Enquiries to: Metro South
Human Research Ethics Committee
Phone: 07 3443 8049
Fax: 07 3443 8003
HREC Ref: LNR/2018/QMS/46866
E-mail: MSH-Ethics@health.qld.gov.au

Dr Jonathon Fanning
Anaesthesia Department
Princess Alexandra Hospital

Dear Dr Fanning,

HREC Reference number: LNR/2018/QMS/46866
Protocol title: Prothombotic Changes Associated with Aortic Valve Management
Project Id: 46866

Thank you for submitting the above research protocol to the Metro South Health Human Research Ethics Committee for ethical and scientific review. This protocol was considered by the Low Risk Review Panel and will be ratified at the next Metro South HREC meeting.

You are reminded that this letter constitutes ethical approval only. You must not commence this research protocol at a site until separate authorisation from the Hospital Health Service Chief Executive (CE) or Delegate of that site has been obtained.

A copy of this approval must be submitted to the Research Governance Office(r)/Delegate of the relevant institution with a completed Site Specific Assessment (SSA) Form for authorisation from the CE or Delegate to conduct this research at the Princess Alexandra Hospital.

If this study currently receives grant funding, please remember to forward a copy of this approval letter to the relevant Grants Office of the Administering Institution(s) for the grant.

I am pleased to advise that the Low Risk Review Panel of the HREC has granted approval of this research protocol. The documents reviewed and approved include:

Document	Version	Date
LNR submitted via ERM		19/11/2018
PCI_TAVI_SAVR Study Protocol	1	21/09/2018
TAVR_AVR Protocol	3.0	09/10/2018
PICF: PAH_Thrombosis_PICF	1	21/09/2018
Thrombotic changes in TAVI, AVR and PCI	3.0	23/11/2018
Data Collection Forms	1.0	n.d
UCH LNRA – noted only		n.d
UNH HREA – noted only		n.d
CV for Investigators		n.d

This HREC approval is valid from 16/01/2019 until 16/01/2022

Please note the following conditions of approval:

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the protocol in the specified format, including unforeseen events that might affect continued ethical acceptability of the protocol.
2. Amendments to the research protocol which may affect the ongoing ethical acceptability of a protocol must be submitted to the HREC for review. Major amendments should be reflected in revised study documentation and a cover letter from the principal investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study. Hard

copies of the revised documents and the cover letter, with *tracked changes*, must also be submitted to the HREC office as per standard HREC SOP.

3. Amendments to the research protocol which only affect the ongoing site acceptability of the protocol are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r.
4. Proposed amendments to the research protocol which may affect both the ethical acceptability and site suitability of the protocol must be submitted firstly to the HREC for review and, once HREC approval has been granted, then submitted to the Research Governance Office/r.
5. Amendments which do not affect either the ethical acceptability or site acceptability of the protocol (e.g. typographical errors) should be submitted electronically (track changes) and in hard copy (final clean copy) to the HREC Coordinator. These should include a cover letter from the Principal Investigator or Study Co-ordinator providing a brief description of the changes and the rationale for the changes, and accompanied by all relevant updated documents with tracked changes.
6. The HREC will be notified, giving reasons, if the protocol is discontinued at a site before the expected date of completion.
7. The Coordinating Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.
8. If you require an extension for your study, please submit a request for an extension in writing outlining the reasons. Note: One of the criteria for granting an extension is the compliance with the approval's conditions including submission of progress reports.
9. Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes (WHO / ICMJE 2008 definition) should be registered, including early phase and late phase clinical trials (phases I-III) in patients or healthy volunteers (WHO Recommendation / ICMJE policy). If in doubt, registration is recommended. All studies must be registered prior to the study's inception, i.e. prospectively. http://www.anzctr.org.au/

Should you have any queries about the HREC's consideration of your protocol please contact Ethics Secretariat on 07 3443 8049.

Please note that the Metro South HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Attached is the HREC Composition with specialty and affiliation with the Hospital (Attachment I).

The Metro South HREC wishes you every success in your research.

Yours sincerely,

Nicolla Lewin
A/Chair - Low Risk Review Panel
Metro South Hospital and Health Service
Human Research Ethics Committee (EC00167)
Centres for Health Research
Princess Alexandra Hospital

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C.c. Dr Shaun Roberts