

Enquiries to: ResearchTPCH@health.qld.gov.au
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Our Ref: HREC Final Approval



14 February 2018

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

Professor David Healey
C/- Professor Laurence J Walsh
The University of Queensland
School of Dentistry
UQ Oral Health Centre
288 Herston Road
HERSTON QLD 4006

Dear Professor Healey,

Re: HREC/18/QPCH/7: Ecological approaches to dental caries prevention: A controlled trial to evaluate the influence of CPP-ACP – Cranberry toothpastes in effecting an ecological change in the oral plaque microbiome

Thank you for submitting the requested documents for the above project for further review which was received on 10 January 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/AF43310	
Protocol	1	5 January 2018
Participant Information Sheet and Consent Form – Parent/ Guardian	1.1	31 January 2018
Participant Information Sheet and Consent Form – Adult Participant	1.1	31 January 2018
Documents acknowledged:	Version	Date
eBS Submission Document for a Clinical Trial Application Application No.: CT-2017-CTN-05069-1 Submission No.: CT-2018-00034-1	-	-
eCTN application CT-2017-CTN-05069-1	-	8 January 2018
Australian Register of Therapeutic Goods Certificate ARTG Identifier: 271415	-	26 February 2016

Investigator CV: A/Prof David Healey	-	-
Investigator CV: Professor Laurence Walsh	-	-

This information will be tabled at the next meeting on 22 March 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. In addition the Investigator must provide, at least six monthly, a summary of serious adverse events, in the specified format, including a comment as to suspected causality.
2. Amendments to the research project which may affect the ongoing ethical acceptability of a project must 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 which may affect both the ethical acceptability and site suitability of the project must be submitted firstly the TPCH HREC for review and, once TPCH HREC approval has been granted, submitted to the RGO.
4. Amendments which do not affect either the ethical acceptability or site acceptability of the project (e.g. typographical errors) should be submitted in hard copy to the TPCH HREC coordinator. These should include a cover letter from the principal investigator providing a brief description of the changes and the rationale for the changes, and accompanied by all relevant updated documents with tracked changes.
5. 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>
6. 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.
7. 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 **14 February 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.	UQ Oral Health Centre	Associate Professor David Healey

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 25 January 2018 when the approval was granted for **HREC/18/QPCH/7** is listed in the table below.

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