be requested in an application via the eProtocol system together with the inclusion of a progress report.
- That you will provide a copy of the Sponsor's final report when this becomes available.

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**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. A member listing is available as an attachment in eProtocol. 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.

This study has been given the above reference number. Please remember to log on to eProtocol for all further correspondence with the Committee.

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

Yours sincerely

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

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**PRINCIPAL INVESTIGATOR SIGNATURE DATE**