Government of South Australia
SA Health

Central Adelaide Local Health Network
Human Research Ethics Committee (TQEH/LMH/MH)
The Queen Elizabeth Hospital
Basil Hetzel Institute DX465101
28 Woodville Road
Woodville South SA 5011
Telephone: 08 8222 6841
Email: Health.CALHNResearchEthics@sa.gov.au

7 November 2017

A/Prof Margaret Arstall
Department of Cardiology
Lyell McEwin Hospital

Dear A/Prof Arstall,

Project title: **C**oronary and Peripheral Haemodynamic Studies in Angina with No Obstructive Coronary Artery Disease and International COVADIS Registry. Project A.

HREC reference number: HREC/17/TQEH/156

CALHN reference number: Q20170706

RE: Ethics Application APPROVAL

Thank you for submitting the above project for ethical and scientific review. The project was first considered by The Queen Elizabeth Hospital Human Research Ethics Committee (TQEH/LMH/MH) at its meeting held on 14 August 2017, and subsequent re-review on. 9 October 2017.

The HREC has reviewed all responses, and I am pleased to advise that your protocol has been granted full ethics approval and meets the requirements of the *National Statement on Ethical Conduct in Human Research, incorporating all updates*. The documents reviewed and approved include:

Document	***Version***	***Date***
NEAF Application Revised NEAF Application	AU/1/4A7F219 AU/1/5560316	23 July 2017 30 August 2017
Cover Letter	-	20 July 2017
Protocol	2	21 August 2017
Participant Information Sheet and Consent Form	4	30 October 2017
LMH Medical Coronary Angiogram Information Sheet	MR 861	01/2013
LMH Medical Consent Form	MR 800	Rev 12/2014
Spasm Testing Case Report Form	1	20 July 2017
Questionnaires - OSA50 Screening Questionnaire - STOPBANG Sleep Apnea Questionnaire - Epworth Sleepiness Scale	1	20 July 2017
Letter to Treating Cardiologist	1	20 July 2017
Letter from Treating Cardiologist to Potential Participant	1	20 July 2017
NOCAD Study Visit Schedule	2	21 August 2017
NOCAD OSA Study Visit Schedule	2	21 August 2017
NOCAD Flow Chart – Coronary Angiogram	2	21 August 2017
Sample Size Calculation by Statistician	1	12 September 2016
Data Management Plan	1	20 July 2017
NOCAD OSA Outcomes Study Baseline Form	2.0	25 September 2017
NOCAD OSA Outcomes Study 1 Month Form	2.0	25 September 2017
NOCAD OSA Outcomes Study 6 Month Form	2.0	25 September 2017
NOCAD OSA Outcomes Study 12 Month Form	2.0	25 September 2017
Radiation Report – 1.7 mSv	-	11 August 2017

Sites covered by this approval:

- **Lyell McEwin Hospital, SA: PI – A/Prof Margaret Arstall**

HREC approval is valid for **5 years** from **7 November 2017 to 7 November 2022.**

Please quote the **HREC Reference number, HREC/17/TQEH/156** and the **CALHN Reference number, Q20170706** allocated to your study on all future correspondence.

GENERAL TERMS AND CONDITIONS OF ETHICAL APPROVAL:

1. For all clinical trials, the study must be registered in a publicly accessible trials registry prior to enrolment of the first participant.
2. This HREC is certified with the NHMRC for National Mutual Acceptance of Single Ethical and Scientific Review of Multi-Centre Clinical Trials. Any study sites that are not listed on this letter are not covered by this ethics approval. Any study-sites that wish to be added must contact the CPI, who must write formally to this HREC requesting the additional study site.
3. Adequate record-keeping is important and must be maintained in accordance with GCP, NHMRC and state and national guidelines. If the project involves signed consent, you should retain the completed consent forms which relate to this project and a list of all those participating in the project, to enable contact with them in the future if necessary. The duration of record retention for all clinical research data is 15 years.
4. Researchers must notify the HREC of anything which might warrant review of the approval of the study, 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 study.
5. The Committee must be notified within 72 hours of any Urgent Safety Measures (USMs) occurring at this or any approved sites.
6. Confidentiality of the research participants shall be maintained at all times as required by law.
7. Approval is valid for **5 years** from the date of this letter, after which an extension must be applied for.
8. Annual review reports must be submitted to the HREC, every 12-months on the anniversary of the above approval date. Each site covered by this HREC must submit a report, and it is the responsibility of the Coordinating Principal Investigator to ensure this is provided to the TQEH HREC Executive Officer, within 10 working days on each anniversary of the approval date, using the Annual Review Form available at: http://www.basilhetzelinstitute.com.au/research/information-for-researchers/human-research-ethics-committee/
9. The HREC must be advised with a final report or in writing, and a copy of any published material within 30 days of completion of the project.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at any site until separate authorisation from the Chief Executive or delegate of that site has been obtained. For any queries, please contact the CALHN Governance Office:
Health.CALHNResearchGovernance@sa.gov.au

This Committee is constituted in accordance with the NHMRC *National Statement on the Ethical Conduct of Human Research (2007)* incorporating all updates.

Should you have any queries about the HREC's consideration of your project, please contact Mrs Heather O'Dea, HREC Executive Officer on 08 8222 6841 or Health.CALHNResearchEthics@sa.gov.au

The HREC wishes you every success in your research.

Yours sincerely

Professor Richard E Ruffin
Chairman, Human Research Ethics Committee (TQEH/LMH/MH)

RR:HO

Cc: Site Research Governance Officer