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: 29 June 2023

Professor Sepehr Shakib
Department of Clinical Pharmacology,
Royal Adelaide Hospital

Dear Professor Shakib

CALHN Reference Number: 17554

Project Title: Addressing safety, quality, and cost of care through a novel, telehealth, outpatient transitional care model: the TTOMMI trial

Thank you for submitting the above proposal for review. The above submission was considered by the CALHN Human Research Ethics Committee (CALHN HREC) at its meeting held on 18 May 2023 and governance review has been conducted by 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 CALHN HREC determined that the waiver request meets the requirements of section 2.3.10 of the NHMRC National Statement. Waiver of consent has been granted for access to all electronic and hard medical records for the above project as detailed below:

- Waiver of Consent to access participants' medical records both hard and electronic to pre-screen for eligibility for the above project.

The project is also **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	-	21 February 2023
Protocol	6	28 June 2023
Data Collection Spreadsheet (The Edmonton Frail Scale)	1	21 April 2023
Patient Continuity of Care Questionnaire - Short (PCCQ-Short)	1	21 April 2023
EQ-5D-3L Questionnaire	1	21 April 2023
Participant Information Sheet	2	21 April 2023
Data Collection Spreadsheet Codebook	1	21 April 2023
Participant log Codebook	1	21 April 2023
Participant Consent Form	-	August 2021

Sites covered by CALHN HREC approval:

Site	State	Principal Investigator
Royal Adelaide Hospital	SA	Professor Sepehr Shakib

The Queen Elizabeth Hospital	SA	Professor Sepehr Shakib

Project authorisation is valid for **one (1) year** from **29 June 2023 to 29 June 2024**. 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.**

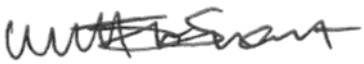
You are reminded that this letter constitutes ethical approval only and governance authorisation for CALHN sites. You must not commence this research project at [Site/s] until governance authorisation at that site has been obtained.

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

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29 June 2023