



Queensland
Government

Metro North Health

Royal Brisbane & Women's Hospital
Human Research Ethics Committee

Enquiries to: Ann-Maree Gordon
Coordinator
Telephone: 07 3647 1007
File Ref: HREC/2021/QRBW/77711
Email: RBWH-Ethics@health.qld.gov.au

Dr Dwarakanathan Ranganathan
Nephrology Department
Royal Brisbane & Women's Hospital
Herston Qld 4029

Dear Dr Ranganathan,

Re: Ref N^o: HREC/2021/QRBW/77711: Clinical phenotypes and incidence of Anti-Neutrophilic Cytoplasmic Autoantibodies positive renal vasculitis: The effect of environmental and occupational exposure

Thank you for submitting the above research project for single ethical review. This project was validated by the Royal Brisbane & Women's Hospital Human Research Ethics Committee (RBWH HREC) (**EC00172**) on 29 July 2021 and was reviewed by a sub-Committee of the HREC. 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 sub-Committee has approved of this low risk research project. This approval was ratified by the RBWH Human Research Ethics Committee on 20 September 2021.

A **waiver of consent** for Phase 1 (Data Collection) 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. If a Public Health Act (PHA) application is applicable, please visit the Health and Medical Research Unit website at:

http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp

Ongoing approval is for the duration of the project, conditional on:

1. In accordance with Section 5.5.6 (b) of the National Statement, the Principal Investigator will report to the HREC annually (**Due by 30 April each year**) in the specified format with a final report to be submitted on completion of the study.
<https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval->

[reporting/default.asp](#)

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.
 - b. Serious Adverse Events that materially impact on the continued ethical acceptability of the project.
3. Amendments to the research project are to be submitted to the HREC for review. 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. Further advice on submitting amendments is available from:
<https://metronorth.health.qld.gov.au/research/ethics-and-governance/post-approval-reporting>
4. The Principal Investigator will notify the HREC if the project is discontinued at the participating site(s) with reasons provided.
5. If additional sites are engaged prior to the commencement of, or during the research project, the Principal Investigator is required to notify the HREC. Notification of the withdrawn sites should also be provided to the HREC in a timely fashion accompanying a close out report for that site.

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>
Cover Letter		<i>Received on</i> 29 July 2021
Data Collection Form	1.5	30 June 2021
CQ University Research Ready Grant Program (RRGP) 2021 Phase 2 Funding Approval Letter		04 June 2021
Approval letter for study HREC/17/QRBW/661 (ERM: 38653) – Queensland Renal Biopsy Registry (<i>noted</i>)		23 January 2018
Amendment approval letter for study HREC/17/QRBW/661 (ERM: 38653) – Queensland Renal Biopsy Registry (<i>noted</i>)		13 July 2021
Curriculum Vitae of A/Prof Dwarakanathan Ranganathan		11 February 2021
Curriculum Vitae of Dr Ken Wang Tat Chau		26 June 2021
Curriculum Vitae of Katherine Kang		27 June 2021

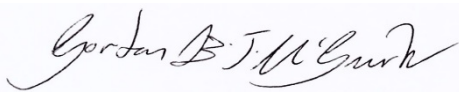
Curriculum Vitae of Nyi Nyi Aung		24 June 2021
Response to request for further information		<i>Received on</i> 23 August 2021
Protocol	1.4	20 August 2021
Study Questionnaire	1.3	21 August 2021
Justification for waiver of consent		<i>Received on</i> 02 September 2021
Response to request for further information		16 September 2021
HREA	Sep ver 6	17 September 2021
Participant Information Sheet & Consent Form	1.3	20 September 2021

The nominated participating sites for this project are:

- Royal Brisbane & Women's Hospital
- Toowoomba Hospital
- Rockhampton Hospital

The Royal Brisbane & Women's Hospital Human Research Ethics Committee wishes you every success in your research.

Yours sincerely,



Dr Gordon McGurk
Chairperson RBWH Human Research Ethics Committee
Metro North Health
21 September 2021

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.