University of the Sunshine Coast

5 August 2016

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Mr Graham Kell
Prof Mary Katsikitis
Mrs Amanda Rao

Dear Researchers

Ethics approval for research project: A randomised placebo controlled clinical trial on the efficacy of Caralluma supplement for reducing anxiety and stress in healthy adults over eight weeks (S/16/936)

On 4 July 2016 the Human Research Ethics Committee decided to defer approval of the application, subject to modifications and/or clarifications to the satisfaction of the HREC Acting Chairperson and selected HREC members. A response to the modifications and/or clarifications request by the Human Research Ethics Committee was received on 4 August 2016.

This letter is to confirm that on 5 August 2016, the Acting Chair of the Human Research Ethics Committee confirmed that the modifications and/or clarifications made were satisfactory and granted ethics approval.

The period of ethics approval is from 5 August 2016 to 27 October 2017. Please note that the ethics approval number for the project is S/16/936. This number should be quoted in your Research Project Information Sheet and in any written communication when you are recruiting participants.

The standard conditions of ethics approval are listed overleaf. If you have any queries in relation to this ethics approval or if you require further information please contact a Research Ethics Officer by email at humanethics@usc.edu.au or by telephone on +61 7 5459 4574 or 5430 2823.

I wish you well with the success of your project.

Yours sincerely

Michelle Searle
Director, Office of Research

STANDARD CONDITIONS OF ETHICS APPROVAL

The standard conditions of approval for all human research projects are the following:

1. Conduct the research project strictly in accordance with the research proposal submitted and granted ethics approval, including any amendments required to be made to the proposal by the Human Research Ethics Committee.

2. Inform the Human Research Ethics Committee immediately of anything which may warrant review of ethics approval of the research project, including: serious or unexpected adverse effects on participants; unforeseen events that might affect continued ethical acceptability of the project; and a written report about these matters must be submitted to the Chairperson of the Human Research Ethics Committee by no later than the next working day after recognition of an adverse occurrence/event.

3. Provide the Committee with a written report on the research project each year from the ethics approval start date and on completion of the project using the proforma 'Annual / Final Report'.

4. Advise the Committee in writing as soon as practicable if the research project is discontinued.

5. Make no change to an ethics approved project, including any approved documentation wording, without prior written approval of the Committee. To request a change to an ethics approved project, please submit an 'Amendment Request Cover Sheet' along with revised versions of your approved application documentation (with all relevant changes clearly tracked or highlighted).

Please note that compliance with these conditions of approval is a requirement of the University's *Human Research Ethics – Governing Policy* and the *National Statement on Ethical Conduct in Human Research*.

Please note that all USC Human Research Ethics Policies, Procedures, Guidelines, and Forms are available from the USC Portal (Blackboard) via USC Community >Research and Research Training>Research Ethics>Human Research Ethics; and MyUSC via Research > Ethics > Human Research Ethics.