Government of South Australia
Health
Central Adelaide Local Health Network

Central Adelaide Local Health Network
Research Services

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ABN: 96 269 526 412

Authorisation Date: 25 May 2022

Dr Angela Molga
Clinical Pharmacology Department
Royal Adelaide Hospital

Dear Dr Molga

CALHN Reference Number: 16419

Project Title: The SA Long COVID study: A clinical registry defining the care needs for patients with Post-COVID conditions in South Australia

Thank you for submitting the above proposal for review. This project has undergone ethics and governance review via the expedited processes of the Central Adelaide Local Health Network (CALHN) Human Research Ethics Committee (HREC) and CALHN Research Services.

I am pleased to advise that your project has been granted full ethics approval and meets the requirements of the National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Human Research 2007* incorporating all updates. The project is **authorised** by CALHN Research Services for conduct at the Royal Adelaide Hospital and The Queen Elizabeth Hospital.

The CALHN HREC is constituted in accordance with the NHMRC *National Statement on the Ethical Conduct of Human Research* (2007).

Documents reviewed and approved:

Document	Version	Date
Ethics and Governance Application (EGA) Form	-	26 April 2022
Protocol	1	13 May 2022
Participant Information Consent Form	1	12 May 2022
Data Linking Sheet	-	-
Appendix 1 – Covid 19 Yorkshire Rehab Screen (C19-YRS)	-	-
Appendix 2 – Pittsburg Sleep Quality Index (PSQI)	-	1989
Appendix 3 – Structured Interview	2	July 2020
Appendix 4 – CALHN Consumer Experience Survey	3	-
Appendix 4 – Consumer Experience Survey A3 FA	-	-

Sites covered by CALHN HREC approval:

Site	State	Principal Investigator
Royal Adelaide Hospital	SA	Dr Angela Molga
The Queen Elizabeth Hospital		Dr Renjy Nelson

Project authorisation is valid for **one (1) year** from **25 May 2022 to 25 May 2023**. An annual progress report requesting an extension must be submitted if the duration of the project continues beyond this period.

GENERAL TERMS AND CONDITIONS OF PROJECT AUTHORISATION:

1. The CALHN HREC is the South Australian (SA) 'lead HREC' for the purpose of this ethics approval. Any study sites that are not listed on this letter are not covered by the CALHN HREC approval.
2. The study must be conducted in accordance with the standards outlined in the National Statement on

Ethical Conduct in Human Research (2007), the Australian Code for the Responsible Conduct of Research (2018), and SA Health policies.

3. Adequate record keeping must be maintained in accordance with Good Clinical Practice, and the NHMRC, state, and national guidelines. The duration of record retention for all low risk research data is five years from the date of publication.
4. Proposed amendments to the research protocol or conduct of the research which may affect the ongoing ethical acceptability of the project and/or the site acceptability of the project must to be submitted to CALHN Research Services. Researchers are required to immediately report anything which might warrant review of ethical approval of the study, including:
   a) Adverse events which warrant protocol change or notification to research participants;
   b) Changes to the protocol;
   c) Changes to the safety or efficacy of the investigational product, device or method;
   d) Matters that may affect the conduct of the project;
   e) Premature termination of the study.
   5. Confidentiality of the research participants must be maintained at all times as required by law.
6. A report of the progress of the project at least annually, and related to the degree of risk to participants. The report is due on the anniversary of project authorisation. Continuation of approval is contingent on submission of this report, due within 14 days of the approval anniversary. Failure to comply may result in suspension of the project
7. A final report if the outcome of the project must be submitted on completion of the project. A copy of any published material must also be provided with the report, or following when available.
8. A copy of this letter should also be maintained on file by the Coordinating Principal Investigator as evidence of project authorisation.
9. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements. **A copy of compliance confirmation must be forwarded to CALHN Research Services upon receipt.**

You are reminded that this letter constitutes ethical approval only and governance authorisation for CALHN sites.

Should you have any queries about the consideration of your project, please contact Health.CALHNResearchLNR@sa.gov.au.

All future correspondence regarding this study must include the CALHN reference number in the subject header.

We wish you every success in your research.

Yours sincerely,

Ian Tindall
Chair, CALHN Human Research Ethics Committee

Bernadette Swart
Manager, CALHN Research Services

31 May 2022