



Queensland
Government

Metro North
Hospital and Health Service

Royal Brisbane & Women's Hospital
Human Research Ethics Committee

Enquiries to: Ann-Maree Gordon
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File Ref: HREC/17/QRBW/661
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A/Prof Dwarakanathan Ranganathan
Department of Renal Medicine
Level 9, Ned Hanlon Building
Royal Brisbane & Women's Hospital
Herston Qld 4029

Dear Dr Ranganathan,

Re: Ref N^o: HREC/17/QRBW/661: Queensland Renal Biopsy Registry

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 11 December 2017. 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 sites for this project are:

- Royal Brisbane & Women's Hospital
- Gold Coast University Hospital
- Logan Hospital
- Toowoomba Hospital
- Hervey Bay Hospital
- Bundaberg Hospital
- Mackay Base Hospital
- Rockhampton Hospital
- Townsville Hospital

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 RBWH HREC. Notification of withdrawn sites should also be provided to the RBWH HREC in a timely fashion.

This letter constitutes ethical approval only. This project cannot proceed at any site until separate research governance authorisation has been obtained from the CEO or Delegate of the institution under whose auspices the research will be conducted at that site.

The approved documents include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		14 November 2017
Application: NEAF (<i>Submission Code: AU/1/FB22312</i>)	2.2 (2014)	15 November 2017
Curriculum Vitae of Dwarakanathan Ranganathan		
Curriculum Vitae of Wendy Hoy		
Curriculum Vitae of Anne Cameron		
Curriculum Vitae of Dr Sree Krishna Venuthurupalli		
Curriculum Vitae of Dr Andrew John Mallett		06 April 2017
Curriculum Vitae of Sudhakar Dakshina Murthy Divi		
Curriculum Vitae of Roy Koshy Cherian		
Curriculum Vitae of Zaw Thet		
Curriculum Vitae of Dev Krish Jegatheesan		
Curriculum Vitae of Dr Krishan Madhan		
Curriculum Vitae of Dr Valli Manickam		
Curriculum Vitae of Peter Trnka		
Curriculum Vitae of Dr Jeremy Frazier		
Curriculum Vitae of Dr George Tharayil John		
Curriculum Vitae of Glenda C Gobe	January 2016	
Response to Request for Further Information		16 January 2018
Protocol	1.2	15 January 2018
Master Participant Information Sheet & Consent Form	1.2	15 January 2018
Terms of Reference - Queensland Glomerulonephritis (Qld.GN) Registry Steering Committee		20 September 2016

Approval of this project from the RBWH HREC is valid from **23.01.2018** to **23.01.2021** 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 <https://www.health.qld.gov.au/metronorth/research/ethics-governance/hrec-approval/default.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 <https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.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 **23.01.2019** and a final report is to be submitted on completion of the study. These instructions can be found at <https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.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 <https://www.health.qld.gov.au/metronorth/research/ethics-governance/hrec-approval/default.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 all site Principal Investigators to the Research Governance Office at each participating institution in a timely manner to enable the institution to authorise the commencement of the project at its site/s.
- 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 <https://www.health.qld.gov.au/metronorth/research/ethics-governance/hrec-approval/membership/default.asp>.

The RBWH HREC wishes you every success in your research.

Yours sincerely,



Dr Allison Sutherland

A/Chairperson RBWH Human Research Ethics Committee

Metro North Hospital and Health Service

23.01.2018

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 multi-centre research proposals have been certified by the National Health and Medical Research Council.