

6 November 2014

A/Prof Ronny Gunnarsson
JCU Clinical School
College of Medicine and Dentistry

Dear Ronny

Re: **Clinical Trial Approval C16: Low dose of oral steroids in the treatment of otitis externa (swimmer's ear)**

The HREC reviewed your clinical trial application at its meeting of 24 September 2014 and resolved to approve the application subject to further clarification (HREC letter 26 September 2014) and receipt of scientific review of the study. We thank you for your response to the HREC's request for further information of 2 October 2014 and your clarifications to the scientific reviewer (27 October 2014).

The HREC reviewed this further information and resolved that final approval for the trial could be released. The approval number for this study is C16. The expiry date for the study is 30 August 2016.

Please note that:

- All subsequent records and correspondence relating to this project must refer to the approval number released.
- That there must be no departure from the protocols approved by the James Cook University HREC, unless prior approval has been granted by the Committee.
- The Principal Investigator must advise the HREC:
 - periodically of the progress of the project;
 - when the project is completed, suspended or prematurely terminated for any reason;
 - within 48 hours of any adverse effects experienced by a participant/s, or the occurrence of any unexpected serious adverse event;
 - of any unforeseen events that might affect the continued ethical acceptability of the project.
- In compliance with the National Statement on Ethical Conduct in Human Research, 2007, it is mandatory that you report at least annually on the progress and conduct of your project.

Documents submitted and approved:

NEAF		20 August 2014
Clinical Trial Protocol	Version 28	10 July 2014
GP Practical Information Sheet		9 July 2014
Pharmacists		14 April 2014
GP Screening Sheet		25 October 2012
Inclusion Sheet		9 July 2014
Patient Information: List of pharmacies		9 July 2014
Patient Information Sheet	Version 4	20 August 2014
Patient Consent Form	Version 3	20 August 2014
Daily Diary	Version 2	9 July 2014
Questionnaire	Version 2	9 July 2014


Please note that the CTN form must be completed and submitted to Research Services for authorisation.

The James Cook University Human Research Ethics Committee (HREC) is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research, 2007*, *NHMRC Australian Code for the Responsible Conduct of Research, 2007* and *the CPMP/ICH Note for Guidance on Good Clinical Practice*.

James Cook University HREC is a NHMRC accredited ethics committee. Our registration number is EC00164

HREC composition is outlined in the table attached.

Thank you

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

Dr Anne Swinbourne
Chair, Human Research Ethics Committee

Att: 1

Membership

James Cook University Human Research Ethics Committee (HREC)

Constituted in accordance with the National Statement on Ethical Conduct in Human research, 2007

Name	Category	
Dr Anne Swinbourne	a	A chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under this National Statement
Mrs Sheena Bradshaw Mr Richard Wallace Mr Jeff Williams	b	At least 2 lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work.
A/Prof Sarah Larkins	c	A person with knowledge of, and current experience in, the professional care, counselling or treatment of people.
Mrs Valda Wallace	d	A person who performs a pastoral care role in a community
Mr Shaune Williams	e	A lawyer, where possible one who is not engaged to advise the institution
A/Prof Anthony Leicht Dr Lynn Woodward A/Prof Reesa Sorin Dr Kerry McBain Ms Amanda Nickson	f	A person with current research experience that is relevant to research proposals to be considered at the meetings they attend. This member may be selected from an established pool of inducted members with relevant expertise.