Online Forms
National Ethics Application Form

Within which Jurisdictions will your research application be submitted to: *(tick all that apply)*

- [x] New South Wales
- [ ] Queensland
- [x] South Australia
- [x] Victoria

HREC Application Reference Number: HREC/15/SAC/341

1. TITLE AND SUMMARY OF PROJECT

1. Title

What is the formal title of this research proposal?
Australian and New Zealand Collaborative Perfusion Registry (formally Perfusion Downunder Collaborative Database)

What is the short title / acronym of this research proposal (if applicable)?
ANZCPR

2. Description of the project in plain language

Give a concise and simple description (not more than 400 words), in plain language, of the aims of this project, the proposal research design and the methods to be used to achieve those aims.

Cardiopulmonary bypass (CPB) plays a vital role in cardiac surgery, providing an extra-corporeal circuit to temporarily replace the function of the “heart” and the “lungs” for patients during procedures including coronary artery bypass graft (CABG) surgery and valve replacement surgery. In Australia between 81%-93.3% of CABG surgery patients undergo CPB (Baker et al., 2005; Dinh et al., 2006). Even though the CPB procedure is performed in 100,000’s of patients annually, and has been used routinely for the past five decades, there are key questions relating to the performance of CPB that need to be addressed and have not been clearly defined in the literature.

The Australian and New Zealand Collaborative Perfusion Registry (ANZCPR) (formally the Perfusion Downunder Collaboration Database (PDUCD) Project) aims to cultivate and grow a multiple site clinical database to foster and develop high quality research in the perfusion sciences, and to be able to address the key questions that are still not clearly defined in literature. This will be achieved through the maintenance of a prospective data set on cardiac surgical procedures performed in multiple sites throughout Australia and New Zealand and through a collaborative network of perfusion and interested researchers, who share the commitment to cooperation and collaboration in the pursuit of excellence in perfusion. The ANZCPR aims to improve patient outcomes through its ability to provide research infrastructure and support to the Australian and New Zealand perfusion community, and by its ability to produce relevant and timely research publications.

Vision:
Empower all cardiac surgery team members to improve the understanding and practice of cardiopulmonary bypass to optimise patient outcomes

Mission Statement:
Maintain and develop the Australian and New Zealand Collaborative Perfusion Registry for cardiac surgical procedures performed throughout Australia and New Zealand.

Promote the reporting and understanding of the effect of cardiopulmonary bypass on patient outcomes through encouraging evidence based practices, quality assurance, quality improvement and research.

Primary Aims:
1. To maintain and develop the Australian and New Zealand Collaborative Perfusion Registry for cardiac surgical procedures performed throughout Australia and New Zealand.

2. To promote the reporting and understanding of the effect of cardiopulmonary bypass on patient outcomes through encouraging evidence based practices, quality assurance, quality improvement and research.

2. RESEARCHERS / INVESTIGATORS

2. Principal researcher(s) / investigator(s)

Principal researcher / investigator 1

Title:	Forename/Initials:	Surname:
Associate Professor	Robert	Baker

Mailing Address:	Cardiac and Thoracic Surgical Unit
	Flinders Medical Centre and Flinders University
	Level 6, Flinders Private Hospital, Room 6R304
Suburb/Town:	Bedford Park
State:	SA
Postcode:	5042
Country:	Australia
Organisation:	Flinders Medical Centre
Department*:	Cardiac and Thoracic Surgical Unit
Position:	Director, Cardiac Surgery Research and Perfusion
E-mail:	Rob.Baker@sa.gov.au
Phone (BH):	+61 8 8404 2015
Phone (AH)*:	
Mobile*:	0401125402
Pager*:	
Fax:	+61 8 8404 2019

Is this person the contact person for this application?
(•) Yes ( ) No

Summary of qualifications and relevant expertise
BMedSci (Hons), Dip Perf, CCP (Aus), PhD; Prof Baker is Director of Perfusion and the Cardiac Surgery Research Group at Flinders Medical Centre. He has been involved in numerous investigator driven and multicentre studies on bypass management, pharmacology and perfusion. He has written chapters for books (Cardiopulmonary Bypass 3rd Ed and Aortic Arch Surgery: Principles, Strategies and Outcomes), served as editor and reviewer for journals and has nearly 100 peer reviewed publications. As an Associate Professor at Flinders University, he supervises PhD's and MSurg candidates. He has been a faculty/invited speaker for many local and international meetings (e.g. Outcomes, AMSECT International) and has received numerous awards for his presentations. He is vice president of the Australian and New Zealand College of Perfusion and fellow of the Cardiac Society of Australia and New Zealand, chair of the Perfusion Downunder Collaboration, and a steering committee member of the International Consortium of Evidence Based Perfusion.

Please declare any general competing interests
Not applicable

Name the site(s) for which this principal researcher / investigator is responsible.
Flinders Medical Centre; Flinders Private Hospital

Describe the role of the principal researcher / investigator in this project.
Oversight of project; write up of findings. A/Prof Baker has both a supervisory and practical role in this project. The principal researcher has contributed to the initiation and design of this project and will ensure that this project continues successfully.

Is the principal researcher a student? ( ) Yes (•) No

Principal researcher / investigator 2

Title:	Forename/Initials:	Surname:
Prof	Alan	Merry

Mailing Address:	Department of Anaesthesiology
	Faculty of Medical and Health Sciences
	University of Auckland
Suburb/Town:	Auckland
State:	
Postcode:	1023
Country:	New Zealand
Organisation:	University of Auckland
Department*:	Department of Anaesthesiology
Position:	Head of Department
E-mail:	a.merry@auckland.ac.nz
Phone (BH):	+64 9 3737599 *89300
Phone (AH)*:	
Mobile*:	
Pager*:	
Fax:	+64 9 3737970

Is this person the contact person for this application?
○ Yes ◉ No

Summary of qualifications and relevant expertise
FFPMANZCA; FANZCA; MbChB; Safety in Anaesthesia; Medicolegal Concepts Related to Negligence; Cardiothoracic Anaesthesia; Management of Postoperative and Chronic Pain; Prof Merry's publications, international and national presentations and current grants reflect interests in safety in anaesthesia, medicolegal concepts related to negligence, cardiothoracic anaesthesia and management of postoperative and chronic pain, demonstrating his productivity in research. He chairs the Quality and Safety Committee of the World Federation of Societies of Anaesthesiologists, leads the Safe Anaesthesia limb of the WHO Safe Surgery Saves Lives project and is Councillor of the Australian and New Zealand College of Anaesthetists. He is coauthor of books such as Errors, Medicine and the Law and Essential perioperative Transoesophageal Echocardiography.

Please declare any general competing interests
N/A

Name the site(s) for which this principal researcher / investigator is responsible.
N/A - Consultant/Advisor/Steering Committee

Describe the role of the principal researcher / investigator in this project.
Prof Merry assists in the development of the deidentified data, and management of the Perfusion Downunder Collaborative Database (PDUCD) throughout cardiac centres in Australia and New Zealand.

Is the principal researcher a student? ○ Yes ◉ No

Principal researcher / investigator 3

Title:	Forename/Initials:	Surname:
Mr	Timothy	Willcox

Mailing Address:	Chief Clinical Perfusionist
	Green Lane Perfusion
	Auckland City Hospital
Suburb/Town:	Grafton
State:	Auckland
Postcode:	1023
Country:	New Zealand
Organisation:	Auckland City Hospital
Department*:	Green Lane Perfusion
Position:	Chief Perfusionist
E-mail:	Timw@adhb.govt.nz
Phone (BH):	+64 9 3074980

Phone (AH)*:

Mobile*:

Pager*:

Fax: +64 9 6309873

Is this person the contact person for this application?
◯ Yes ◯ No

Summary of qualifications and relevant expertise
CCP Dip Perf; Mr Willcox has worked as a Clinical Perfusionist since 1972 and is Honorary Senior Clinical Lecturer in the Department of Anaesthesiology, University of Auckland. He has authored a chapter in the book Cardiac Intensive Care. He is the founding and current chair of Perfusion Downunder and is a member of the Australasian Board of Cardiovascular Perfusion. He has extensively served as invited faculty internationally and has received numerous awards (e.g. ASCVP “Best Scientific Paper” 1997, 1999, 2000). He has convened/co-convened
scientific symposia (e.g. Tongariro Cardiac Surgery Meeting 19912005) and served on organising committees for scientific meetings internationally.

Please declare any general competing interests
N/A

Name the site(s) for which this principal researcher / investigator is responsible.
Auckland City Hospital

Describe the role of the principal researcher / investigator in this project.
Mr Willcox assists in the management of the de-identified data source known as the PDUCD throughout cardiac centres in Australia and New Zealand.

Is the principal researcher a student? ◯ Yes ◉ No

Principal researcher / investigator 4

Title:	Forename/Initials:	Surname:
Prof	Paul	Myles

Mailing Address: PO Box 315

Suburb/Town: Melbourne
State: VIC
Postcode: 3004
Country: Australia
Organisation: Alfred Hospital & Monash University
Department*: Department of Anaesthesia & Perioperative Medicine
Position: Director
E-mail: P.Myles@alfred.org.au
Phone (BH): +61 3 9276 3707
Phone (AH)*:
Mobile*:
Pager*:
Fax: +61 3 9276 2813

Is this person the contact person for this application?
◯ Yes ◉ No

Summary of qualifications and relevant expertise
MB.BS, MPH, MD, FCARCSI, FANZCA, FRCA
Director, Department of Anaesthesia and Perioperative Medicine, Alfred Hospital and Monash University

Please declare any general competing interests
N/A

Name the site(s) for which this principal researcher / investigator is responsible.
N/A - Consultant/Advisor/Steering Committee

Describe the role of the principal researcher / investigator in this project.
Prof Myles works as a consultant for data and manages the development of the Perfusion Downunder

Collaboration Database (PDUCD) throughout cardiac centres in Australia and New Zealand.

Is the principal researcher a student? ○ Yes ◉ No

Principal researcher / investigator 5

Title:	Forename/Initials:	Surname:
Mr	Richard	Newland

Mailing Address:	Cardiac Surgery Research Level 6 Flinders Medical Centre
Suburb/Town:	Bedford Park
State:	SA
Postcode:	5042
Country:	Australia
Organisation:	Flinders Medical Centre
Department*:	Cardiac and Thoracic Surgery
Position:	Advanced Perfusionist
E-mail:	Richard.Newland@health.sa.gov.au
Phone (BH):	6188025683
Phone (AH)*:	
Mobile*:	0404125405
Pager*:	
Fax:	

Is this person the contact person for this application?
○ Yes ○ No

Summary of qualifications and relevant expertise
BSc, Dip Perf, CCP (Aus)

Please declare any general competing interests
Not applicable

Name the site(s) for which this principal researcher / investigator is responsible.
Flinders Medical Centre; Flinders Private Hospital

Describe the role of the principal researcher / investigator in this project.
Oversight of project; write up of findings. Mr Newland has a supervisory and practical role in this project. This principal researcher ensures that this project continues successfully.

Is the principal researcher a student? ○ Yes ◉ No

3. Associate Researcher(s) / investigator(s)

How many known associate researchers are there? (You will be asked to give contact details for these associate researchers / investigators) 8

Do you intend to employ other associate researchers / investigators? ◉ Yes ○ No

Associate Researcher / Investigator 1

Title:	Forename/Initials:	Surname:
Mrs	Jane	Ottens

Mailing Address:	Ashford Hospital 55 Anzac Highway
Suburb/Town:	Ashford
State:	SA
Postcode:	5035
Country:	Australia

Organisation:	Ashford Hospital
Department*:	Perfusion, Theatres
Position:	Chief Perfusionist
E-mail:	janeottens@acha.org.au
Phone (BH):	+61883755219
Phone (AH)*:	0419820584
Mobile*:	0419520584
Pager*:	
Fax:	+61883755846

Is this person the contact person for this application?
○ Yes ◉ No

Summary of qualifications and relevant expertise
B.Sc Dip Perfusion (CCP) Australia
28 years experience in Clinical Perfusion; Head of perfusion 22 years at Ashford Hospital.

Please declare any general competing interests
N/A

Description of the role of the associate researcher / investigator in this project.
Coordination and oversight of PDUCD data entry and data management

Name the site at which the associate researcher / investigator has responsibility.
Ashford Hospital

Is this associate researcher / investigator a student? ○ Yes ◉ No

Associate Researcher / Investigator 2

Title:	Forename/Initials:	Surname:
Mr	Michael	McDonald

Mailing Address:	Perfusion Services Pty Ltd
	2/91 Tulip St.
Suburb/Town:	Cheltenham
State:	VIC
Postcode:	3194
Country:	Australia
Organisation:	Perfusion Services Pty Ltd
Department*:	Perfusion
Position:	Director
E-mail:	mmcdonald@perfusionservices.com.au
Phone (BH):	+61395856011
Phone (AH)*:	
Mobile*:	0419103375
Pager*:	
Fax:	

Is this person the contact person for this application?
○ Yes ◉ No

Summary of qualifications and relevant expertise
RN (Div 1); Dip Perf.

Please declare any general competing interests
N/A

Description of the role of the associate researcher / investigator in this project.
Coordination and oversight of PDUCD data entry and data management

Name the site at which the associate researcher / investigator has responsibility.
Cabrini Hospital Malvern

Is this associate researcher / investigator a student? ○ Yes ◉ No

Associate Researcher / Investigator 3

Title:	Forename/Initials:	Surname:
Assoc/Prof	Peter	Klineberg

Mailing Address:	Director of Westmead Anaesthesia
	Westmead Hospital
	Cnr Hawkesbury Road and Darcy Road
Suburb/Town:	Westmead
State:	NSW
Postcode:	2145
Country:	Australia
Organisation:	Westmead Hospital
Department*:	Westmead Anaesthesia
Position:	Director of Westmead Anaesthesia & Perfusion
E-mail:	peter.klineberg@sydney.edu.au
Phone (BH):	+61 2 9845 6447
Phone (AH)*:	
Mobile*:	0419751680
Pager*:	
Fax:	+61 2 9633 3764

Is this person the contact person for this application?
○ Yes ◉ No

Summary of qualifications and relevant expertise
MB, BS; FANZCA, Director of Anaesthesia & Perfusion; Westmead Hospital

Please declare any general competing interests
N/A

Description of the role of the associate researcher / investigator in this project.
Coordination and oversight of PDUCD data entry and data management

Name the site at which the associate researcher / investigator has responsibility.
Westmead Hospital

Is this associate researcher / investigator a student? ○ Yes ◉ No

Associate Researcher / Investigator 4

Title:	Forename/Initials:	Surname:
Ms	Carmel	Fenton

Mailing Address:	Cardiothoracic Unit
	Royal Hobart Hospital
	48 Liverpool St
Suburb/Town:	Hobart
State:	TAS
Postcode:	7000
Country:	Australia
Organisation:	Royal Hobart Hospital
Department*:	Cadiothoracic Unit
Position:	Senior Perfusionist
E-mail:	Carmel.Fenton@dhhs.tas.gov.au
Phone (BH):	03 6222 8840
Phone (AH)*:	0408 127 983
Mobile*:	0408 127 983
Pager*:	
Fax:	03 62313055

Is this person the contact person for this application?

○ Yes ◉ No

Summary of qualifications and relevant expertise
Dip Perf, CCP (Aust), Senior Perfusionist

Please declare any general competing interests
N/A

Description of the role of the associate researcher / investigator in this project.
Coordination and oversight of PDUCD data entry and data management

Name the site at which the associate researcher / investigator has responsibility.
Royal Hobart Hospital

Is this associate researcher / investigator a student? ○ Yes ◉ No

Associate Researcher / Investigator 5

Title:	Forename/Initials:	Surname:
Mr	James	Anderson

Mailing Address:	Operating Suite
	The Alfred Hospital
	PO Box 315
Suburb/Town:	Prahran
State:	VIC
Postcode:	3181
Country:	Australia
Organisation:	Alfred Health
Department*:	Perfusion Department
Position:	Head of Perfusion Department
E-mail:	J.Anderson@alfred.org.au
Phone (BH):	+61 3 9076 3185
Phone (AH)*:	
Mobile*:	
Pager*:	
Fax:	+61 3 9076 2222

Is this person the contact person for this application?
○ Yes ◉ No

Summary of qualifications and relevant expertise
M.SC; Dip Perf, CCP (Aust); CCP (USA).

Please declare any general competing interests
N/A

Description of the role of the associate researcher / investigator in this project.
Coordination and oversight of PDUCD data entry and data management

Name the site at which the associate researcher / investigator has responsibility.
The Alfred Hospital

Is this associate researcher / investigator a student? ○ Yes ◉ No

Associate Researcher / Investigator 6

Title:	Forename/Initials:	Surname:
Mr	Brian	Wright

Mailing Address:	Level 1, Main Theatres
	East Block
	Fiona Stanley Hospital
Suburb/Town:	Murdoch
State:	WA
Postcode:	6150
Country:	Australia

Organisation:	Fiona Stanley Hospital
Department*:	Clinical Perfusion
Position:	Chief Clinical Perfusionist
E-mail:	brian.wright@health.wa.gov.au
Phone (BH):	+618 61526417
Phone (AH)*:	0435 254 199
Mobile*:	0435 254 199
Pager*:	
Fax:	

Is this person the contact person for this application?
○ Yes ◉ No

Summary of qualifications and relevant expertise
BA; Btech (Medical Science)l ACP ECCP PGMP (management), 20 years clinical experience as perfusionist, UK certified and registered perfusionist.

Please declare any general competing interests
N/A

Description of the role of the associate researcher / investigator in this project.
Coordination and oversight of PDUCD data entry and data management

Name the site at which the associate researcher / investigator has responsibility.
Fiona Stanley Hospital

Is this associate researcher / investigator a student? ○ Yes ◉ No

Associate Researcher / Investigator 7

Title:	Forename/Initials:	Surname:
Mr	Joshua	Byrne

Mailing Address:	CJOB Cardiothoracic Surgery Department
	The Alfred
	Commercial Road
Suburb/Town:	MELBOURNE
State:	VIC
Postcode:	3004
Country:	AUSTRALIA
Organisation:	THE ALFRED
Department*:	Perfusion Services
Position:	Perfusionist
E-mail:	J.Byrne@alfred.org.au
Phone (BH):	
Phone (AH)*:	
Mobile*:	
Pager*:	
Fax:	

Is this person the contact person for this application?
○ Yes ◉ No

Summary of qualifications and relevant expertise
Dip Perf, CCP (Aust).

Please declare any general competing interests
N/A

Description of the role of the associate researcher / investigator in this project.
Coordination and oversight of PDUCD data entry and data management

Name the site at which the associate researcher / investigator has responsibility.
THE ALFRED

Is this associate researcher / investigator a student? ○ Yes ◉ No

Associate Researcher / Investigator 8

Title:	Forename/Initials:	Surname:
Ms	Rona	Steel

Mailing Address:	Westmead Hospital Cnr Hawkesbury Road and Darcy Road
Suburb/Town:	Westmead
State:	NSW
Postcode:	2145
Country:	AUSTRALIA
Organisation:	Westmead Hospital
Department*:	Perfusion
Position:	Clinical Perfusionist
E-mail:	ronasteel@yahoo.com
Phone (BH):	+61 2 9845 6447
Phone (AH)*:	+61 2 9845 6447
Mobile*:	N/A
Pager*:	
Fax:	+61 2 9633 3764

Is this person the contact person for this application?
○ Yes ◉ No

Summary of qualifications and relevant expertise
Dip Perf, CCP (Aust).

Please declare any general competing interests
N/A

Description of the role of the associate researcher / investigator in this project.
Coordination and oversight of PDUCD data entry and data management

Name the site at which the associate researcher / investigator has responsibility.
Westmead Hospital

Is this associate researcher / investigator a student? ○ Yes ◉ No

5. Other personnel relevant to the research project

5a. How many known other people will play a specified role in the conduct of this research project?

1

5b. Describe the role, and expertise where relevant (e.g. counsellor), of these other personnel.

Bronwyn Pesudovs, Clinical Project Coordinator, Flinders Medical Centre, Cardiac Surgery Research and Perfusion. Coordinating Ethics Committee and Regulatory Correspondence. Ph: 08 8404 2018; Mobile: 0408 153290; Email: bronwyn.pesudovs@sa.gov.au

5c. Is it intended that other people, not yet known, will play a specified role in the conduct of this research project?

◉ Yes ○ No

6. Certification of researchers / investigators

6a. Are there any relevant certification, accreditation or credentialing requirements relevant to the conduct of this research?

○ Yes ◉ No

7. Training of researchers

7a. Do the researchers / investigators or others involved in any aspect of this research project require any additional training in order to undertake this research?

○ Yes ◉ No

3. RESOURCES

Project Funding / Support

1. Indicate how the project will be funded?

Type of funding.

[Please note that all fields in any selected funding detail column (with the exception of the code) will need to be completed.]

Funding	Confirmed or Sought?
External Competitive Grant	○ Confirmed ○ Sought ◉ Not Sought
Internal Competitive Grant	○ Confirmed ○ Sought ◉ Not Sought
Sponsor	○ Confirmed ○ Sought ◉ Not Sought
By Researchers Department or Organisation	○ Confirmed ○ Sought ◉ Not Sought

2. How will you manage a funding shortfall (if any)?

As no additional activities on top of routine practice will be required for this study, no funding is required.

3. Will the project be supported in other ways eg. in-kind support/equipment by an external party eg. sponsor?

○ Yes ◉ No

4. Is this a study where capitation payments are to be made, and will participants be made aware of these payments to clinicians or researchers / investigators?

No - N/A

Duality of Interest

5. Describe any commercialisation or intellectual property implications of the funding/support arrangement.

N/A

6. Does the funding/support provider(s) have a financial interest in the outcome of the research?

○ Yes ◉ No

7. Does any member of the research team have any affiliation with the provider(s) of funding/support, or a financial interest in the outcome of the research?

○ Yes ◉ No

8. Does any other individual or organisation have an interest in the outcome of this research?

○ Yes ◉ No

9. Are there any restrictions on the publication of results from this research?

◉ Yes ○ No

Describe these restrictions.
The information collected about the participants in the database will be used in publications on peer reviewed journals in the key areas identified for the collaboration as well as on additional information derived from the dataset. Data will only be available via password protected processes, and made available only for ethically rigorous inquiries.

Perfusionists and other interested clinicians who have submitted appropriate requests to investigate the non-identifiable data set will have access to the data.

Annual reports are generated on the data collected. To support the aims of the ANZCPR collaboration, this report is available to all Cardiac Surgery units in the country to enable them, if they wish to, to benchmark there current practice against what will be the largest and only detailed data set on perfusion available in Australia and New Zealand.

Authorship of the principal publications from the group on the key areas identified for the collaboration to address will depend on the leadership group for each study. The information will remain the property of the ANZCPR collaboration investigators. Other publications which describe additional information derived from the dataset must be approved by the ANZCPR Steering Committee and authorship includes those investigators who have participated.

The custodian of the data will be the ANZCPR collaboration and intellectual property generated by this initiative will be owned by the ANZCPR collaboration. A Memorandum of Understanding has been generated to underpin the activity of the ANZCPR with contributing individuals, currently this is managed through individual site ethics applications.

4. PRIOR REVIEWS

Ethical Review

Some HRECs may require researchers to provide information additional to that contained in a NEAF proposal. For this reason, it is prudent to check whether the HRECs to whom you propose to submit this proposal require additional information.

Duration and location

1. In how many Australian sites, or site types, will the research be conducted?

8

2. In how many overseas sites, or site types, will the research be conducted?

1

3. Provide the following information for each site or site type (Australian and overseas, if applicable) at which the research is to be conducted

1

Site / Site Type Name:	Flinders Medical Centre
Site / Site Type Location:	Flinders Drive Bedford Park SA 5042 AUSTRALIA

2

Site / Site Type Name:	Flinders Private Hospital
Site / Site Type Location:	1 Flinders Drive Bedford Park SA 5042 AUSTRALIA

3

Site / Site Type Name:	Ashford Hospital
Site / Site Type Location:	55 Anzac Highway Ashford SA 5035 AUSTRALIA

4

Site / Site Type Name:	The Alfred
Site / Site Type Location:	55 Commercial Road Prahran VIC 3181 AUSTRALIA

5

Site / Site Type Name:	Royal Hobart Hospital
Site / Site Type Location:	48 Liverpool St Hobart TAS 7000 AUSTRALIA

6

Site / Site Type Name:	Cabrini Hospital - Malvern
Site / Site Type Location:	181-183 Wattletree Road Malvern VIC 3144 AUSTRALIA

7

Site / Site Type Name:	Westmead Hospital
Site / Site Type Location:	Cnr Hawkesbury Road and Darcy Road Westmead NSW 2145 AUSTRALIA

8

Site / Site Type Name:	Fiona Stanley Hospital
Site / Site Type Location:	102-118 Murdoch Drive Murdoch WA 6150 AUSTRALIA

9

Site / Site Type Name:	Auckland City Hospital
Site / Site Type Location:	2 Park Rd Grafton 1010 NEW ZEALAND

4. Provide the start and finish dates for the whole of the study including data analysis

Anticipated start date: 01/03/2008 *(dd/mm/yyyy)*
Anticipated finish date: 01/03/2099 *(dd/mm/yyyy)*

5. Are there any time-critical aspects of the research project of which an HREC should be aware?

○ Yes ◉ No

6. To how many Australian HRECs (representing site organisations or the researcher's / investigator's organisation) is it intended that this research proposal be submitted?

1
A list of NHMRC registered Human Research Ethics Committees (HRECs), along with their institutional affiliations and contact details is available on the NHMRC website at the following web address: http://www.nhmrc.gov.au/health_ethics/hrecs/overview.htm#d.

7. HRECs

HREC 1

Name of HREC:
Southern Adelaide Clinical Research Ethics Committee (EC00188)

Provide the start and finish dates for the research for which this HREC is providing ethical review:
Anticipated start date or date range: 15/09/2015 *(dd/mm/yyyy)*
Anticipated finish date or date range: 31/12/2099 *(dd/mm/yyyy)*

For how many sites at which the research is to be conducted will this HREC provide ethical review?
1

Site 1

Name of Site: Flinders Medical Centre

Principal Researcher 1

Principal Researcher Name:
Associate Professor Robert Baker

8. Have you previously submitted an application, whether in NEAF of otherwise, for ethical review of this research project to any other HRECs?

◉ Yes ○ No

To how many other HRECs have you submitted a proposal relating to this research project:
5

9. HRECs

HREC 1

Name of HREC:
Southern Adelaide Clinical Research Ethics Committee (EC00188)

Status of this review:
Approved

Explain why an application for ethical review was submitted to the HREC/s identified in answer to question 3, eg. it may be for another phase of the research project which has very different characteristics. Describe the wider project context, where appropriate.
Project # 149.09 - Approval for the project to be conducted at Flinders Medical Centre; Flinders Private Hospital; Ashford Hospital given 17 June 2009.
This application now seeks a Multi-site National Ethics approval.

Please provide a copy of the approval letter as an attachment to this application.

HREC 2

Name of HREC:
Alfred Hospital Ethics Committee (EC00315)

Status of this review:
Approved

Explain why an application for ethical review was submitted to the HREC/s identified in answer to question 3, eg. it may be for another phase of the research project which has very different characteristics. Describe the wider project context, where appropriate.
Approval for the project to be conducted at The Alfred Hospital given 07 May 2013.

Please provide a copy of the approval letter as an attachment to this application.

HREC 3

Name of HREC:
Tasmania Health & Medical Human Research Ethics Committee (EC00337)

Status of this review:
Approved

Explain why an application for ethical review was submitted to the HREC/s identified in answer to question 3, eg. it may be for another phase of the research project which has very different characteristics. Describe the wider project context, where appropriate.
Approval for the project to be conducted at Royal Hobart Hospital given 11 July 2008.

Please provide a copy of the approval letter as an attachment to this application.

HREC 4

Name of HREC:
Cabrini Human Research Ethics Committee (EC00239)

Status of this review:
Approved

Explain why an application for ethical review was submitted to the HREC/s identified in answer to question 3, eg. it may be for another phase of the research project which has very different characteristics. Describe the wider project context, where appropriate.
Approval for the project to be conducted at Cabrini Hospital given 24 January 2011.

Please provide a copy of the approval letter as an attachment to this application.

HREC 5

Name of HREC:
Sydney South West Area Health Service Human Research Ethics Committee (Western Zone) (EC00136)

Status of this review:
Approved

Explain why an application for ethical review was submitted to the HREC/s identified in answer to question 3, eg. it may be for another phase of the research project which has very different characteristics. Describe the wider project context, where appropriate.
Approval for the project to be conducted at Westmead Hospital given 20 April 2010.

Please provide a copy of the approval letter as an attachment to this application.

Research conducted overseas

Peer review

11. Has the research proposal, including design, methodology and evaluation undergone, or will it undergo, a peer review process?

◉ Yes ○ No

Provide details of the review and the outcome. A copy of the letter / notification, where available, should be attached to this application.
Discussion and peer review of the design, methodology and evaluation was originally performed in a special session held at the Perfusion Down Under Collaboration(PDUC) Meeting in August 2008. The project is reviewed every year at the PDUC Meeting, held in August/September.

5. PROJECT

1. Type of Research

Tick as many of the following 'types of research' as apply to this project. Your answers will assist HRECs in considering your proposal. A tick in some of these boxes will generate additional questions relevant to your proposal (mainly because the National Statement requires additional ethical matters to be considered), which will appear in Section 9 of NEAF.

The project involves:

☐ Research using qualitative methods

☑ Research using quantitative methods, population level data or databanks, e.g survey research, epidemiological research

- [ ] Clinical research
- [ ] Research involving the collection and / or use of human biospecimens
- [ ] Genetic testing/research
- [ ] A cellular therapy
- [ ] Research on workplace practices or possibly impacting on workplace relationships
- [ ] Research conducted overseas involving participants
- [ ] Research involving ionising radiation
- [ ] Research involving gametes or use or creation of embryos
- [ ] None of the above

Does the research involve limited disclosure to participants?

○ Yes ◉ No

Does the research involve:

- [x] Opt out approach
- [ ] Waiver
- [ ] None of the above

Research plan

2. Describe the theoretical, empirical and/or conceptual basis, and background evidence, for the research proposal, eg. previous studies, anecdotal evidence, review of literature, prior observation, laboratory or animal studies.

Cardiopulmonary bypass (CPB) plays a vital role in cardiac surgery, providing an extra-corporeal circuit to temporarily replace the function of the heart and the lungs for patients during procedures such as coronary artery bypass graft (CABG) and valve replacement surgery. In Australia between 81%-93.3% of CABG surgery patients undergo CPB (Baker et al., 2005; Dinh et al., 2006). Even though the CPB procedure is performed in 100,000's of patients annually and has been used routinely for the past five decades, there are key questions relating to the performance of CPB that need to be addressed and have not been clearly defined in the literature.

Cardiac surgery requires a team of specialised clinicians (surgeons, anaesthetists, perfusionists, nurses and intensivists) to successfully complete the clinical pathway for the cardiac surgical patient. However, research in cardiac surgery has largely overlooked a critical time period of the procedure - the time the patient is on bypass. In part, this omission has been due to the extreme difficulty of collecting data during that period. Until recently there has been no means to collect accurate continuous data for both the physiological measurements (e.g., blood pressure, nasopharyngeal temperature) and perfusion parameters (e.g., flow, arterial outlet temperature), however the era of electronic perfusion data management now allows the possibility for this to occur (Newland et al., 2006). Advances in technology have seen the data that is electronically collected be able to be integrated to other data systems, with the ability to be stored in formats that are available for analysis and evaluation for quality control and research initiatives (Newland et al., 2006; Ottens et al., 2005). Individually, units have a wealth of untapped data, and collectively, we can make this an enormous resource of information.

The most efficient way of bringing these clinical data from multiple sites together is through the use of a purpose dedicated perfusion database. With current computer technology, data can be easily collected, processed, stored,

retrieved and analysed.

The advantages include the ability to generate large samples rapidly from high numbers of participating centres; the opportunity to study rare conditions and interventions; the provision of accurate information for clinical practice, audit and administration; the wide ownership and high generalisability of results through the participation of many centres; and the capability to allow easy and timely access to a considerable amount of data (Black, 1997; Black, 1999; Dziuban, 1999; Russek et al., 1997). The Australasian Society of Cardiac and Thoracic Surgeons (ASCTS) has recognised the importance of data collection and has developed a comprehensive cardiac surgical database. The database which reported in 2005/2006 activity from 6 Victorian Hospitals, with an additional 8-10 centres joining in 2006/2007, collects in excess of 260 variables. This database collects only 4 variables that relate to CPB.

The Perfusion Downunder Collaboration (PDUC) is a group of individuals who, through the creation of a collaborative network of perfusion and interested researchers, share the commitment to cooperation and collaboration in the pursuit of excellence in perfusion. The PDUC are uniquely positioned to promote the establishment of a unique source of information for the Cardiac Surgical (Perfusion) community.

3. State the aims of the research and the research question and/or hypotheses, where appropriate.

Vision: Empower all cardiac surgery team members to improve the understanding and practice of cardiopulmonary bypass to improve cardiac surgical patient outcomes.

Mission: Maintain and develop the Australian and New Zealand Collaborative Perfusion Registry for cardiac surgical procedures performed throughout Australia and New Zealand.

Promote the reporting and understanding of the effect of cardiopulmonary bypass on patient outcomes through encouraging evidence based practices, quality assurance, quality improvement and research.

Objectives:
ANZCPR aims to empower cardiac surgical team members through the collection and reporting of data relevant to the practice of cardiopulmonary bypass. This will be achieved through the maintenance of a prospective data set on cardiac surgical procedures performed in multiple sites throughout Australia and New Zealand and through the collaborative network of perfusion and interested researchers, who share the commitment to cooperation and collaboration in the pursuit of excellence in perfusion.

The ANZCPR aims to improve patient outcomes through its ability to provide research infrastructure and support to the Australian and New Zealand perfusion community, and by its ability to produce relevant and timely research publications.

Primary Aims:
To maintain and develop the Australian and New Zealand Collaborative Perfusion Registry for cardiac surgical procedures performed throughout Australia and New Zealand.

To promote the reporting and understanding of the effect of cardiopulmonary bypass on patient outcomes through encouraging evidence based practices, quality assurance, quality improvement and research.

4. Has this project been undertaken previously?

(•) Yes ( ) No

Benefits/Risks

In answering the following questions (Q 5 – 11) please ensure that you address all issues relevant to the type of participants that will be involved in your research project. Refer for guidance to relevant chapters of the National Statement.

5. Does the research involve a practice or intervention which is an alternative to a standard practice or intervention?

( ) Yes (•) No

7. What expected benefits (if any) will this research have for the wider community?

PDUC aims to improve patient outcomes through its ability to provide research infrastructure and support to the Australian and New Zealand perfusion community, and by its ability to produce relevant and timely research publications.

This research may have benefits for the wider community by being able to improve outcomes in cardiac surgery.

8. What expected benefits (if any) will this research have for participants?

It is not expected that this research will have direct benefit for participants.

9. Are there any risks to participants as a result of participation in this research project?

○ Yes ◉ No

10. Explain how the likely benefit of the research justifies the risks of harm or discomfort to participants.

Not applicable. Patients who participate in this study will not be exposed to any additional risk or burden as a result of this project. Standard institutional practice will be followed in all matters in relation to the patient.

11. Are there any other risks involved in this research? eg. to the research team, the organisation, others

○ Yes ◉ No

12. Is it anticipated that the research will lead to commercial benefit for the investigator(s) and or the research sponsor (s)?

○ Yes ◉ No

16. Is there a risk that the dissemination of results could cause harm of any kind to individual participants - whether their physical, psychological, spiritual, emotional, social or financial well-being, or to their employability or professional relationships - or to their communities?

○ Yes ◉ No

Monitoring

17. What mechanisms do the researchers / investigators intend to implement to monitor the conduct and progress of the research project?

The quality of data collection is assured through;
- inbuilt validation checks within the electronic data entry forms
- automated identification of outlier data within the database and report generation
- data processing and report generation following submission of de-identified site data to the central database
- site co-ordinator meetings to discuss areas of improvement in the data collection process
- inbuilt functionality to allow a self-audit process at each site
- annual external auditing process is in development

6. PARTICIPANTS

1. Research participants

The National Statement identifies the need to pay additional attention to ethical issues associated with research involving certain specific populations.

This question aims to assist you and the HREC to identify and address ethical issues that are likely to arise in your research, if its design will include one or more of these populations. Further, the National Statement recognizes the cultural diversity of Australia's population and the importance of respect for that diversity in the recruitment and involvement of participants. Your answer to this question will guide you to additional questions (if any) relevant to the participants in your study.

Tick as many of the following 'types of research participants' who will be included because of the project design, or their inclusion is possible, given the diversity of Australia's population. If none apply, please indicate this below.

If you select column (a) or (b), column (c) will not apply.

The participants who may be involved in this research are: ***If you select column (a) or (b), column (c) will not apply.***	**a) Primary intent of research**	**b) Probable coincidental recruitment**	**c) Design specifically excludes**
People whose primary language is other than English (LOTE)	☐	☑	☐
Women who are pregnant and the human fetus	☐	☑	☐
Children and/or young people (ie. <18 years)	☐	☑	☐
People in existing dependent or unequal relationships	☐	☑	☐
People highly dependent on medical care	☐	☑	☐
People with a cognitive impairment, an intellectual disability or a mental illness	☐	☑	☐
Aboriginal and/or Torres Strait Islander peoples	☐	☑	☐
People who may be involved in illegal activity	☐	☑	☐
None apply	☐		

You have indicated that it is probable that
- People whose primary language is other than English (LOTE)
- Women who are pregnant and the human fetus
- Children and/or young people (ie. <18 years)
- People in existing dependent or unequal relationships
- People highly dependent on medical care
- People with a cognitive impairment, an intellectual disability or a mental illness
- Aboriginal and/or Torres Strait Islander peoples
- People who may be involved in illegal activity

may be coincidentally recruited into this project. The National Statement identifies specific ethical considerations for these groups(s).

Please explain how you will address these considerations in your proposed research.
This project involves all adult patients undergoing cardiac surgical procedures irrespective of ethnicity; age; health status or dependency - as any patient will potentially have Cardiac Surgery, this study does not exclude any of the groups specified above. No minority group is penalised by involvement in this research project.

Participant description

2. How many participant groups are involved in this research project?

1

3. What is the expected total number of participants in this project at all sites?

N/A

4. Groups

Group 1

Group name for participants in this group:	All patients undergoing cardiac procedures
Expected number of participants in this group:	Ongoing
Age range:	> 18 years of age

Other relevant characteristics of this participant group:
All adult patients undergoing cardiac surgical procedures, with or without cardiopulmonary bypass (CPB), will be registered in the database. A full data set will only be collected on patients who undergo surgical procedure with CPB.

Using the current ANZSCTS report we would expect a case distribution of 62% coronary artery bypass grafting (CABG), 15% valve only and 10% valve/CABG and it is predicted that from all participating sites, 2,000 patients will be recruited for 2008/2009, and patients to be recruited in the successive year to be 3,500 (2009/2010), 4,500 (2010/2011) and 5,500 (2011/2012) (total approximately 15-17,000 patients). All cardiac surgical patients will be included in this project.
Why are these characteristics relevant to the aims of the project?
N/A

Participant experience

6. Provide a concise detailed description, in not more than 200 words, in terms which are easily understood by the lay reader of what the participation will involve.

Participants undergo routine clinical management in all cases during their cardiac surgery. Data currently routinely collected is transferred to a local, existing database and then is transferred, once de-identified, to the Australian and New Zealand Collaborative Perfusion Registry (ANZCPR) at Flinders Medical Centre. Data collected for this project is only accessed by the member of the project research team, the nominated perfusionist who is the site-coordinator,the ANZCPR Steering Committee and ANZCPR Data Managers.

Data is stored in the password protected local and central PDUCD. Data that is sent to the PDUCD only contains non-identifiable data, records are simply identified with an auto procedure number. Data is only available via a password protected process, and made available only for ethically rigorous enquiries.

Data in the PDUCD is stored indefinitely and no long term storage of data in paper form occurs In the event that the Principal Investigator ceases to be engaged at the current organisation, the information collected for, used in, or generated by this project is maintained and will continue to be managed by the PDUC and stored in the secure PDUCD.

Relationship of researchers / investigators to participants

7. Specify the nature of any existing relationship or one likely to rise during the research, between the potential participants and any member of the research team or an organisation involved in the research.

Participants of this project may be patients of the investigators. The investigators, as well as other surgeons, perfusionists, and anaesthetists will not be involved in recruiting participants, although they will be informed that patient data is being collected.

The process developed to gather data for the ANZCPR allows for data to be imported into a permanently non-identified database without the need for any clinician screening of identified data off site. The identified data is de-identified on site and only the encrypted data is sent to the central database. The data file is not viewed during this

process and the data screening is performed electronically. All of the data collected is already available (albeit not necessarily collected into one common data file) to clinicians involved in the management of patients.

9. Describe what steps, if any, will be taken to ensure that the relationship does not impair participants' free and voluntary consent and participation in the project.

N/A

10. Describe what steps, if any, will be taken to ensure that decisions about participation in the research do not impair any existing or foreseeable future relationship between participants and researcher / investigator or organisations.

N/A

11. Will the research impact upon, or change, an existing relationship between participants and researcher / investigator or organisations?

○ Yes ◉ No

Recruitment

13. What processes will be used to identify potential participants?

All patients having Cardiac Surgery are identified.

14. Is it proposed to 'screen' or assess the suitability of the potential participants for the study?

○ Yes ◉ No

15. Describe how initial contact will be made with potential participants.

N/A. All data collected is routinely collected as part of the patients stay in hospital. Any information in the database is non-identifiable. All patients will receive a Patient Information Sheet specifying that their data is being collected with an option to 'Opt-Out' if they so wish.

16. Do you intend to include both males and females in this study?

◉ Yes ○ No

What is the expected ratio of males to females that will be recruited into this study and does this ratio accurately reflect the distribution of the disease, issue or condition within the general community?
All cardiac surgery patients, regardless of sex, are invited to participate in the project. Currently, 71.2% of cardiac surgery patients at FMC are male.

17. Is an advertisement, e-mail, website, letter or telephone call proposed as the form of initial contact with potential participants?

○ Yes ◉ No

18. If it became known that a person was recruited to, participated in, or was excluded from the research, would that knowledge expose the person to any disadvantage or risk?

○ Yes ◉ No

Consent process

Do you propose to obtain consent from individual participants for your use of their stored data/samples for this research project?

○ Yes ◉ No

All patients will receive a Patient Information Sheet (not written consent) with the option to Opt- Out as per the NHMRC Natio Ethical Conduct in Human Research (2007) – updated May 2015; Section 2.3: Qualifying or Waiving Conditions for Consen Out Approach' (2.3.5 - 2.3.8) and Australian Commissions operating principle 10: 32 for registries.

You have indicated that the project involves research where it is proposed that the HREC qualify or waive the conditions for consent

22. Why is explicit consent neither practical nor feasible?

As this is a registry, gaining consent from every participant is neither required nor feasible and meets the registry guidelines 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.

23. Is the research low or negligible risk?

◉ Yes ○ No

24. How does the public interest in the proposed activity substantially outweigh the public interest in the protection of privacy?

The information that can be gained in Quality Improvement and in Cardiac Surgery through this registry outways the protection of privacy and as all information will be de-identified, protection of privacy is not considered a risk in this study - also as the patient will have an option to 'Opt-Out' there personal rights are met.

25. Why is near-complete data on outcomes required?

The Cardiac Surgery outcomes generated by this registry would be compromised if the participation rate is not near complete, and the requirement for explicit consent would compromise the necessary level of participation in this registry.

26. Does the information provided to the participants describe the nature of the data to be collected, the purpose for collecting it, and the procedure to decline participation or withdraw?

◉ Yes ○ No

27. How much time has been allowed between the participant receiving information and the use of the data?

The data is transported quarterly with 3 months grace period, allowing adequate time for the patient to 'Opt-Out' if the patient so desires.

28. What mechanism(s) are there for participants to obtain further information and register for non-participation?

The Patient Information Sheet provides details on who to contact and how to 'Opt-Out' if the patient so desires. The Project Manager can remove the information for any patient who chooses to Opt-Out.

29. Is there a governance process in place that delineates specific responsibility for the project and the appropriate management of the data in accordance with relevant security standards?

◉ Yes ○ No

7. Participants Specific

21. In what language(s) will the research be conducted?

☑ English

☐ Other

8. CONFIDENTIALITY/PRIVACY

Answers to the questions in section 8.1 will establish whether an HREC will need to apply guidelines under federal or State/territory privacy legislation in reviewing your application. Answers to questions in the remaining parts of section 8 will show how confidentiality of participants is to be protected in your research.

1. Do privacy guidelines need to be applied in the ethical review of this proposal?

Indicate whether the source of the information about participants which will be used in this research project will involve:

☐ collection directly from the participant

☐ collection from another person about the participant

☐ use or disclosure of information by an agency, authority or organisation other than your organisation

☑ use of information which you or your organisation collected previously for a purpose other than this research project

Information which will be used for this research project which you or your organisation collected previously for a purpose other than this research project

1b. Indicate from which of the following you will be collecting information for this research project and indicate how many databases from each source.

Commonwealth	
State/Territory	1
Private Sector	1

Organisations databases

1

Name of agency / organisation	Each independent institution
Database source:	○ A Commonwealth government department or agency ◉ A state/territory authority ○ A private sector organisation
Name/description of the database	Each centre has their own electronic records database from which they source the information for the ANZCPR. All centres also use Cardiopulmonary Bypass machines that collect information during the procedure. The variables that are then migrated to the ANZCPR in a non-identifiable format are under the following headings: Procedure Type; Demography (includes age, sex, date of birth,

Describe the information that will be collected. List all data items.	weight and height only); Clinical Information (such as family history, smoking history, risk factor history, previous intervention, previous surgery, etc.); Perfusion Data (including bypass time, cross clamp time, pericardial suction blood information, circuit information, monitoring information, glucose information, temperature information, blood pressure information, blood flow information, haemoglobin/haematocrit information, renal function information); Procedure Data; Outcome variables (such as discharge, death in hospital, mortality within 30 days, stroke, new renal failure etc.) and Perfusion Electronic Data.

The information used by the research team about participants will be in the following form(s). Tick more than one box if applicable.

- ☐ Identified
- ☐ Re-identifiable
- ☑ De-identified

2

Name of agency / organisation	Each independent institution
Database source:	○ A Commonwealth government department or agency ○ A state/territory authority ◉ A private sector organisation
Name/description of the database	Each private institution involved in this project has their own electronic records database from which they source the information for the ANZCPR. All centres also use Cardiopulmonary Bypass machines that collect information during the procedure.
Describe the information that will be collected. List all data items.	The variables that are then migrated to the ANZCPR in a non-identifiable format are under the following headings: Procedure Type; Demography (includes age, sex, date of birth, weight and height only); Clinical Information (such as family history, smoking history, risk factor history, previous intervention, previous surgery, etc.); Perfusion Data (including bypass time, cross clamp time, pericardial suction blood information, circuit information, monitoring information, glucose information, temperature information, blood pressure information, blood flow information, haemoglobin/haematocrit information, renal function information); Procedure Data; Outcome variables (such as discharge, death in hospital, mortality within 30 days, stroke, new renal failure etc.) and Perfusion Electronic Data.

The information used by the research team about participants will be in the following form(s). Tick more than one box if applicable.

- ☐ Identified
- ☐ Re-identifiable
- ☑ De-identified

1c. Will the information to be used in medical research?

○ Yes ◉ No

1d. Does this application include an attachment relevant to state/territory privacy legislation?

◉ Yes ○ No

1e. Is the information health information?

◉ Yes ○ No

Using information from participants

2. Describe how information collected about participants will be used in this project.

The non-identified information collected in the database is available to be used in publications on peer reviewed journals in the key areas identified for the collaboration as well as on additional information derived from the dataset. Data is only available via password protected processes, and made available only for ethically rigorous enquiries that have been through Ethics Committee approval processes. Perfusionists and other interested clinicians who have submitted appropriate requests to investigate the non-identifiable data set will have access to the data once they have gained approval from their local Ethics Committee to access the data. An annual report is generated on the non-identified data collected. To support the aims of the PDUC, this report is available to all Cardiac Surgery units in the country to enable them, if they wish to, to benchmark there current practice against what is the largest and only detailed data set on perfusion available in Australia and New Zealand.

Authorship of the principal publications from the group on the key areas identified for the collaboration to address depend on the leadership group for each study. The information remains the property of the PDUC. Other publications which describes additional information derived from the dataset must be approved by the PDUC Steering Committee and authorship will include those investigators who have participated.

The custodian of the data is the ANZCPR and intellectual property generated by this initiative is owned by the ANZCPR Steering Committee.

3. Will any of the information be used by the research team be in identified or re-identifiable (coded) form?

○ Yes ◉ No

4. List ALL research personnel and others who, for the purposes of this research, will have authority to use or have access to the information and describe the nature of the use or access. Examples of others are: student supervisors, research monitors, pharmaceutical company monitors.

The non-identifiable information collected in the database is used in publications on peer reviewed journals in the key areas identified for the collaboration as well as on additional information derived from the dataset. Data is only available via password protected processes, and made available only for ethically rigorous enquiries. Perfusionists and other interested clinicians who have submitted appropriate requests to investigate the non-identifiable data set will have access to the data. An annual report is generated on the data collected. To support the aims of the PDUC, this report is available to all Cardiac Surgery units in the country to enable them, if they wish to, to benchmark there current practice against what is the largest and only detailed data set on perfusion available in Australia and New Zealand.

Authorship of the principal publications from the group on the key areas identified for the collaboration to address depend on the leadership group for each study. The information remains the property of the PDUC. Other publications which describes additional information derived from the dataset must be approved by the PDUC Steering Committee and authorship will include those investigators who have participated.

The custodian of the data is the ANZCPR Steering Committee and intellectual property generated by this initiative is owned by the ANZCPR Steering Committee.

Storage of information about participants during and after completion of the project

5. In what formats will the information be stored during and after the research project? (eg. paper copy, computer file on floppy disk or CD, audio tape, videotape, film)

Data collected for this project is only accessed by the member of the project research team, the nominated perfusionist who is the site-coordinator, and the ANZCPR data managers.

Data is stored in the password protected local and central ANZCPR. Data that is sent to the ANZCPR only contains non-identifiable data, records simply identified with an auto number. Data is only available via a password protected process, and made available only for ethically rigorous enquiries.

Data in the ANZCPR will be stored electronically indefinitely and no long term storage of data in paper form will occur. In the event that the Principal Investigator ceases to be engaged at the current organisation, the information collected for, used in, or generated by this project will be maintained will continue to be managed by the PDUC and stored in the secure ANZCPR.

6. Specify the measures to be taken to ensure the security of information from misuse, loss, or unauthorised access while stored during and after the research project? (eg. will identifiers be removed and at what stage? Will the information be physically stored in a locked cabinet?)

Data collected for the ANZCPR is data already routinely collected. Data is stored in the password protected local and central ANZCPR. Data that is sent to the ANZCPR only contains non-identifiable data, records simply identified with an auto number. Data is only available via a password protected process, and made available only for ethically rigorous enquiries.

9. The information which will be stored at the completion of this project is of the following type(s). Tick more than one box if applicable.

- ☐ individually identifiable
- ☐ re-identifiable
- ☑ non-identifiable

10. For how long will the information be stored after the completion of the project and why has this period been chosen?

The information will continue to be stored, in a non-identifiable format, indefinitely. The process developed to gather data for the ANZCPR allows for data to be imported into a permanently non-identified database without the need for any clinician screening of identified data off site. The identified data is de-identified on site and only the encrypted data is sent to the central database. The data file is not viewed during this process and the data screening is performed electronically. All of the data collected is already available (albeit not necessarily collected into one common data file) to clinicians involved in the management of patients.

11. What arrangements are in place with regard to the storage of the information collected for, used in, or generated by this project in the event that the principal researcher / investigator ceases to be engaged at the current organisation?

Data in the ANZCPR is stored indefinitely and no long term storage of data in paper form occurs. In the event that the Principal Investigator ceases to be engaged at the current organisation, the information collected for, used in, or generated by this project is maintained and will continue to be managed by the PDUC and stored in the secure ANZCPR.

Ownership of the information collected during the research project and resulting from the research project

13. Who is understood to own the information resulting from the research, eg. the final report or published form of the results?

Authorship of the principal publications from the PDUC group on the key areas identified for the collaboration to address depend on the leadership group for each study. The information remains the property of the ANZCPR Steering Committee. Other publications which describe additional information derived from the dataset must be approved by the ANZCPR Steering Committee and authorship those investigators who have participated.

14. Does the owner of the information or any other party have any right to impose limitations or conditions on the publication of the results of this project?

◉ Yes ○ No

Specify any limitations on publication:
As above. The custodian of the data is the ANZCPR Steering Committee and intellectual property generated by this

initiative is owned by the ANZCPR. Individual site data remains the property of each contributing site.

Disposal of the information

15. Will the information collected for, used in, or generated by this project be disposed of at some stage?

○ Yes ◉ No

Reporting individual results to participants and others

16. Is it intended that results of the research that relate to a specific participant be reported to that participant?

○ Yes ◉ No

Explain/justify why results will not be reported to participants:
Results are not reported to participants as the data for evaluation is non-identifiable
and as such the original patient about whom the data results relate is not able to be identified.

17. Is the research likely to produce information of personal significance to individual participants?

○ Yes ◉ No

18. Will individual participant's results be recorded with their personal records?

○ Yes ◉ No

19. Is it intended that results that relate to a specific participant be reported to anyone other than that participant?

○ Yes ◉ No

20. Is the research likely to reveal a significant risk to the health or well being of persons other than the participant, eg family members, colleagues

○ Yes ◉ No

21. Is there a risk that the dissemination of results could cause harm of any kind to individual participants - whether their physical, psychological, spiritual, emotional, social or financial well-being, or to their employability or professional relationships - or to their communities?

○ Yes ◉ No

22. How is it intended to disseminate the results of the research? eg report, publication, thesis

As the ANZCPR data collection will continue indefinitely, there will be no report or publication - however it is the aim of the ANZCPR to facilitate research by allowing continual peer review, publications, and quality improvement initiatives from using this de-identified data. The strength of the collaborative data set is in its availability to all members which allows them to utilise the data for appropriate research initiatives. The ANZCPR brings together key data from multiple sites around Australia and New Zealand. Data from remote sites is gathered, de-identified, and stored at the central database at Flinders Medical Centre (FMC) in a purpose designed and built secure SQL database.

23. Will the confidentiality of participants and their data be protected in the dissemination of research results?

(•) Yes ( ) No

Explain how confidentiality of participants and their data will be protected in the dissemination of research results:
The process developed to gather data for the ANZCPR allows for data to be imported into a permanently non-identified database without the need for any clinician screening of identified data off site. The identified data is de-identified on site and only the encrypted data is sent to the central database. The data file is not viewed during this process and the data screening is performed electronically. All of the data collected is already available (albeit not necessarily collected into one common data file) to clinicians involved in the management of patients.

10. Declarations And Signatures

Applicant / Principal Researchers (including students where permitted)

Project Title (in full):	Australian and New Zealand Collaborative Perfusion Registry (formally Perfusion Downunder Collaborative Database)
HREC to which this application is made:	
HREC Reference number:	HREC/15/SAC/341

I/we certify that:

- All information is truthful and as complete as possible.
- I/we have had access to and read the National Statement on Ethical Conduct in Research InvolvingHumans.
- The research will be conducted in accordance with the National Statement.
- The research will be conducted in accordance with the ethical and research arrangements of the organisations involved.
- The research will be conducted in accordance with the ethical and research arrangements of the organisations involved.
- I/we have consulted any relevant legislation and regulations, and the research will be conducted in accordance with these.
- I/we will immediately report to the HREC anything which might warrant review of the ethical approval of the proposal (NS 2.37), including:
- serious or unexpected adverse effects on participants;
- proposed changes in the protocol; and
- unforseen events that might affect continued ethical acceptability of the project.
- I/we will inform the HREC, giving reasons, if the research project is discontinued before the expected date of completion (NS 2.38);
- I/we will not continue the research if ethical approval is withdrawn and will comply with any special conditions required by the HREC (NS. 2.45);
- I/we will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements. At a minimum annual progress reports and a final report will be provided to the HREC.

Applicant / Chief Researcher(s) / Principal Researcher(s)

	..... Signature	...../ ...../ ..... Date
Associate Professor Robert Baker Flinders Medical Centre	..... Signature	...../ ...../ ..... Date
Prof Alan Merry University of Auckland	..... Signature	...../ ...../ ..... Date

Mr Timothy Willcox Auckland City Hospital	..... Signature	...../ ...../ ..... Date
Prof Paul Myles Alfred Hospital & Monash University	..... Signature	...../ ...../ ..... Date
Mr Richard Newland Flinders Medical Centre	..... Signature	...../ ...../ ..... Date

Associate Researchers

Mrs Jane Ottens Ashford Hospital	..... Signature	...../ ...../ ..... Date
Mr Michael McDonald Perfusion Services Pty Ltd	..... Signature	...../ ...../ ..... Date
Assoc/Prof Peter Klineberg Westmead Hospital	..... Signature	...../ ...../ ..... Date
Ms Carmel Fenton Royal Hobart Hospital	..... Signature	...../ ...../ ..... Date
Mr James Anderson Alfred Health	..... Signature	...../ ...../ ..... Date
Mr Brian Wright Fiona Stanley Hospital	..... Signature	...../ ...../ ..... Date
Mr Joshua Byrne THE ALFRED	..... Signature	...../ ...../ ..... Date
Ms Rona Steel Westmead Hospital	..... Signature	...../ ...../ ..... Date

Supervisor(s) of student(s)

Project Title (in full):	Australian and New Zealand Collaborative Perfusion Registry (formally Perfusion Downunder Collaborative Database)
HREC to which this application is made:	
HREC Reference number:	HREC/15/SAC/341

I/we certify that:

- I/we will provide appropriate supervision to the student to ensure that the project is undertaken in accordance with the undertakings above;
- I/we will ensure that training is provided necessary to enable the project to be undertaken skilfully and ethically.

Heads of departments/schools/research organisation

Project Title (in full):	Australian and New Zealand Collaborative Perfusion Registry (formally Perfusion Downunder Collaborative Database)
HREC to which this application is made:	
HREC Reference number:	HREC/15/SAC/341

I/we certify that:

- I/we are familiar with this project and endorse its undertaking;
- the resources required to undertake this project are available;
- the researchers have the skill and expertise to undertake this project appropriately or will undergo appropriate training as specified in this application.

..... Title	..... First Name	..... Surname
..... Position	..... Organisation Name	
..... Signature	...../ ...../ ..... Date	

11. Attachments

List of Attachments

Core Attachments	Attachments which may be required/appropriate
Recruitment/invitation	Copy of advertisement, letter of invitation etc
Participant Information	Copy or script for participant Copy or script for parent, legal guardian or person responsible as appropriate
Consent Form	Copy for participant For parent, legal guardian or person responsible as appropriate For, optional components of the project eg. genetic sub study
Peer review	Copy of peer review report or grant submission outcome

HREC approvals	Copy of outcome of other HREC reviews

Attachments specific to project or participant group	**Attachments which may be required/appropriate**
People whose primary language is other than English (LOTE)	English translation of participant information/consent forms
Children and/or young people (ie.<18 years)	Information/consent form for parent, legal guardian or person responsible
People with an intellectual or mental impairment	Information/consent form for legal guardian or person responsible
People highly dependent on medical care	Information/consent form for legal guardian or person responsible
Aboriginal and/or Torres Strait Islander peoples	Evidence of support / permission of elders and/or other appropriate bodies

Participant information elements

Core Elements
Provision of information to participants about the following topics should be considered for all research projects.

Core Elements	**Issues to consider in participant information**
About the project	Full title and / or short title of the project Plain language description of the project Purpose / aim of the project and research methods as appropriate Demands, risks, inconveniences, discomforts of participation in the project Outcomes and benefits of the project Project start, finish, duration
About the investigators / organisation	Researchers conducting the project (including whether student researchers are involved) Organisations which are involved / responsible Organistions which have given approvals Relationship between researchers and particpants and organisations
Participant description	How and why participants are chosen How participants are recruited How many participants are to be recruited
Participant experience	What will happen to the particant, what will they have to do, what will they experience? Benefits to individual, community, and contribution to knowledge Risks to individual, community Consequences of participation
Participant options	Alternatives to participation Whether participation may be for part of project or only for whole of project Whether any of the following will be provided: counselling, post research follow-up, or post research access to services, equipment or goods
Participants rights and responsibilities	That participation is voluntary That participants can withdraw, how to withdraw and what consequences may follow Expectations on participants, consequences of non-compliance with the protocol

	How to seek more information How to raise a concern or make a complaint
Handling of information	How information will be accessed, collected, used, stored, and to whom data will be disclosed Can participants withdraw their information, how, when Confidentiality of information Ownership of information Subsequent use of information Storage and disposal of information
Unlawful conduct	Whether researcher has any obligations to report unlawful conduct of participant
Financial issues	How the project is funded Declaration of any duality of interests Compensation entitlements Costs to participants Payments, reimbursements to participants Commercial application of results
Results	What will particpants be told, when and by whom Will individual results be provided What are the consequences of being told or not being told the results of research How will results be reported / published Ownership of intellectual property and commercial benefits
Cessation	Circumstances under which the participation of an individual might cease Circumstances under which the project might be terminated

Research Specific Elements

Provision of information to participants about the following topics should be considered as may be relevant to the research project.

Specific to project or participant group	**Additional issues to consider in participant information**
Aboriginal and/or Torres Strait Islander peoples	Describe consultation process to date and involvement of leaderswhether ATSI status will be recorded