

25 November 2015

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Dear Ronny

Re: **Clinical Trial Approval C16: Low dose of oral steroids in the treatment of otitis externa (swimmer's ear – Amendment 22 November 2015**

At its meeting 28 October 2015, the James Cook University Human Research Ethics Committee approved your request to amend the above listed trial as follows:

- Removal of Sherwood House Medical Practice Innisfail as a site;
- Inclusion of additional sites: Kuranda Discount Drug Store, LiveLife Pharmacy Port Douglas and Mt Sheridan Pharmacy.

The approval number for this study is C16. The expiry date for the study is 30 August 2017.

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.

Thank you



Dr Anne Swinbourne
Chair, Human Research Ethics Committee