



HUMAN RESEARCH ETHICS COMMITTEE

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26 April 2018

Dr Praveen Indraratna
Department of Cardiology
Level 3, Campus Centre - Dickinson Building
Prince of Wales Hospital
RANDWICK NSW 2031

Dear Dr Indraratna,

HREC ref no: 18/008 (HREC/18/POWH/91)

Project title: Total Cardiac Care – a randomised controlled trial of a comprehensive smartphone application-centric model of care to improve outcomes in patients with cardiovascular disease

Thank you for submitting the above application for ethical and scientific review. The application was first considered by the South Eastern Sydney Local Health District Human Research Ethics Committee (HREC) at a meeting on **27 February 2018**.

Your recent correspondence was reviewed at the HREC Executive Committee meeting on **24 April 2018**.

I am pleased to advise that that the proposal meets the requirements of the National Statement on Ethical Conduct of Human Research.

Ethics approval is granted for the following site(s):

- Prince of Wales Hospital
- Sutherland Hospital
- Port Macquarie Hospital
- Royal North Shore Hospital
- Liverpool Hospital

Ethics approval is granted for the following documents:

- NEAF / HREA submission code AU/1/EDD3311, dated 02 February 2018
- Protocol Version 2 dated 03 April 2018
- MASTER PIS&CF Version 2 dated 03 April 2018
- Short Form Survey Instrument (SF-36)
- Case Report Form 1.1
- INSTRUCTION_MANUAL_UA_767NFC
- INSTRUCTION_MANUAL_UC_324NFC

Prince of Wales Hospital
Community Health Services
Barker Street
Randwick NSW 2031

Conditions of approval

1. This approval is valid for 5 years from the date of this letter.
2. Annual reports must be provided on the anniversary of approval.
3. A final report must be provided at the completion of the project.
4. Proposed changes to the research protocol, conduct of the research, or length of approval will be provided to the Committee.
5. The Principal Investigator will immediately report matters which might warrant review of ethical approval, including unforeseen events which might affect the ethical acceptability of the project and any complaints made by study participants.

Optional It is the responsibility of the sponsor or the principal (or co-ordinating) investigator of the project to register this study on a publicly available online registry (eg Australian New Zealand Clinical Trials Registry www.anzctr.org.au).

For Public Health Sites Only: You are reminded that this letter constitutes ethical approval only. You must not commence this research project until you have submitted your Site Specific Assessment (SSA) to the Research Governance Officer of the appropriate institution and have received a letter of authorisation from the General Manager or Chief Executive of that institution.

Should you have any queries, please contact the Research Support Office on (02) 9382 3587. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Research Support Office website:
<http://www.seslhd.health.nsw.gov.au/POWH/researchsupport/default.asp>.

Please quote **18/008** in all correspondence.

We wish you every success in your research.

Yours sincerely



Andrew Bohlken
Executive Officer, Human Research Ethics Committee

This 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*.