Townsville Campus
Townsville Qld 4811 Australia
Telephone (07) 4781 4111
International +61 7 4781 4111
www.jcu.edu.au

Dr Anne Swinbourne
Chair, Human Research Ethics Committee (HREC)
Telephone (07) 4781 5011
International +61 7 4781 5011
Facsimile (07) 4781 5521
Email: Tina.Langford@jcu.edu.au

8 September 2015

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 21 August 2015**

At its meeting 26 August 2015, the James Cook University Human Research Ethics Committee approved your request to amendment the above listed clinical trial to include:

- Clarification of reminder methodology for patients as per Protocol Version 29 "Patients will be phoned 1-3 days after inclusion to hear how they are doing and to remind them of the daily diary and questionnaire".

  Pharmacies will send an email to cindy.woods@jcu.edu.au stating that they have included a patient. The email does not contain any information about the patient, just name and phone number to the pharmacies with more information. Cindy Woods will ring the pharmacist and retrieve name, phone number and study id number for that patient. Cindy Woods registers this in an Excel file and allocates the phone call to be made by any of the participating researchers mentioned on the title page of the study protocol. Cindy Woods email will be auto forwarded to any of the other participating researchers if she is away from work and this person will do the allocation instead.
- Revised Instructions for 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:

Instructions for pharmacists	Version 2	Dated: 21 August 2015

Thank you

Dr Anne Swinbourne
Chair, Human Research Ethics Committee