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Our Ref: HREC Final Approval



2 December 2015

Human Research Ethics Committee
Metro North Hospital and Health Service
The Prince Charles Hospital
Building 14
Rode Road, Chermiside QLD 4032

Ms Sue Cornes
C/- Mr Daniel Williamson
Manager, Performance and
Accountability
Aboriginal & Torres Strait Islander
Health Unit
GPO Box 48
Brisbane QLD 4001

Dear Ms Cornes

**Re: HREC/15/QPCH/289: ABORIGINAL AND TORRES STRAIT ISLANDER BETTER
CARDIAC CARE COLLABORATIVE DATA LINKAGE PROJECT FOR QUEENSLAND**

This project was considered by Metro North Hospital and Health Service - The Prince Charles Hospital Human Research Ethics Committee (HREC) on 26 November 2015.

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 Human Research Ethics Committee has granted final approval of this research project. The documents reviewed and approved for the above mentioned project include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Application (AU/1/0872211)		
Protocol	5	November 2015

Please note the following conditions of approval:

1. A Waiver of Consent has been granted for access to the databases.
2. 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.

Office	Postal	Phone
Research, Ethics & Governance Office The Prince Charles Hospital	Building 14 Rode Road, Chermiside Q 4032	(07) 3139 4500 (07) 3139 4198

- 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.
3. Amendments to the research project which may affect the ongoing ethical acceptability of a project must be submitted to the 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 HREC coordinator as per standard HREC SOP. Further advice on submitting amendments is available from http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp
4. Amendments to the research project which only affect the ongoing site acceptability of the project are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r (by-passing the HREC).
5. Proposed amendments to the research project which may affect both the ethical acceptability and site suitability of the project must be submitted firstly the HREC for review and, once HREC approval has been granted, submitted to the RGO.
6. 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 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.
7. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.
8. The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.
9. 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 **31 December 2018**.

Should you have any queries about the HREC's consideration of your project please contact the Executive Officer 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.

Once authorisation to conduct the research has been granted, please complete the Commencement Form http://www.health.qld.gov.au/tpch/documents/form_notification.dot and return to the office of the Human Research Ethics Committee.

The HREC wishes you every success in your research.

Yours faithfully



Dr Russell Denman

Chair

HUMAN RESEARCH ETHICS COMMITTEE

METRO NORTH HOSPITAL AND HEALTH SERVICE

List of approved Sites:

No.	Site
1.	Statistical Analysis Linkage Team
2.	Australian Institute of Health & Welfare Data Linkage Unit

List of approved Datasets:

No.	Site
1.	Medical Benefits Schedule (MBS)
2.	Pharmaceutical Benefits Scheme (PBS)
3.	National Death Index (NDI)
4.	Queensland Hospital Admitted Patient Data Collection (QHAPDC)
5.	Queensland ARF?RHD Registry data
6.	AusLAB
7.	Australian Bureau of Statistics (ABS) populations

The members present at the Metro North Hospital & Health Services, Human Research and Ethics Committee meeting on the 26 November 2015 when the approval was granted for HREC/15/QPCH/289 is listed in the table below.

Attendees	Present	Apology
(Chair) Medical Representative Cardiology (a/f) [M]	X	
(Acting Chair) Medical Representative - Geriatrics (f) [F]	X	
Layman (b) [M]	X	
Research Scientist (c) [F]	X	
Pharmacy Representative [M]	X	
Medical Representative-Psychiatry (c) [M]		X
Laywoman (b) [F]	X	
Medical Representative - Critical Care & Anaesthetics (f) [M]		X
Executive Director, Medical Services [M]		X
Senior Researcher (f) [M]	X	
A/Executive Officer - Research and Ethics [F]	X	
Legal Representative (e) [F]	X	
Nursing Representative (c) [M]	X	
Religious Representative (d) [F]	X	
Medical Representative - Thoracics (f) [M]	X	
Medical Representative - Obstetrics & Gynaecology (f) [F]		X

This is also to certify that TPCHMNHSHSREC 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 HREC is constituted in accordance with the NHMRC National Statement on Ethical Conduct in Human Research (March 2007).