

17 December 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 - Amendment Request 2 December 2014**

At its meeting 16 December 2014, the James Cook University Human Research Ethics Committee approved your request to amend the above listed clinical trial to include:

- Additional Co-Investigator Dr Harsha Shetty;
- Additional recruitment of GPs and Pharmacists through a website (<http://www.otitisexterna.net/>);
- Additional information on the study via a pen given to GPs and Pharmacists;
- Instruction sheet/checklist to GPs and Pharmacists.

Please refer to the list below for the documents approved. 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.

List of Documents submitted and approved:

Clinical Trial Protocol	Version 29	28 November 2014
GPs Instruction Sheet	Version 1	27 November 2014
Pharmacists Instruction Sheet	Version 1	27 November 2014
CV Dr Harsha Shetty		16 December 2014

Thank you



Dr Anne Swinbourne
Chair, Human Research Ethics Committee