



Northern Adelaide Local Health Network

19 Dec 2017

A/Prof Margaret Arstall
Department of Cardiology
Lyell McEwin Hospital
Haydown Rd
ELIZABETH VALE SA 5112

Research Governance Office
Level 2, Clinical Trials Unit
Lyell McEwin Hospital
Haydown Road
ELIZABETH VALE SA 5112
Tel: 08 8182 9346
Email: healthnalhnrgo@sa.gov.au

Dear A/Prof Arstall,

HREC reference number: HREC/17/TQEH/156

SSA reference number: SSA/17/NALHN/98

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

I am pleased to advise that the above project is approved to be conducted at Lyell McEwin Hospital.

This approval is subject to compliance with the conditions set out below in addition to the conditions specified by the reviewing HREC.

1. Record keeping is maintained in accordance with GCP, NHMRC, State and National guidelines.
2. Notify the NALHN Research Governance Office of:

- Any HREC approved amendments to the project
- The annual progress of the project (annual report)
- Extensions to the ethical approval of the project
- Serious or unexpected adverse effects for NALHN participants
- Site based protocol deviations
- Any changes to the indemnity, insurance arrangements or CTRA for the project
- Your inability to continue as Principal Investigator or any other change in research personnel involved in this project
- Failure to commence the study within 12 months of site approval / or if a decision is taken to end the study at this site
- Any other unforeseen events
- Any other matters which may impact the conduct of the project in NALHN
- A comprehensive final report at study completion including any published material
- Site audits and final audit report

3. Maintain confidentiality of NALHN participants at all times, as required by law.
4. Dispose of research materials in accordance with the requirements outlined in the NHMRC Australian Code for the Responsible Conduct of Research.
5. Principal Investigators should check their state legislation requirements regarding research involving exposure of research participants to ionising radiation before commencement of this study.
6. For all clinical trials, ensure the study is registered in a publicly accessible trials registry prior to enrolment of the first participant

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.

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The NALHN Research Governance Office may conduct an audit of the project at any time.

Please note: templates for the post approval submission of documents to the RGO can be accessed from: <http://www.basilhetzelinstitute.com.au/research/information-for-researchers/nalhn/forms-and-templates/>

Should you have any queries about the consideration of your Site Specific Assessment form, please contact me on 08 8182 9346 or healthnalhnrqo@sa.gov.au

The SSA reference number should be quoted in any correspondence about this matter.

Yours sincerely

Alison Barr
Research Governance Officer
Northern Adelaide Local Health Network (LMH/MH/PHC)

Key Dates:

Document	Due date
Annual Report	07 Nov 2018

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