Government of South Australia
SA Health

Central Adelaide Local Health Network
CALHN Human Research Ethics Committee
Level 3, Roma Mitchell House
136 North Terrace
Adelaide, South Australia, 5000
Telephone: +61 8 7117 2229
Email: Health.CALHNResearchEthics@sa.gov.au

Approval Date: 13 December 2017

Ms Erica Tilley
School of Psychology, Social Work and Social Policy
UNIVERSITY OF SOUTH AUSTRALIA

Dear Ms Tilley

Project Title: "Development of Risk Models for Cognitive Decline and Delirium in Aortic Stenosis and Transcatheter Aortic Valve Implantation (TAVI)."

HREC reference number: HREC/17/RAH/391

CALHN Reference number: R20170916

RE: Ethics Application APPROVAL

Thank you for submitting the above project for ethical and scientific review. The project was first considered by the Royal Adelaide Hospital Human Research Ethics Committee at its meeting held on 28 September 2017.

Please note: The RAH HREC has now merged into the CALHN Human Research Ethics Committee, effective from 1 January 2018.

The HREC has reviewed all responses, and I am pleased to advise that your protocol has been granted full ethics approval. The study 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***
CALHN Low/Negligible Risk Ethics and Governance Application	-	12 December 2017
Protocol	2	1 November 2017
TAVI Participant Information Sheet and Consent Form - Self	3	12 December 2017
TAVI Participant Information Sheet and Consent Form – Person Responsible	3	12 December 2017
Control Participant Information Sheet and Consent Form - Self	3	12 December 2017
Control Participant Information Sheet and Consent Form - Person Responsible	3	12 December 2017
Family Member Control Participant Information Sheet and Consent Form - Self	2	9 November 2017
Family Member TAVI Participant Information Sheet and Consent Form - Self	2	15 November 2017
TAVI Assessment Booklet	2	2 November 2017
Recruitment brochure – TAVI	-	14 November 2017
Recruitment brochure – Control	-	14 November 2017
Recruitment flyer - Control	-	14 November 2017

Sites covered by this approval:

- **Royal Adelaide Hospital, SA: CPI – Ms Erica Tilley**

HREC approval is valid for **5 years** from **13 December 2017 to 13 December 2022.**

Please quote the **HREC Reference number, HREC/17/RAH/391** and the **CALHN Reference number, R20170916** allocated to your study on all future correspondence.

GENERAL TERMS AND CONDITIONS OF ETHICAL APPROVAL:

- For all clinical trials, the study must be registered in a publicly accessible trials registry prior to enrolment of the first participant.
- This HREC is certified with the NHMRC for National Mutual Acceptance of Single Ethical and Scientific Review of Multi-centre Clinical Trials. This HREC will act as a 'lead HREC' for the purpose of this ethics approval. 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.
- 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.
- 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.
- Researchers must notify the Research Ethics Committee 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 study.
- The Committee must be notified within 72 hours of any Urgent Safety Measures (USMs) occurring at this or any approved sites.
- Confidentiality of the research participants shall be maintained at all times as required by law.
- Approval is valid for **5 years** from the date of this letter, after which an extension must be applied for.
- **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 CALHN HREC Executive Officer, within 10 working days on each anniversary of the approval date, using the Annual Review Form available at: https://www.rahresearchfund.com.au/rah-research-institute/for-researchers/human-research-ethics/
- The REC 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's *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, Executive Officer on 08 7117 2229, or Health.CALHNResearchEthics@sa.gov.au.

The HREC wishes you every success in your research.

Yours sincerely,

Ian Tindall
CHAIRMAN
CALHN HUMAN RESEARCH ETHICS COMMITTEE
cc: Site Research Governance Officer