

From: no_reply@regis.health.nsw.gov.au
To: nicholas.collins@health.nsw.gov.au
Cc: [Natasha Baker](#)
Subject: 2020/ETH01269: Application HREA - Approved
Date: Monday, 20 July 2020 12:44:17 PM

Date of Decision Notification: 20 Jul 2020

Dear A/Professor Collins

Thank you for submitting the following Greater than low risk review pathway Human Research Ethics Application (HREA) for HREC review;

2020/ETH01269: Assessment of cognitive function and cerebral blood flow in patients undergoing aortic valve intervention

This project was considered by the Hunter New England Human Research Ethics Committee at its meeting held on 17 June 2020 and was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007).

This project has been Approved to be conducted at the following site/s:

- John Hunter Hospital

The following documentation was reviewed and is included in this approval:

- HREA (Version 3 created 13 July 2020)
- Response to HNEHREC Requirements (undated)
- TAVI-COG Protocol No 1.0 (Amended date 2 July 2020)
- Information Sheet (Version 1.2 dated 16 July 2020)
- Consent Form (Version 1.1 dated 16 July 2020)
- Health Related Questionnaire (Version 1.1 dated 29 June 2020)

[Application Documents](#) - (Please note : Due to security reasons, this link will only be active for 14 days.)

It is noted that the Hunter New England Human Research Ethics Committee is constituted in accordance with the National Statement on Human Conduct in Research, 2007 (NHMRC). The approval is for a period of 5 years from the date of this e-mail (20 Jul 2020) , on condition of the submission of Annual Reports.

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.

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.

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

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.

Kind regards

Debbie Madden

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Research Office

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