

Enquiries to: ResearchTPCH@health.qld.gov.au
Office Ph: (07) 3139 4198
(07) 3139 4500
Our Ref: HREC Final Approval



20 June 2018

**The Prince Charles Hospital
Human Research Ethics Committee**
The Prince Charles Hospital
Building 14
Rode Road, Chermside QLD 4032

Prof Saso Ivanovski
Director of Research
School of Dentistry, The University of
Queensland
Oral Health Centre Herston, 288
Herston Rd, Herston QLD, 4006

Dear Dr Saso Ivanovski

Re: HREC/18/QPCH/186 Systemic administration of azithromycin as an adjunct to non-surgical periodontal therapy in severe chronic periodontitis- a randomized controlled trial.

Thank you for submitting the requested documents for the above project for further review which was received on 9 May 2018. This project was considered by The Prince Charles Hospital Human Research Ethics Committee (HREC) (EC00168).

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*, *NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

I am pleased to advise that this proposal meets the requirements of the National Statement and that The Prince Charles Hospital Human Research Ethics Committee has granted final approval of this research project. The documents reviewed and approved for the above mentioned project include:

Document	Version	Date
Application	AU/1/C016310	
Protocol	1	27 April 2018
Participant Information Sheet and Consent Form	1.1	4 June 2018
Investigator CV: Professor Saso Ivanovski	-	-
Investigator CV: Dr Vincent O'Rourke	-	-
Investigator CV: Dr Ryan Lee	-	-
Investigator CV: Mr Srinivas Sulugodu Ramachandra	-	-

This information will be tabled at the next meeting on 28 June 2018 for noting.

Please note the following conditions of approval:

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
 - a. Unforeseen events that might affect continued ethical acceptability of the project.
 - b. Serious Adverse Events that materially impact on the continued ethical acceptability of the project.
2. Amendments to the research project are to be submitted to the TPCH HREC for review. Major amendments should be reflected in a cover letter from the principal investigator, providing a description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study. Hard copies of the revised amendments, the cover letter and all relevant updated documents with tracked changes must also be submitted to the TPCH HREC coordinator as per standard HREC SOP. Further advice on submitting amendments is available from

http://www.health.qld.gov.au/ohmr/documents/researcher_userguide.pdf
3. Proposed amendments to the research project must be submitted firstly to the TPCH HREC for review and, once TPCH HREC approval has been granted, submitted to the RGO.
4. In accordance with Section 3.3.22 (b) of the National Statement the Principal Investigator will report to the TPCH HREC annually in the specified format and a final report is to be submitted on completion of the study.
<https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp>
5. The Principal Investigator will notify the TPCH HREC if the project is discontinued at the participating site before the expected completion date, with reasons provided. Any plan to extend the duration of the project past the approved period, the Principal Investigator will submit any associated required documentation for TPCH HREC approval **before** expiry of the project, listed below.
6. The Hospital & Health Service Administration and the Human Research Ethics Committee may inquire into the conduct of any research or purported research, whether approved or not and regardless of the source of funding, being conducted on hospital premises or claiming any association with the Hospital; or which the Committee has approved if conducted outside The Prince Charles Hospital & Health Services.

HREC approval is valid until **8 June 2021**.

Please advise The Prince Charles Hospital Human Research Ethics Committee of the date you commence the research project for the approved site(s) using the Notification of Commencement Form: <https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp>

If the research does not commence within 3 months of this letter, please inform the committee in formal correspondence of any delays occurring with your project.

Should you have any queries about the TPCH HREC's consideration of your project please contact the Manager of Research, Ethics & Governance Unit on the above phone numbers or email addresses. The HREC terms of Reference, Standard Operating Procedures, membership and standard forms are available from

http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Hospital & Health Services CEO or Delegate of that site has been obtained.

A copy of this approval must be submitted to the relevant Hospital & Health Services Research Governance Officer/s or Delegated Personnel with a completed Site Specific Assessment (SSA) Form for authorisation from the CEO or Delegate to conduct this research at the site/s.

The Prince Charles Hospital Human Research & Ethics Committee wishes you every success in your research.

Yours faithfully



Dr Russell Denman

**Chair
The Prince Charles Hospital
Human Research Ethics Committee**

List of approved Sites:

No.	Site	Investigator
1	Herston Oral Health Centre	Dr Saso Ivanovski

Note: If additional sites are engaged prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify the TPCH HREC. Notification of the withdrawn sites should also be provided to the TPCH HREC in a timely fashion accompanying a close out report for that site.

The members present at The Prince Charles Hospital Human Research and Ethics Committee meeting on the 24 May 2018 when the approval was granted for **HREC/18/QPCH/186** is listed in the table below.

Attendees	Present	Apology
(Chair) Medical Representative Cardiology {NS 5.1.30 (a)} [M]	X	
Medical Representative – Geriatrics {NS 5.1.30 (f)} [F]	X	
Layman {NS 5.1.30 (b)} [M]		X
Research Scientist {NS 5.1.30 (c)} [F]	X	
Director of Pharmacy {NS 5.1.30 (c)} [M]	X	
Medical Representative Psychiatry {NS 5.1.30 (f)} [M]		X
Laywoman {NS 5.1.30 (b)} [F]	X	
Medical Representative Obstetrics & Gynaecology {NS 5.1.30 (c)} [F]	X	
Executive Director, Medical Services [F]	X	
Senior Researcher {NS 5.1.30 (f)} [M]	X	
Executive Officer – Research and Ethics [F]		X
Legal Representative {NS 5.1.30 (e)} [F]	X	
Nursing Representative {NS 5.1.30 (c)} [M]	X	
Religious Representative {NS 5.1.30 (d)} [F]	X	
Medical Representative – Thoracic {NS 5.1.30 (f)} [M]	X	
Medical Representative – Anaesthetics/Intensive Care {NS 5.1.30 (f)} [M]	X	

This is also to certify that TPCHMNHSHREC is a NHMRC accredited Ethics Committee. Our Registered Number is EC00168.

Our accredited Ethics Committee is organised, complies and operates within the GCP and ICH Guidelines.

Note: The composition of the TPCH HREC is constituted in accordance with the NHMRC National Statement on Ethical Conduct in Human Research (March 2007).

Please be advised that in the instance of an investigator being a member of the TPCH HREC, they are absented from the decision making process relating to that study.

For further information please The Prince Charles Hospital Research, Ethics & Governance Office on 3139 4198 or email: ResearchTPCH@health.qld.gov.au

Enquiries to: ResearchTPCH@health.qld.gov.au
Office Ph: (07) 3139 4198
(07) 3139 4500
Amendment Ref: Amendment 01



17 October 2018

**The Prince Charles Hospital
Human Research Ethics Committee**
The Prince Charles Hospital
Building 14
Rode Road,
Chermside QLD 4032

Prof Saso Ivanovski
Director of Research
School of Dentistry, The University of
Queensland
Oral Health Centre Herston, 288 Herston
Rd, Herston QLD, 4006

Dear Dr Saso Ivanovski

Re: Project ID 40730 Systemic administration of azithromycin as an adjunct to non-surgical periodontal therapy in stage III and IV periodontitis- a randomized controlled trial.

I am pleased to advise that The Prince Charles Hospital Human Research Ethics Committee (TPCH HREC) reviewed the amendments submitted and upon recommendation, the Chair has granted approval for the following:

- Change in study title.
- Protocol Version 1.1 dated 23 July 2018
- Participant Information Sheet Version 1.2 dated 23 July 2018
- Consent Form & Revocation of consent Forms Version 1.1 dated 23 July 2018
- Questionnaire: - Patient Reported Experience Measures Version 1 dated 15 September 2018

This information will be tabled at the HREC meeting on 28 November 2018 for noting.

A copy of this approval must be forwarded to each of the Principal Investigators at each site who should provide a copy to their own Hospital & Health Service Research Governance Officer/s or Delegated Personnel, along with updated Site Specific documentation, for CEO or Delegated authorisation for each site.

List of approved Sites:

No.	Site	Investigator
1	The Herston Oral Health Centre	Dr Saso Ivanovski

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*, *NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

Please be advised that in the instance of an investigator being a member of the HREC, they are absented from the decision making process relating to that study.

Office
Research, Ethics & Governance Office
The Prince Charles Hospital

Postal
Building 14
Rode Road, Chermside Q 4032

Phone
(07) 3139 4500
(07) 3139 4198

On behalf of the Human Research Ethics Committee, I would like to wish you every success with your research endeavour.

Yours truly,



Anne Carle
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Anne Carle
Executive Officer
Research, Ethics and Governance Unit
The Prince Charles Hospital

26 February 2019

**The Prince Charles Hospital
Human Research Ethics Committee**
The Prince Charles Hospital
Building 14
Rode Road,
Chermside QLD 4032

Prof Saso Ivanovski
Director of Research
School of Dentistry, The University of Queensland
Oral Health Centre Herston
288 Herston Rd
HERSTON QLD, 4006

Dear Prof Ivanovski,

Project ID 40730 HREC/18/QPCH/186: Systemic administration of azithromycin as an adjunct to non-surgical periodontal therapy in severe chronic periodontitis- a randomized controlled trial.

I am pleased to advise that The Prince Charles Hospital Human Research Ethics Committee (TPCH HREC) reviewed the amendments submitted and upon recommendation, the Chair has granted approval for the following:

Document	Version	Date
Protocol	1.2	4 February 2019
Master Participant information sheet and consent form	1.3	4 February 2019
Additional sites: Brisbane City Periodontics and Implants – Brisbane Brisbane City Periodontics and Implants – Mt Gravatt Specialist Dental Centre - Penrith	-	-
Additional Investigators: Dr Roderick Marshall Dr Valerie Woodford Dr Tino Mercado	-	-

The Committee acknowledges receipt of:

- Investigator CV: Dr Roderick Marshall
- Investigator CV: Dr Valerie Woodford
- Investigator CV: Dr Tino Mercado

This information will be tabled at the HREC meeting on 28 March 2019 for noting.

A copy of this approval must be forwarded to each of the Principal Investigators at each site.

List of approved Sites:


No.	Site	Investigator
1	Herston Oral Health Centre	Prof Saso Ivanovski
2	Brisbane City Periodontics and Implants – Brisbane	Dr Roderick Marshall
3	Brisbane City Periodontics and Implants – Mt Gravatt	Dr Valerie Woodford
4	Specialist Dental Centre - Penrith	Dr Tino Mercado

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Please be advised that in the instance of an investigator being a member of the HREC, they are absented from the decision making process relating to that study.

On behalf of the Human Research Ethics Committee, I would like to wish you every success with your research endeavour.

Yours truly,


Anne Carle
2019.02.26
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Anne Carle
Executive Officer
Research, Ethics and Governance Unit
The Prince Charles Hospital