

386.15 - The Perfusion Downunder Collaboration Database Project

Principal Investigator: Associate Professor Robert A Baker

Response to Ethics Committee Minute dated 07 October 2015

Conditionally approved L2

We would like firstly to inform you that since our initial Ethics Committee submission the Perfusion Downunder Collaboration and database has changed its name to the Australian and New Zealand Collaborative Perfusion Registry (ANZCPR). Please therefore change the name of the application to: **386.15 – The Australian and New Zealand Collaborative Perfusion Registry (ANZCPR)**. The collaboration has welcomed your input, and in response has taken steps to meet the

1. David Gordon has a conflict of interest as the principal investigator is his brother in law. The committee have asked him to stay for the discussion and agree he will leave the room if he feels uncomfortable with the discussion.
[Thank you, we acknowledge Professor Gordon's conflict of interest, and are grateful for the Ethics Committee's decision. We do recognise that Professor Gordon is now no longer Chair of the committee.](#)
2. The PDUCD project aims to cultivate a multiple site clinical database to foster and grow high quality research in the perfusion sciences, and to be able to address key questions that are still not clearly defined in literature. The main concerns with this application are the issue of whether or not it can be submitted under the NMA and who owns the data
[The issue of whether NMA consideration is appropriate for a national database/registry is a difficult one, however our reason for submitting under NMA is the variance of submission requirements we have dealt with across Australia to date. Where Victorian Ethics have requested full NMA submission, other states such as NSW have requested low risk submission. We have therefore opted for the most stringent Ethics consideration to meet the demands of all states.](#)

[In regard to who owns the data, as it currently stands, the national data is non-identified, and therefore data ownership is primarily owned by the 5 principal investigators that make up the Steering Committee – please see Appendix 8 – ANZCPR Steering Committee Guidelines Version 1.0 dated 15Feb2016. In regard to each site data, their local data is owned by each individual site investigator.](#)

3. This registry is already running at a national level, with individual approval for each site. The researcher wishes to submit one application to cover all sites compliant with the National Mutual Approach (NMA) and cancel the individual site approvals. This application may not comply with the National Mutual Approach guidelines, although registries are permitted as a post-trial activity to studies already conducted.

The above understanding is not quite correct: Flinders Medical Centre would like to cancel the previous individual site Ethics Committee approval 149.09, and replace with the National Mutual Approval, and all future sites will be covered by the National Approval (each new site will be submitted to SAC HREC for approval prior to being able to commence), however previously approved sites will be given the option to maintain their current approval, or change across to National Approval as accepted by their own local Ethics Committee. If the latter, the site will first be submitted to SAC HREC for approval. If remaining under their current approval, all changes and updates to the protocol, introduction of the Patient Information Sheet, etc., will be submitted as an amendment by the site to their Ethics Committee to ensure the study is consistent across all sites once approval has been received from SAC HREC.

4. A waiver of consent has also been requested, as it involves only the collection of already existing data collected for the Cardiac Surgery Registry or during the procedure by the data management system of the anaesthetic or heart-lung machine.

Although previously a waiver of consent was requested, in line with meeting the Strategic Framework for Australian Clinical Quality Registries by the Australian Commission on Safety and Quality in Healthcare, we propose introducing a Patient Information Sheet (Appendix 2). Please see more information in our response to Question 5.0, below.

5. The committee agreed that the application meets The National Statement chapter 3.2 on Databanks, but does not comply with the Australian Commission guidelines, that contains 41 guidelines for setting up a database.

Thank you for your comments. In view of meeting the Australian Commission on Safety and Quality in Healthcare's Strategic Principles for a National Approach to Australian Quality Registries principles, please see the document attached (Appendix 1 – ANZCPR Compliance with ACSQH Principles for Registries) where we supply a response regarding ANZCPR complying with each of the 10 principles, including the 41 desired attributes.

For Strategic Principle 10: Operating principles for Australian Clinical Quality Registries, point 32: we would like to propose introducing a participant's information sheet that combines the ANZSCTS Cardiac Surgery Database (SAC HREC Project ID: 173.056) and ANZCPR in the one information sheet. Currently at FMC, every cardiac surgery patient receives the ANZSCTS Cardiac Surgery Database patient information sheet on admission to hospital. This information sheet will allow the option to 'Opt Out' as per the NHMRC National Statement on Ethical Conduct in Human Research (2007) – updated May 2015; Section 2.3: Qualifying or Waiving Conditions for Consent: Guidelines, 'Opt Out Approach' (2.3.5 - 2.3.8) and Australian Commissions operating principle 10: 32.

If a new site currently contributes to the ANZSCTS cardiac surgery database, they will use the combined ANZSCTS/ANZCPR information sheets (Patient and Next of Kin), attached, if they contribute to the ANZCPR registry only, they will use the ANZCPR patient information sheets (Patient and Next of Kin) – please see attachments (Appendix 2).

6. The committee also agree that the design of the database cannot be questioned as it has already been approved under the SAC HREC application 149.09.

Noted, thank you.

7. Please clarify who owns the database.

The database is owned by the Registry Steering Committee; comprised of the 5 Principal Investigators (see ANZCPR Steering Committee Guidelines, Appendix 8).

8. Please advise who has access to the data.

Access to the ANZCPR data is controlled via the ANZCPR Clinical Registry Data Access and Publication Policy Version 1.1 dated 15Feb2016 (see appendix 6). Data is reported back to the sites on an annual basis and more frequently if requested. Currently 3 reports are produced. Each site has access to its own data under local governance conditions.

9. Please clarify how the security of collected data will be maintained when the data is transferred from another site to FMC.

Data that is transferred to FMC is via a secure website and is stored on server drives protected via SA Health IT security policies, which requires username and password access. Currently all data is de-identified prior to being exported to Flinders Medical Centre. This is outlined in the ANZCPR Privacy and Security Policy (Appendix 5).

10. Please advise what would happen to the data if the principal investigator left Flinders Medical Centre.

The Steering Committee would decide where the data was to be housed. At the current time, the data would remain at FMC, as there are 2 principal investigators from FMC on the Steering Committee. At the time that both investigators left Flinders Medical Centre, the data server would be transferred to another member of the Steering Committee.

11. Please provide details on the source of funding for the ongoing maintenance of the database.

Ongoing funding is currently being negotiated with corporate sponsors involved in the Perfusion community who currently also provide support to the Australian and New Zealand College of Perfusion. Long term support in association with the Australian and New Zealand College of Perfusion is also being discussed. Currently funding has been available through the support of the Australian and New Zealand College of Perfusion and the Cardiac and Thoracic Surgery Unit at Flinders Medical Centre using special purpose funds.

12. If the patient undergoes two cardiac surgeries, will the patient be recorded twice? If so, will there be any linkage between the two surgeries?

In the event that a patient undergoes multiple surgeries under separate admissions to hospital, then the procedures are recorded separately without linkage. If the surgeries occur within the same admission, the preoperative details are recorded once, with a link created between procedures. Outcome data is reported for the first procedure only, however there is an opportunity to record certain variables relevant to the subsequent procedure (e.g. 4hr postoperative blood loss).

13. Please provide a copy of the dataset being planned for the database.

A copy of the dataset is attached – please see [Appendix 4: ANZCPR Data Definitions Version 1.1 dated 28Oct2015](#).

14. Please provide a list of sources (e.g. medical records, OASIS etc) from which data will be collected.

Data sources vary between contributing institutions, however they include both electronic and written sources. At FMC, data is collected by direct electronic transfer from the primary source of Flinders Medical Cardiac Surgery Registry (data entered by doctors directly into database), ATS and OACIS; medical records; ECHO, Angiography reports, etc.; and Perfusion data collection software utilised on the heart lung machine (*DMS (Sorin), Connect (Sorin), Jicap (Maquet)*). Sites contributing to the ANZSCTS database have the ability to transfer data to ANZCPR.

15. Please provide a contingency plans for possible discrepancies identified in terms of patient outcomes between hospitals.

Differences in patient outcomes are reported to the ANZCPR Steering Committee by the Project Manager following data transfer review. If the committee identifies that a particular site has outcome differences that need to be addressed, this will be communicated directly with the institution and measures are put into place to address discrepancies and harmonise activities between contributing institutions.

16. Please provide details on the 'security compliance' protocols for the database.

Please see [Appendix 5 – ANZCPR Privacy and Security Policy Version 1.1 dated 15Feb2016](#). The database is stored on hospital server/network drives that are protected by institutional IT policies. The database must not be copied to external drives. Each database user must have a username and password, and logout from the database at the completion of data entry.

17. Please advise what the publication policy is for the registry.

Please see [Appendix 6 – ANZCPR Clinical Registry Data Access and Publication Policy Version 1.1 dated 15Feb2016](#) and [Appendix 7 – Data Access Request Form Version 1.0 dated 29Jan2016](#).

Please find attached as [Appendix 9](#) a revised General Research Application incorporating the changes highlighted as part of this response.

APPENDICES:

Appendix 1: ANZCPR Compliance with Australian Commission on Safety and Quality in Healthcare's Strategic Framework for Australian Clinical Quality Registries Version 1.0 dated 15Feb2016.

Appendix 2: Patient Information Sheets:

- (1) ANZSCTS and ANZCPR Patient Information Sheet Version 1.0 dated 08Feb2016 AUS Template
- (2) ANZSCTS and ANZCPR Patient Information Sheet for Next of Kin Version 1.0 dated 08Feb2016 AUS Template
- (3) ANZCPR Patient Information Sheet Version 1.0 dated 08Feb2016 AUS Template
- (4) ANZCPR Next of Kin Information Sheet Version 1.0 dated 08Feb2016 AUS Template
- (5) ANZSCTS and ANZCPR Patient Information Sheet V1.0 dated 08Feb2016 FMC
- (6) ANZSCTS and ANZCPR Next of Kin Information Sheet V1.0 dated 08Feb2016
- (7) ANZSCTS and ANZCPR Patient Information Sheet V1.0 dated 08Feb2016 Tracked Changes

Appendix 3: ANZCPR Protocol Version 1.4 dated 22 January 2016

Appendix 4: ANZCPR Data Definitions Version 1.1 dated 28Oct2015

Appendix 5: ANZCPR Privacy and Security Policy Version 1.1 dated 15Feb2016

Appendix 6: ANZCPR Clinical Registry Data Access and Publication Policy Version 1.1 dated 15Feb2016

Appendix 7: Data Access Request Form Version 1.0 dated 29Jan2016

Appendix 8: ANZCPR Steering Committee Guidelines Version 1.0 dated 15Feb2016.

Appendix 9: Revised General Research Application 22Jan2016