



15 February 2016

Prof John Beltrame
Department of Medicine
The Queen Elizabeth Hospital

Dear Prof Beltrame,

Project title: Ticagrelor In Coronary Microvascular Dysfunction Program-2: Anti-anginal Efficacy in Primary Coronary Microvascular Disorders.

HREC reference number: HREC/15/TQEH/4

RE: Ethics Application APPROVAL

Thank you for submitting the above project for ethical and scientific review. The project was first considered by The Queen Elizabeth Hospital Human Research Ethics Committee (TQEH/LMH/MH) at its meeting held on 9 February 2015.

The HREC has reviewed all responses, and I am pleased to advise that your protocol has been granted full ethics approval and 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
Covering Letter	-	14 January 2015
NEAF Application:	AU/1/9F8C111	15 January 2015
ESR-14-10465 Protocol, TIC 2 Depression	1	20 January 2016
Participant Information Sheet and Consent Form	4	27 January 2016
Seattle Angina Questionnaire	1	14 November 2014
Short Form Health Survey	1	14 November 2014
Brilinta® Ticagrelor CMI		June 2011
Response to Request for Further Information	-	6 January 2016
Further Response letter	-	20 January 2016
Further Response letter	-	27 January 2016

Sites covered by this approval:

- **The Queen Elizabeth Hospital, SA: Prof John Beltrame**

HREC approval is valid for **5 years** from **28 January 2016 to 28 January 2021**.

Please quote the HREC Reference number, HREC/15/TQEH/4 on all future correspondence.

GENERAL TERMS AND CONDITIONS OF ETHICAL APPROVAL:

1. For all clinical trials, the study must be registered in a publicly accessible trials registry prior to enrolment of the first participant.
2. This HREC will act as the South Australian '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 SA study-sites within the public health system that wish to be added must contact the CPI, who must write formally to this HREC requesting the additional study site.
3. Adequate record-keeping must be maintained in accordance with GCP, NHMRC and state and national guidelines. The duration of record retention for all clinical research data is 15 years from the date of publication.

4. Researchers must notify the HREC of anything which might warrant review of ethical approval of the study, including:
 - (a) serious or unexpected adverse effects on participants which warrant protocol change or notification to participants;
 - (b) proposed changes in the study; and
 - (c) premature termination of the study.
5. The HREC must be notified within 72 hours of any Serious Adverse Events occurring at any approved site.
6. Confidentiality of the research subjects shall be maintained at all times as required by law.
7. Annual review reports must be submitted to the HREC, every 12-months from the date of approval. Each site covered by this HREC must submit a report, and it is the responsibility of the Coordinating Principal investigator to ensure this is carried out.
8. The HREC 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 cannot commence this project until you receive site authorisation from the CEO or delegate, even if ethics approval is received.

This Committee is constituted in accordance with the NHMRC *National Statement on the Ethical Conduct of Human Research (2007)* and incorporating all updates.

Should you have any queries about the HREC's consideration of your project please the HREC Executive Officer on 08 8222 6841 or Health.CALHNResearchEthics@sa.gov.au

The HREC wishes you every success in your research.

Yours sincerely



Professor Richard E Ruffin
Chairman, Human Research Ethics Committee (TQEH/LMH/MH)

RR:HO

Cc: Site Research Governance Officer(s)