



Queensland
Government

Royal Brisbane & Women's Hospital
Human Research Ethics Committee

Metro North Health

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File Ref: HREC/2021/QRBW/74899
Email: RBWH-Ethics@health.qld.gov.au

Prof Janet Davies
Research Department
Metro North Health Emergency Operations Control
Level 6, Block 6
Royal Brisbane & Women's Hospital
Herston Qld 4029

Dear Prof Davies,

Re: Ref N^o: HREC/2021/QRBW/74899: Queensland CoViD-19 Vaccination Safety and Efficacy Trial (QoVAX SET) Program – Pilot Study

Thank you for submitting the above research project for single ethical review. This project was received by the Royal Brisbane & Women's Hospital Human Research Ethics Committee (RBWH HREC) (**EC00172**) on 21 May 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 will be noted by the RBWH Human Research Ethics Committee at its meeting to be held on 12 July 2021.

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		
HREA	May ver 1	21 May 2021
Curriculum Vitae of Prof Janet Davies	February 2020	
Curriculum Vitae of A/Prof Krispin Hajkowitz		
Curriculum Vitae of Prof Michael Kimlin		
Curriculum Vitae of Kirsty Renfree Short		
Curriculum Vitae of Nicola (Nic) Waddell		
Curriculum Vitae of Rebecca Gregory		
Curriculum Vitae of Tony Kenna		
Response to request for further information		10 June 2021
QoVAX SET Pilot Pre-Vaccine Questionnaire	2.0	10 June 2021
QoVAX SET Pilot Post-Vaccine Questionnaire2.0	2.0	10 June 2021
Response to request for further information		01 July 2021
Protocol	2.1	29 June 2021
Participant Information Sheet & Consent Form	2.1	30 June 2021

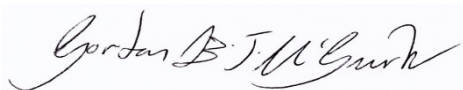
<i>Document</i>	<i>Version</i>	<i>Date</i>
Pilot Promotional Material Content	1	30 June 2021
Curriculum Vitae of Dr Andrew Martin Redmond		09 October 2020

The nominated participating sites for this project are:

- Metro North Health
- Metro South Health
- Cairns and Hinterland Hospital and Health Service

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](#)
05 July 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.