

Enquiries to: ResearchTPCH@health.qld.gov.au
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Low Risk Final Approval



5 September 2017

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

Dr Manju Chandrasegaram
The Prince Charles Hospital

Dear Dr Chandrasegaram

**Re: HREC/17/QPCH/295: Characteristics of staging, treatment and outcome amongst patients with colorectal cancer
A Prince Charles Hospital observational study**

Thank you for submitting your Low Risk project for ethical and scientific review. I am pleased to advise that The Prince Charles Hospital Human Research Ethics Committee reviewed your submission and upon recommendation, the Chair has granted final approval for your low risk project.

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 The Prince Charles Hospital Human Research Ethics Committee has granted approval of this research project. The documents reviewed and approved on 1 September 2017 include:

Document	Version	Date
Low Risk Application	(AU/10/91EF212)	
Protocol	1	23 August 2017
Colorectal Cancer Data Collection Sheet	1	23 August 2017

This information will be tabled at the next HREC meeting held 28 September 2017 for noting.

Please note the following conditions of approval:

1. A **waiver of consent** has been approved. Please consider permissions under the *Hospital and Health Boards Act 2011* or *Public Health Act 2005* to enable access to confidential information for the purposes of research without consent.
2. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including any unforeseen events that might affect continued ethical acceptability of the project.
3. 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,

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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

4. Proposed amendments to the research project which may affect both the ethical acceptability and site suitability of the project must be submitted firstly to the TPCH HREC for review and, once TPCH HREC approval has been granted, submitted to the RGO.
5. 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.
6. 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>
7. 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.
8. 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 **5 September 2020**.

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 HREC's consideration of your project please contact the Manager of Research, Ethics & Governance Unit on 3139 4500. 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.

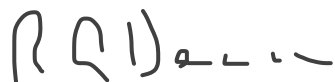
You are reminded that this letter constitutes ethical approval only. *You must not commence this research project at a site until separate authorisation from the Hospital and Health Service CEO or Delegate of that site has been obtained.*

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 listed below.

The HREC 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:
1	The Prince Charles Hospital