Office for Research

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Government of South Australia
SA Health
Southern Adelaide Local Health Network

Final approval for ethics application

You are reminded that this letter constitutes **ethical** approval only. **Ethics approval is one aspect of the research governance process.**
You must not commence this research project at any SA Health sites listed in the application until a Site Specific Assessment (SSA), or Access Request for data or tissue form has been authorised by the Chief Executive or delegate of each site.

16 June 2016

A/Professor Robert Baker
Cardiac and Thoracic Surgical Unit
Flinders Medical Centre
BEDFORD PARK SA 5042

Dear A/Professor Baker

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) have reviewed and provided ethical approval for this application which appears to meet the requirements of the *National Statement on Ethical Conduct in Human Research.*

Application Number: OFR # 386.15 - HREC/15/SAC/341

Title: The Australian and New Zealand Collaborative Perfusion Registry (ANZCPR)

Chief investigator: A/Professor Robert Baker

Approval Date: 15 June 2016

Approval Period: 15 June 2016 to 15 June 2020

Public health sites approved under this application:

- Flinders Medical Centre, SA
- The Alfred, VIC
- Westmead Hospital, NSW

The below documents have been reviewed and approved:

- General Research Application form v1.2 dated 15 February 2016
- NEAF AU/1/1944216 dated 22 February 2016
- ANZCPR Data Access and Publication Policy v1.1 dated 15 February 2016
- ANZCPR Compliance with ACSQH Principles for Registries v1.0 dated 15 February 2016
- ANZCPR Release of Data Application form v1.0 dated 29 January 2016
- ANZCPR Data Definitions v1.1 dated 18 October 2015
- Next of Kin Information Sheet v1.0 dated 08 February 2016
- ANZCPR Patient Information Sheet v1.0 dated 08 February 2016
- ANZSCTS Cardiac Surgery Database and ANZCPR Patient Information Sheet v1.0 dated 08 February 2016
- ANZSCTS Cardiac Surgery Database and ANZCPR Next of Kin Information Sheet v1.0 dated 08 February 2016
- ANZCPR Project Protocol v1.4 dated 08 January 2016
- Steering Committee Guidelines Policy v1.0 dated 15 February 2016
- Users Guide v1.1 dated 15 February 2016

TERMS AND CONDITIONS OF ETHICAL APPROVAL
As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below and with the *National Statement chapter 5.5.*

Final ethical approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. The approval only covers the science and ethics component of the application. A SSA will need to be submitted and authorised before this research project can commence at any of the approved sites identified in the application.
2. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
3. Compliance with the *National Statement on Ethical Conduct in Human Research* (2007) & the *Australian Code for the Responsible Conduct of Research* (2007).
4. To immediately report to SAC HREC anything that may change the ethical or scientific integrity of the project.
5. Report Significant Adverse events (SAE's) as per SAE requirements available at our website.
6. Submit an annual report on each anniversary of the date of final approval and in the correct template from the SAC HREC website.
7. Confidentiality of research participants MUST be maintained at all times.
8. A copy of the signed consent form must be given to the participant unless the project is an audit.
9. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
10. All requests for access to medical records at any SALHN site must be accompanied by this approval email.
11. To regularly review the SAC HREC website and comply with all submission requirements, as they change from time to time.
12. Once your research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable) Please refer to the relevant committee link on the SALHN intranet for further information.

Kind Regards

Paula Davies
Manager, Office for Research