



20 December 2016

Prof John Beltrame  
Michelle Professor of Medicine  
Division of Medicine - Cardiology Unit  
The Queen Elizabeth Hospital  
28 Woodville Road  
WOODVILLE SOUTH SA 5011

Dear Prof Beltrame,

**Project title:** The Coronary Angiogram Database of South Australia (CADOSA)

**HREC reference number:** HREC/15/TQEH/252

**CALHN reference number:** Q20151217 (Old TQEH Reference No. 2011012)

**RE: Ethics Application AMENDMENT APPROVAL**

Thank you for submitting the above project amendment for ethical and scientific review. The amendment was considered expeditely by the Chairman of The Queen Elizabeth Hospital Human Research Ethics Committee (TQEH/LMH/MH). I am pleased to advise that the Amendment has been granted approval including:

<b>Document</b>	<b>Version</b>	<b>Date</b>
Amendment to include all sites under NMA: <ul style="list-style-type: none"> <li>o <i>Inclusion of The Royal Adelaide Hospital site (HREC # 110816) – PI: A/Prof Matthew Worthley</i></li> <li>o <i>Inclusion of Flinders Medical Centre site (HREC # 232.11) – PI: A/Prof Ajay Sinhal</i></li> </ul>	-	12 December 2016
Letter of support from A/Prof Matthew Worthley		23 November 2016
Letter of support from A/Prof Ajay Sinhal		8 November 2016

Current documents previously approved, include:

<b>Document</b>	<b>Version</b>	<b>Date</b>
NEAF Application:	AU/1/D072216	11 November 2015
CADOSA Protocol	6.0	3 November 2015
CADOSA Project Flow Chart	1.0	3 November 2015
MR Form Angio – PCI Risk Info Sheet – CADOSA	1.5	3 November 2015
CADOSA TQEH Opt Off Patient Information Sheet	2.0	3 November 2015
CADOSA LMH Opt Off Patient Information Sheet	2.0	3 November 2015
CADOSA Project Flow Chart	1.1	15 December 2015
Patient Information Sheet/Consent	6.0	18 August 2015
Procedure for PHQ-9 Notification	1.0	18 August 2015
GP Letter for PHQ-9 Notification	1.0	18 August 2015
CADOSA Archiving Procedure	1.1	20 October 2015
A protocol for Requesting and Using SA Health Data for the CADOSA Study	1.0	1 December 2015

Sites covered by this approval:

- **The Queen Elizabeth Hospital, SA – CPI: Prof John Beltrame**
- **Lyell McEwin Hospital, SA – CPI: Prof John Beltrame**
- **Royal Adelaide Hospital, SA: – PI: A/Prof Matthew Worthley**
- **Flinders Medical Centre, SA – PI: A/Prof Ajay Sinhal**

HREC approval is valid for **5 years** from **16 December 2015 to 16 December 2020**.

Please quote the **HREC Reference number, HREC/15/TQEH/252** and the **CALHN Reference number, Q20151217** allocated to your study on all future correspondence.

**GENERAL TERMS AND CONDITIONS OF ETHICAL APPROVAL:**

1. 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.
2. 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.
3. Researchers must notify the HREC of anything which might warrant review of the approval of the study, or which warrant new information being presented to research participants, including:
  - (a) serious or unexpected adverse events which warrant protocol change or notification to participants;
  - (b) changes to the protocol;
  - (c) premature termination of the study.
4. The HREC must be notified within 72 hours of any Serious Adverse Events occurring at any approved site.
5. Confidentiality of the research participants shall be maintained at all times as required by law.
6. Approval is valid for **5 years**, after which an extension must be applied for.
7. 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 TQEH HREC Executive Officer, within 10 working days on each anniversary of the approval date, using the Annual Review Form available at: <http://www.basilhetzelinstitute.com.au/research/information-for-researchers/human-research-ethics-committee/>
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.

This Committee is constituted in accordance with the NHMRC *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 me, Mrs Heather O'Dea, HREC Executive Officer on 08 8222 6841 or [Health.CALHNResearchEthics@sa.gov.au](mailto:Health.CALHNResearchEthics@sa.gov.au)

Yours sincerely,



Mrs Heather O'Dea  
Team Leader, Executive Officer  
Human Research Ethics Committee (TQEH/LMH/MH)