

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



6 March 2017

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

Dr. Gillian Ray-Barruel
Griffith University
Menzies Health Institute Queensland
Building N48
170 Kessels Road
NATHAN QLD 4111

Dear Dr. Ray-Barruel,

Re: HREC/17/QPCH/47: The I-DECIDED Study: An interrupted time-series study to test the effectiveness of a device assessment and removal tool in supporting clinical decision-making to improve intravenous catheter care and reduce redundancy of intravenous catheters in hospital patients

Thank you for submitting the above project for ethical and scientific review. The Prince Charles Hospital Human Research Ethics Committee (TPCH HREC) (EC00168) reviewed the above multi-centered protocol on 23 February 2017.

This HREC has been accredited by the NHMRC as a lead HREC to provide single and scientific review of proposals to conduct research within NSW, Victoria, ACT, South Australia and Queensland. The 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 (NS 5.1.30) 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
NEAF Application	AU/1/C4BB216	
Protocol	6	28 February 2017
Master Participant Information Sheet Form: IV Access and Chart Audit	2	28 February 2017
Master Participant Consent Form: IV Access and Chart Audit	2	28 February 2017
Master Participant Information Sheet Form: Staff Focus Groups	2	28 February 2017
Master Participant Consent Form: Staff Focus Groups	2	28 February 2017
Master Participant Information Sheet Form: Consumer Focus	2	28 February 2017

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The Prince Charles Hospital

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Group		
Master Participant Consent Form: Consumer focus Group	2	28 February 2017
Master Participant Information Sheet Form: Consumer Bedside Interviews	2	28 February 2017
Master Participant Consent Form: Consumer Bedside Interviews	2	28 February 2017
I-DECIDE Device Assessment and Removal Tool	2	28 February 2017
Bedside Interview Introductory Script and Questions	1	20 January 2017
Consumer Focus Groups Introductory Script and Questions	1	20 January 2017
Study Invitation to Participate	2	7 February 2017
Chart Sticker	1	20 January 2017
Clinical Assessment and Audit Tool	1	20 January 2017
Staff Lanyard Wallet Card	1	20 January 2017
Investigator CV: Gillian Ray-Barruel		24 January 2017
Investigator CV: Professor Claire Rickard		25 January 2017
Investigator CV: Professor Marion Mitchell		31 January 2017
Investigator CV: Dr Marie Cooke		30 January 2017
Response to Request for Further Information		28 February 2017

This information will be tabled at the next meeting on 23 March 2017 for noting.

Please note the following conditions of approval:

1. The Coordinating 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 or unexpected adverse events that materially impact on the continued ethical acceptability of the project.
2. The Coordinating Principal Investigator will report protocol deviations/violations to the HREC, with details of procedures put in place to ensure the deviation/violation doesn't recur.
3. Amendments to the research project must be submitted to the TPCH HREC for review. Amendments should be reflected in a cover letter from the coordinating 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 and an electronic copy 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 SOPs. Further advice on submitting amendments is available from https://www.health.qld.gov.au/_data/assets/pdf_file/0029/156791/resrch_user_guide_v1.pdf
4. Proposed amendments to the research project must be submitted firstly the TPCH HREC for review and, once TPCH HREC approval has been granted, submitted to the site Research Governance Officer.
5. In accordance with Section 3.3.22 (b) of the National Statement the Principal Investigator will report to the TPCH HREC annually (due on the anniversary of this letter) in the specified format and a final report is to be submitted on completion of the study. Each site covered by this submission must submit a report, and it is the responsibility of the Coordinating Principal Investigator to submit these reports. <https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp>

6. The Coordinating Principal Investigator will notify the TPCH HREC if the project is discontinued at a 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 **6 March 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 TPCH HREC's consideration of your project please contact the Executive Officer, 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
METRO NORTH HOSPITAL AND HEALTH SERVICE

List of approved Sites:

No.	Site	Investigator
1.	The Prince Charles Hospital	Professor Paul Fulbrook
2.	Logan Hospital	Ms Angelka Opie
3.	Queen Elizabeth II Jubilee Hospital	Mr Peter Brown

The members present at The Prince Charles Hospital Human Research and Ethics Committee meeting on the 23 February 2017 when the approval was granted for HREC/17/QPCH/47 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
Medical Representative - Thoracic (f) [M]	X	
Medical Representative - Anaesthetics/Intensive Care (f) [M]	X	

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