



HREC APPROVAL

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17 September 2019

Professor David Hunter-Smith
Director of Surgical Research
Peninsula Health
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Dear Professor Hunter-Smith

Efficacy of probiotic gargles in reducing post-operative complications in adult patients post-tonsillectomy: A pilot double-blinded randomised controlled trial (feasibility trial)

HREC Reference Number: HREC/51745/PH-2019
Protocol: Version 24:9 September 2019
SSA: SSA/51745/PH-2019

Thank you for submitting the above project which was first considered by the Peninsula Health Human Research Ethics Committee (HREC) on Wednesday 15 May 2019 in accordance with the National Statement on Ethical Conduct in Human Research (2007). Following review of requested amendments and clarifications, and approval from the Drugs & Therapeutics Committee I am pleased to advise that approval to commence has now been granted.

The documents reviewed at Peninsula Health include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Application:	Version 3	12 September 2019
Protocol:	Version 4	17 September 2019
Invitation:	Version 2	9 July 2019
Participant Information and Consent Form:	Version 6	16 September 2019
Telephone Script:		
Prior to surgery:	Version 1	9 July 2019
5 day review:	Version 2	3 May 2019
Patient Instructions and diaries:	Version 3	9 September 2019
Letter re results:	Version 4	16 September 2019
CTN Acknowledgement:		

Please note the following requirements of the Peninsula Health HREC:

- The principal investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
 - any serious or unexpected adverse events
 - unforeseen events that might affect continued acceptability of the project.

2. Proposed changes to the research protocol, conduct of the research, or research completion date will be provided to the Human Research Ethics Committee (HREC) for review in the specified format.

3. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.

4. The principal investigator will provide an annual report to the HREC and at completion of the study a final report, in the specified format.

Should you have any queries about the consideration of your project please contact Ms Lee-Anne Clavarino, Manager, Office for Research. Details of review processes and guidelines are available on the Peninsula Health website <http://www.peninsulahealth.org.au/research-and-education/human-research-ethics-and-governance/>.

Please quote the Peninsula Health Project Number in all correspondence.

The Committee wishes you every success in your research

Yours sincerely



Dr William Slater
Acting Executive Director Medical Services
Acting Executive Sponsor Research

When publishing:

Ensure you list your Peninsula Health appointment as well as academic affiliations. For further information, see Authorship Policy.