Government of South Australia
Health
Central Adelaide Local Health Network

Central Adelaide Local Health Network
Human Research Ethics Committee

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Health.CALHNResearchEthics@sa.gov.au
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ABN: 96 269 526 412

Approval Date: 16 August 2023

Prof Catherine Hill
Rheumatology
THE QUEEN ELIZABETH HOSPITAL

Dear Prof Hill

GEMS HREC Reference Number: 2023/HRE00162

Project Title: (The STERLING-PMR study) Steroid-Reducing Options for ReLapsING PMR : a multi-centre, Phase III, parallel-group, open-label, randomised controlled trial to compare the clinical and cost-effectiveness of adding immunosuppression to steroid-tapering treatment for patients with relapsing PMR, versus steroid-tapering alone

Human Research Ethics Committee APPROVAL

Thank you for submitting the above project for ethical and scientific review. The application was first considered by the Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) at its meeting held on 13 July 2023. The CALHN HREC is constituted in accordance with the NHMRC *National Statement on the Ethical Conduct of Human Research (2007)* incorporating all updates (the National Statement).

The CALHN HREC has reviewed all responses, and I am pleased to advise that the project meets the requirements of the National Statement application and has been granted full ethics approval.

The documents reviewed and approved include:

Document	Version	Date
HREA - 2023/HRE00162	2	19 Jul 2023
CALHN HREC Covering submission letter	-	19 Jun 2023
Protocol - STERLING-PMR	2	24 Jul 2023
METHOTREXATE CMI	1	01 Sep 2014
STERLING-PMR PIS ICD AUS	2.0	03 Aug 2023
EQ- 5D-5L UK	1.2	01 Jan 2009
PMR-IS Questionnaire	1	19 Jun 2023
STERLING-PMR Steroid use questionnaire	1.0	27 Jan 2023
STERLING-PMR Participant pain VAS	1.0	27 Jan 2023
STERLING-PMR Patient ID Card	1.0	19 Jan 2023
AUS STERLING-PMR Patient Invite Letter	1.0	30 May 2023
STERLING-PMR AUS Questionnaire cover letter	1.0	30 May 2023
STERLING-PMR AUS Questionnaire reminder cover letter	1.0	30 May 2023
STERLING-PMR Text message wording templates	1.0	25 Jan 2023
STERLING-PMR Wk 12,36,48,60,72 questionnaire pack cover sheet AUS	1.0	19 Jun 2023
STERLING-PMR Wk 24, 80 questionnaire pack cover sheet AUS	1.0	19 Jun 2023
STERLING GP Letter	0.1	23 May 2023
STERLING-PMR Baseline questionnaire pack cover sheet AUS	1.0	19 Jun 2023
STERLING-PMR Email message wording templates	1.0	25 Jan 2023
Radiation Safety Report	-	03 Aug 2023
Victorian Specific Module (VSM)	-	19 Jun 2023
WA specific Module (WASM)	-	19 Jun 2023
Supporting Documents: • Investigator CV - Dr David Liew • Investigator CV - Dr Helen Keen		

• Investigator CV - Prof Nigel Stocks • Investigator CV – A/Prof Manski-Nankervis • Investigator CV – Dr Carlee Ruediger		
Response to request for further information	-	07 Aug 2023

Sites covered by this approval:

Site	State	Investigator
The Queen Elizabeth Hospital	SA	CPI: Prof Catherine Hill
Austin Health	VIC	PI: Dr David Liew
Fiona Standley Hospital	WA	PI: Dr Helen Keen

CALHN HREC approval is valid for 3 years from: **09 August 2023 to 09 August 2026**

GENERAL TERMS AND CONDITIONS OF ETHICAL APPROVAL:

The CALHN HREC is constituted and operates in accordance with the National Statement on Human Conduct in Research, 2007 (Updated 2018) (NHMRC). The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.

All clinical trials approved by the CALHN HREC must comply with the *NHMRC Guidance on Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (November 2016). The CALHN HREC must be notified within 72 hours of any Urgent Safety Measures (USMs) occurring at any approved sites.

Researchers must notify the CALHN HREC of any events which might warrant review of the approval or which warrant new information being presented to research participants, 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) premature termination of the project.

Confidentiality of the research participants must be maintained at all times as required by law.

Annual Progress Reports must be submitted to the CALHN HREC, every 12 months on the anniversary of the above approval date. In accordance with the National Statement, it is the researchers' responsibility to provide reports of the progress of approved research projects at least annually, and related to the degree of risk to participants, to the reviewing Human Research Ethics Committee (HREC). This report must be completed by the Coordinating Principal Investigator (CPI) for all multi-site projects or the Principal Investigator (PI) for single site projects for all research projects approved under the CALHN HREC. The report is due on the anniversary of HREC approval. Continuation of ethical approval and local governance authorisation is contingent on submission of this report, due within 2 weeks of the approval anniversary. Failure to comply may result in suspension of the project

A Final Report must be submitted to the CALHN HREC on completion of the project and for all site closures. In accordance with the National Statement, it is the researchers' responsibility to provide a final report of the outcome for completed research projects and for all site closures to the reviewing Human Research Ethics Committee (HREC). This report must be completed by the Coordinating Principal Investigator (CPI) for all multi-site research projects or the Principal Investigator (PI) for single site research projects approved under the CALHN HREC.

A report and a copy of any published material should be forwarded to the CALHN HREC at the completion of the project. If the project is discontinued before its completion, the CALHN HREC must be advised immediately and provided with reasons for discontinuing the project.

We wish you all the best with the project and remind you that any changes to the application and safety reports will need to be submitted and reviewed by the approving HREC prior to implementation. You must immediately report to the HREC anything that may change the ethics or scientific integrity of the project.

This email constitutes ethical and scientific approval only. This project cannot proceed at any site until separate research governance authorisation has been obtained from the institution under whose auspices the research will be conducted at that site. *For any queries, please contact the CALHN Governance Office: Health.CALHNResearchGovernance@sa.gov.au*

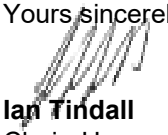
If your study involves a tertiary institution, contact the University to ensure compliance with University requirements prior to commencement of this study. This includes any insurance and indemnification.

Please contact us if you would like to discuss any aspects of this process further, as per the contact details below. We look forward to managing this application with you throughout the project lifecycle.

Should you have any queries about the CALHN HREC's consideration of your project, please contact the CALHN HREC Support Officer on 08 7117 2229, or Health.CALHNResearchEthics@sa.gov.au.

The CALHN HREC wishes you every success in your research.

Yours sincerely,



Ian Tindall
Chair, Human Research Ethics Committee
Central Adelaide Local Health Network