

REPORT FOR RESEARCH OR TEACHING INVOLVING HUMANS

Human Research Ethics Committee

HUMAN ETHICS
APPROVAL NUMBER **C16**

Please submit in hard copy a signed original to: Research Office, Room 128, Faculty Science & Engineering Building (DB17), James Cook University, Townsville, Qld, 4811. Please also email a pdf of this report to ethics@jcu.edu.au.

1	TITLE OF PROJECT	Low dose of oral steroids in the treatment of otitis externa (swimmer's ear)							
2	CATEGORY	Clinical Trial							
3	PERIOD DURING WHICH ACTIVITIES REQUIRING ETHICS APPROVAL OCCURRED								
	COMMENCEMENT DATE	28/10/2015		FINISH DATE	(In progress)				
4	STATUS OF PROJECT (Please tick)	Completed	<input type="checkbox"/>	In Progress	<input checked="" type="checkbox"/>	Abandoned	<input type="checkbox"/>	Not Commenced	<input type="checkbox"/>

5	PRINCIPAL INVESTIGATOR'S DETAILS						
	Last Name, First name and Title		ESN ¹	Orgu	Discipline/School or Institution (Country)		
	Gunnarsson, Ronny A Prof		E		College of medicine and Dentistry		
	Email		Phone		Fax		
	ronny.gunnarsson@jcu.edu.au		(07) 4226 7391				

5a	SUPERVISOR DETAILS 1 (if applicable)						
	Last Name, First name and Title		ESN ¹	Orgu	Discipline/School or Institution (Country)		
	Email		Phone		Fax		

5b	SUPERVISOR DETAILS 2 (if applicable)						
	Last Name, First name and Title		ESN ¹	Orgu	Discipline/School or Institution (Country)		
	Email		Phone		Fax		

¹ Indicate if the Researcher is currently an Employee or a Student of JCU, or a researcher who is Not affiliated with JCU. If the project involves international cooperation, please specify the country.

PLEASE ANSWER ALL QUESTIONS:

6 COMPLIANCE

Did the project comply in all respects with the conditions detailed in the approved ethics application and any subsequent amendments that were approved by the Human Research Ethics Committee

If NO, please provide details below:

Yes	<input checked="" type="checkbox"/>	No	<input type="checkbox"/>
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NUMBER OF PARTICIPANTS INVOLVED IN THE STUDY:

Male		Female		Children	0	Total	25
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NUMBER OF INDIGENOUS PARTICIPANTS INVOLVED IN THE STUDY

Male		Female		Children		Total	
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7 UNEXPECTED ADVERSE EFFECTS or EVENTS

Did any of the participants of the study suffer any unexpected adverse effects? Were there any unexpected events that occurred of which the Human Research Ethics Committee should be aware? If Yes, How did you manage these events? Could these events have any implications for similar research studies?

If YES, please provide details below:

Yes	<input type="checkbox"/>	No	<input checked="" type="checkbox"/>
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8 COMPLAINTS

Were there any complaints from participants, or any other organisation/community group etc involved with the study?

If YES, please provide details below:

Yes	<input type="checkbox"/>	No	<input checked="" type="checkbox"/>
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9 STATEMENT OF REPORT


Please provide a brief statement of the outcomes and conduct of project.

The first patient was recruited 28/10/2015. 25 patients are enrolled so far. Their data has not been analysed so we don't know exact allocation on Caucasian or indigenous participants or gender. We aim to do an interim analysis of data during June-August. One patient has to our knowledge experienced a mild increase in symptoms which subsided after further treatment with their GP. This is an EXPECTED adverse event for patients having otitis externa and is not considered serious.

10 PUBLICATIONS

Please provide a reference list of all publications generated from the project. (Please indicate status of the publications, i.e. submitted, accepted etc)

11 CERTIFICATION PRINCIPAL INVESTIGATOR

<ul style="list-style-type: none"> I declare that the statements made in this report are correct 		
 Signature (Principal Investigator)	Digitally signed by Ronny Gunnarsson DN: cn=Ronny Gunnarsson, o=James Cook University, ou=College of Medicine and Dentistry, email=ronny.gunnarsson@jcu.edu.au, c=AU Date: 2016.03.22 11:49:40 +10'00' Name	Date


Please note: if the principal investigator is an Honours or Higher Degree Student, the supervisor must also sign this report.

12 AUTHORISATION by SUPERVISOR(S)

(Supervisor(s) must sign this declaration)

I/We certify that the statements made in this report are correct..					
Signature (Supervisor)	Name	Date	Signature (Supervisor 2)	Name	Date

13 AUTHORISATION by DEAN OF COLLEGE/DELEGATE:

I certify that the statements made in this report are correct		
 Signature	Professor Richard Murray Dean College of Medicine and Dentistry Name	29/3/16 Date

(No publications so far)

1300
1400
1500