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: 14 June 2018**

**Prof John Beltrame**
**School of Medicine**
**UNIVERSITY OF ADELAIDE**

Dear Prof Beltrame

**Project Title:** Randomized Evaluation of Beta Blocker and ACE Inhibitor/Angiotensin Receptor Blocker Treatment in Myocardial Infarction With Non Obstructive Coronary Arteries (MINOCA) Patients MINOCA BAT Trial

**HREC reference number:** HREC/18/CALHN/157

**CALHN Reference number:** Q20180306

**RE: Ethics Application APPROVAL**

Thank you for submitting the above project for ethical and scientific review. The project was first considered by the CALHN Human Research Ethics Committee at its meeting held on 19 April 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*** |
|---|---|---|
| HREA Application | AU/1/42D4316 | 12 Mar 2018 |
| Cover Letter (including Investigator Statement) | - | 12 Mar 2018 |
| MINOCA-BAT Protocol | 2 | 21 Mar 2018 |
| MINOCA-BAT Participant Information Sheet / Consent Form - TQEH | 2 | 27 Apr 2018 |
| MINOCA-BAT Participant Information Sheet /.Consent Form - RAH | 2 | 27 Apr 2018 |
| MINOCA-BAT Participant Information Sheet / Consent Form - LMH | 2 | 27 Apr 2018 |
| MINOCA-BAT Study Participation Notification Letter | - | 12 Mar 2018 |
| CADOSA Case Report Form | 3.0 | - |
| MINOCA-BAT Clinical Trial Baseline Quality of Life Assessment | 1.0 | 08 Feb 2018 |
| MINOCA-BAT Clinical Trial 1, 6 and 12 Month Follow-Up | 1.0 | 08 Feb 2018 |
| MINOCA-BAT Clinical Trial Annual Follow-Up: 2 – 4 Years | 1.0 | 08 Feb 2018 |
| MINOCA-BAT Trial guidelines for clinicians | 1 | 11 May 2018 |
| PhQ-9 - Notification of Suicidal Ideation Letter | 1.0 | 08 Feb 2018 |
| PhQ-9 Form for GP | - | - |
| Drug and Device checklist | - | - |
| APO-Atenolol Tablets – Product information Australia | - | - |
| APO- Perindopril Arginine Tablets – Product information Australia | - | - |
| APO- Perindopril Erbumine Tablets – Product information Australia | - | - |
| Atacand Candesartan Cilexetil – Product Information Australia | - | - |
| Response letter | - | 14 May 2018 |

Sites covered by this approval:

- The Queen Elizabeth Hospital, SA CPI: Prof John Beltrame
- The Royal Adelaide Hospital, SA CPI: Prof John Beltrame
- The Lyell McEwin Hospital, SA CPI: Prof John Beltrame

HREC approval is valid for **5 years** from **14 June 2018 to 14 June 2022.**

**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.
- 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 HREC 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 HREC 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 Report Form available at: https://www.rahresearchfund.com.au/rah-research-institute/for-researchers/human-research-ethics/ and http://www.basilhetzelinstitute.com.au/research/information-for-researchers/human-research-ethics-committee/
- **A final Annual Review Report must be submitted to the HREC on completion of the study.** 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 using the CALHN Annual Review Report Form available at https://www.rahresearchfund.com.au/rah-research-institute/for-researchers/human-research-ethics/ and http://www.basilhetzelinstitute.com.au/research/information-for-researchers/human-research-ethics-committee/. A copy of any published material must also be provided with the report, or following when available.

***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 HREC endorses the NHMRC Guidance on *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (November 2016)*. https://www.nhmrc.gov.au/guidelines-publications/eh59. The Guidance applies to all Clinical trials for safety monitoring and reporting of Investigational Medicinal Products (IMPs) and Investigational Medical Devices (IMDs), approved by this Committee.

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 the 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**
**CHAIR**
**CALHN HUMAN RESEARCH ETHICS COMMITTEE**