Enquiries to: Metro South Research Ethics
MSH-Ethics@health.qld.gov.au
Telephone: 07 3443 8047 or 07 3443 8049
Our Ref: HREC/2023/QMS/94243
Date: 07 June 2023

Queensland Government

Metro South Health

Metro South Research

Mr Matthew Brown
Office of the Chief Health Officer
Queensland Health

Dear Mr Brown,

HREC Reference Number:	HREC/2023/QMS/94243
Project Title:	Health complications after COVID-19 or Influenza

Thank you for submitting the above research application to the Metro South Health Human Research Ethics Committee (MSH HREC) for ethical and scientific review.

I am pleased to advise your research application meets the requirements of Low Risk Research as outlined in the *National Statement on Ethical Conduct in Human Research (2007, updated 2018),* and ethical clearance has been granted. This ethical clearance is valid from 7th June 2023.

You are reminded that this letter constitutes ethical approval only. You must not commence this research protocol at a site until separate authorisation from the Hospital Health Service Chief Executive (CE) or Delegate of that site has been obtained.

A copy of this approval must be submitted to the Research Governance Office(r)/Delegate of the relevant institution with a completed Site Specific Assessment (SSA) Form for authorisation from the CE or Delegate to conduct this research at the sites listed in the Appendix.

If this study currently receives grant funding, please remember to forward a copy of this approval letter to the relevant Grants Office of the Administering Institution(s) for the grant.

The documents reviewed and approved include:

ERM Document Name	Version	Date
HREA Form submitted via Ethical Review Manager (ERM)	1	May
Protocol	1.3	26.05.2023
CV Brown	1	31.01.2023
CV Jerrard	1	31.01.2023
CV Andrews	1	31.01.2023
CHO LTR - CHO DataCustodian MS Ethics	1	11.04.2023

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

1. In accordance with Section 5.5.6 (b) of the National Statement, to maintain ongoing ethical clearance for the duration of the project 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.

2. A Waiver of Consent has been granted to enable access to retrospective data contained in patient medical records, insofar as outlined in the approved protocol only. 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 contact the Health and Medical Research Unit on PHA@health.qld.gov.au .
3. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the protocol in the specified format, including unforeseen events that might affect continued ethical acceptability of the protocol as per the National Health and Medical Research Council's (NHMRC) guidance on *Safety Monitoring and Reporting in Clinical Trials involving Therapeutic Goods (2016)* and its supplementary documents.
4. Amendments to the research protocol which may affect the ongoing ethical acceptability of a protocol must be submitted to the HREC for review electronically via Ethical Review Manager (ERM). Amendments should be reflected in revised study documentation and a cover letter from the principal investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study.
    a. Amendments to the research protocol which only affect the ongoing site acceptability of the protocol are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r.
    b. Proposed amendments to the research protocol which may affect both the ethical acceptability and site suitability of the protocol must be submitted firstly to the HREC for review and, once HREC approval has been granted, then submitted to the Research Governance Office/r.
    c. Amendments which do not affect either the ethical acceptability or site acceptability of the protocol (e.g. typographical errors) do not need to be submitted to the HREC. Rather the Principal Investigator or Study Co-ordinator should maintain a study log of any such changes made to study documentation.
5. The HREC will be notified, giving reasons, if the protocol is discontinued at a site before the expected date of completion.
6. Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes (WHO / ICMJE 2008 definition) should be registered, including early phase and late phase clinical trials (phases I-III) in patients or healthy volunteers (WHO Recommendation / ICMJE policy). If in doubt, registration is recommended. All studies must be registered prior to the study's inception, i.e. prospectively. http://www.anzctr.org.au/ .
7. Please ensure data is retained for the minimum data retention period of five years post publication, as set out in the Australian Code for the Responsible Conduct of Research, and that appropriate security is maintained.

The Metro South 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, updated 2018), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2018)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. The composition of the Metro South HREC has been included at the end of this letter.

Should you have any queries about the HREC's consideration of your protocol, please contact the Metro South HREC Office on (07) 3443 8049.

We wish you every success in your research.

Yours sincerely,

Dr Mary Boyde
Chair
Human Research Ethics Committee (EC00167)
Metro South Research
Metro South Hospital and Health Service

Appendix: List of Participating Sites

No.	Sites
1.	Queensland Health

TO WHOM IT MAY CONCERN

The following is the current composition of the Metro South Human Research Ethics Committee as at 9 November 2022. It is advised that the Committee abides by the guidelines of the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007, updated 2018)*.

COMPOSITION OF METRO SOUTH HUMAN RESEARCH ETHICS COMMITTEE	MEMBER
Category A – Chairperson	Mary Boyde
Category A – Deputy Chairperson	Kristen Gibbons
Category B - Lay Female	Desley Vine
Category B - Lay Male	Callum Gordon
Category B – Lay Female	Judith Wardell
Category B – Lay Female	Julie Holliday
Category B - Lay Male	David Milne
Category C - Knowledge of Professional Care	Kelly Perkins
Category C - Knowledge of Professional Care	Diana Leary
Category C – Knowledge of Professional Care	Bena Brown
Category C – Knowledge of Professional Care	Andrew Wheaton
Category C – Knowledge of Professional Care	Andrea Baker
Category C – Knowledge of Professional Care	Vera Meeusen
Category D – Pastoral Care Role in Community	Cindy Sinclair
Category D – Pastoral Care Role in Community	Trevor Jordan
Category D – Pastoral Care Role in Community	Rachel McFadyen
Category E – Lawyer	John Bennett
Category E – Lawyer	Denis Stark
Category F - Knowledge of Research	Adam La Caze
Category F - Knowledge of Research	Marianne Wyder
Category F – Knowledge of Research	Theo Theodoros
Category F - Knowledge of Research	Ayesha Shah
Category F – Knowledge of Research	CJ Cabilan
Category F – Knowledge of Research	Aideen McInerney-Leo
Category F – Knowledge of Research	Korinne Northwood
Category F – Knowledge of Research	Rahul Ladwa
Category F – Knowledge of Research	Victoria Atkinson
Category F – Knowledge of Research	Shivanand Hebbandi
Category F – Knowledge of Research	Rachel Phillips
Category F – Knowledge of Research	Enna Stroil-Salama
Category F – Knowledge of Research	Sachdev Singh
Category F – Knowledge of Research	Nicola Pritchard
Category F – Knowledge of Research	Melissa Bloomer
Category F – Knowledge of Research	Janin Chandra
Category F – Knowledge of Research	Tina Ha

Should you require further information, please do not hesitate to contact our office on the telephone number listed above. Attendance at the Committee meeting was in accordance with Guidance of the National Statement 5.2.30.