



Queensland
Government

Royal Brisbane & Women's Hospital
Human Research Ethics Committee

Metro North Health

Enquiries to: Mamta Tanwar
A/Coordinator
Telephone: 07 3647 1007
File Ref: HREC/2021/QRBW/79314
Email: RBWH-Ethics@health.qld.gov.au

Professor Janet Davies
Metro North Health
Emergency Operations Centre
Level 11, Block 7
Royal Brisbane and Women's Hospital
Herston QLD 4029

Dear Prof Davies,

Re: Ref N^o: HREC/2021/QRBW/79314: Queensland CoViD-19 Vaccination (QoVAX SET) Safety and Efficacy Trial – Mixed Dose 1 and 2 Study

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 November 2021.

I am pleased to advise that this research project meets the requirements of the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)* and that the RBWH Human Research Ethics Committee has granted ethical approval of this research project.

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		21 September 2021
HREA Form	Sep ver 1	29 September 2021
Curriculum Viate of Tony Kenna		
Curriculum Viate of Rebecca Gregory		
Curriculum Viate of Peter Francis Bourke		21 April 2021
Curriculum Viate of Nicola Waddell		
Curriculum Viate of Michael Kimlin		

Curriculum Viate of Kirsty Renfree Short		
Curriculum Viate of Kirsty Leo		
Curriculum Viate of Janet Davies		February 2020
Curriculum Viate of Hannah Carter		
Curriculum Viate of Gregory Pratt		
Curriculum Viate of Emma Ballard		
Curriculum Viate of Bavahuna Manoharan		17 March 2021
Curriculum Viate of Andrew Redmond		
Response to request for further information		19 October 2021
Response to request for further information		26 October 2021
Protocol	1.1	25 October 2021
Participant Information Sheet & Consent Form	1.1	26 October 2021
Questionnaire	1.1	26 October 2021
Invitations Transcripts	1.1	26 October 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.

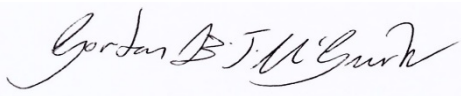
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- **Please advise the HREC of the date you commence the research project for the approved site(s) using the Notification of Commencement Form:**
<https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp>
 - The 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 nominated participating sites for this project are:

- Metro North Health, Emergency Operations Centre
- Metro North Health, Queensland Covid-19 Vaccination Taskforce

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](#)
02 November 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.