

**Royal Brisbane & Women's Hospital
Human Research Ethics Committee**

Enquiries to: Ann-Maree Gordon
A/Coordinator
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File Ref: HREC/16/QRBW/28
Email: RBWH-Ethics@health.qld.gov.au

Dr Christopher Anstey
Intensive Care Department
Nambour General Hospital
Sunshine Coast Hospital and Health Service
PO Box 547
Nambour Qld 4560

Dear Dr Anstey,

Re: Ref N^o: HREC/16/QRBW/28: ACCidHF : Assessment of the Concentration of Citrate during Haemofiltration

Thank you for submitting the above research project for single ethical review. This project was considered by the Royal Brisbane & Women's Hospital Human Research Ethics Committee (RBWH HREC) (**EC00172**) at its meeting held on 08 February 2016. The research project meets the requirements of the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*.

I am pleased to advise that the RBWH Human Research Ethics Committee has granted ethical approval of this research project.

The nominated participating site for this project is:

- Nambour General Hospital, Sunshine Coast Hospital and Health Service

This letter constitutes ethical approval only. This project cannot proceed until separate research governance authorisation has been obtained from the CEO or Delegate of Nambour General Hospital, Sunshine Coast Hospital and Health Service, under whose auspices the research will be conducted.

The approved documents include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		19 January 2016
Application: NEAF (<i>Submission Code: AU/1/7683215</i>)	2.2 (2014)	14 January 2016
Curriculum Vitae of Christopher M Anstey		
Curriculum Vitae of Dr John PR Moore		19 January 2016
Curriculum Vitae of Victoria Kathryn Campbell		
Curriculum Vitae of Dr Fraser Russell		20 January 2016
Response to Request for Further Information		18 February 2016
Participant Information Sheet & Consent Form	2.0	18 February 2016
Participant Information Sheet & Consent Form - Person Responsible	2.0	18 February 2016
ACCid HF Data Collection Tool	1.0	
Response to request for further information		25 February 2016
Response to Request for Further Information		01 March 2016
ACCid HF Protocol	1.3	29 February 2016
Response to Request for Further Information		10 March 2016
Participant Information Sheet (Post Hoc)	1.2	07 March 2016

Approval of this project from the RBWH HREC is valid from **11.03.2016** to **11.03.2019** subject to the following conditions being met:

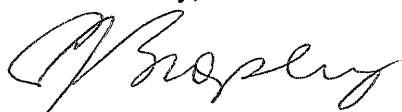
- The Coordinating Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Coordinating Principal Investigator will notify the RBWH HREC of any event that requires a modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the HREC. These instructions can be found at <http://www.health.qld.gov.au/rbwh/research/hrec.asp>.
- The Coordinating Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with the RBWH HREC policy and procedures. These instructions can be found at <http://www.health.qld.gov.au/rbwh/research/hrec.asp>.
- In accordance with Section 3.3.22 (b) of the National Statement the Coordinating Principal Investigator will report to the RBWH HREC annually in the specified format, the first report being due on **11.03.2017** and a final report is to be submitted on completion of the study.

These instructions can be found at
http://www.health.qld.gov.au/ohmr/html/regu/reporting_templates.asp.

- The Coordinating Principal Investigator will notify the RBWH HREC if the project is discontinued before the expected completion date, with reasons provided.
- The Coordinating Principal Investigator will notify the RBWH HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation. Instructions for obtaining an extension of approval can be found at <http://www.health.qld.gov.au/rbwh/research/hrec.asp>.
- The Coordinating Principal Investigator will notify the RBWH HREC of his or her inability to continue as Coordinating Principal Investigator including the name of and contact information for a replacement.
- A copy of this ethical approval letter together with completed Site Specific Assessment (SSA) and any other requirements must be submitted by the Coordinating Principal Investigator to the Research Governance Office at Nambour General Hospital, Sunshine Coast Hospital and Health Service, in a timely manner to enable the institution to authorise the commencement of the project at its site.
- Should you have any queries about the RBWH HREC's consideration of your project please contact the HREC Coordinator on 07 3646 5490. The RBWH HREC's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from <http://www.health.qld.gov.au/rbwh/research/hrec.asp>.

The RBWH HREC wishes you every success in your research.

Yours sincerely,



Dr Conor Brophy
Chairperson RBWH Human Research Ethics Committee
Metro North Hospital and Health Service
11.03.2016

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)*. The processes used by this HREC to review research proposals have been certified by the National Health and Medical Research Council.