# Australian and New Zealand Intensive Care Research Centre

## Terms of Reference

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MONASH University

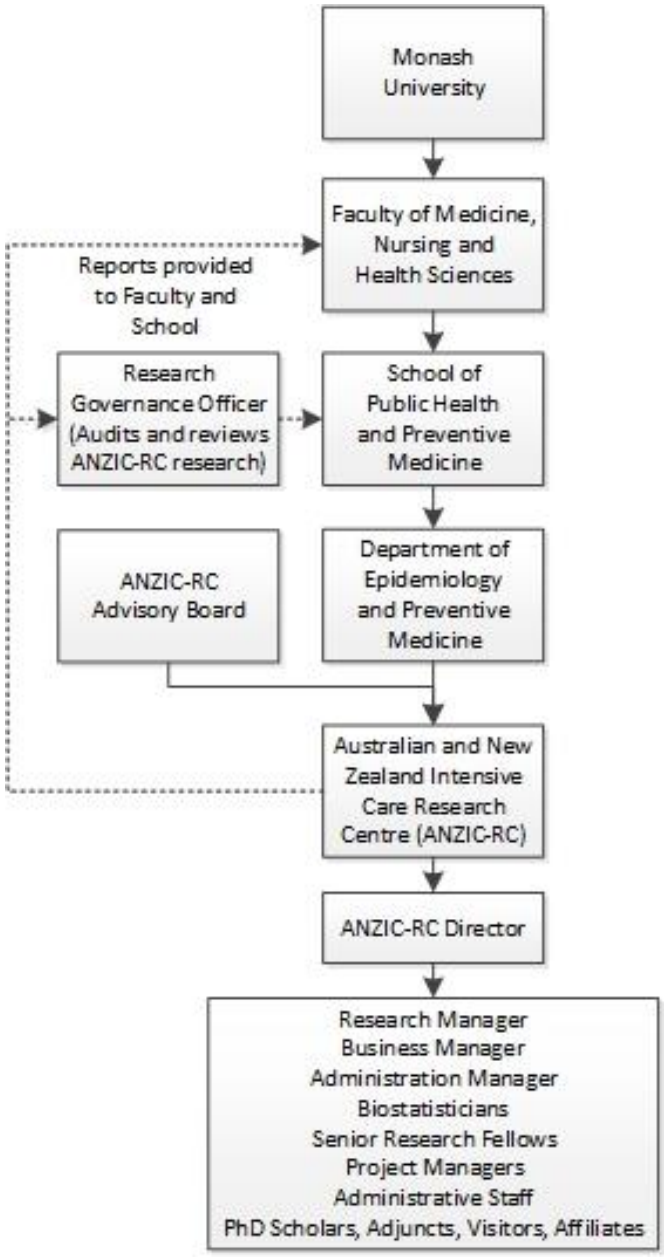
## TABLE OF CONTENTS

## GOVERNANCE AND MANAGEMENT STRUCTURE

The Australian and New Zealand Intensive Care Research Centre (ANZIC-RC) is a Centre within the School of Public Health and Preventive Medicine (SPHPM) in the Faculty of Medicine, Nursing and Health Sciences at Monash University (FMNHS). The Centre is located within the School's Department of Epidemiology and Preventive Medicine (DEPM) at the Alfred Research Alliance, Melbourne, Australia. Annual reports are provided to the FMNHS and the SPHPM, as required by Monash University policy.

The following chart outlines the governance and management structure of the ANZIC-RC at Monash University:

**Figure 1: Governance and Management Structure**




### RESEARCH GOVERNANCE

Research conducted within the ANZIC-RC will comply with the SPHPM's *Guide to Good Research Practice* (https://www.monash.edu/__data/assets/pdf_file/0003/1031079/grp-guide.pdf) and is subject to the SPHPM's audit processes.

## ADVISORY BOARD

The ANZIC-RC is governed by an Advisory Board, established under the auspices of Monash University. The Advisory Board reviews the Centre's progress and advises on future initiatives.

### COMPOSITION

The ANZIC-RC is administered by an Advisory Board comprised of the following:

1. The Head of SPHPM
2. The Monash University Director of the ANZIC-RC
3. The Co-Director of the ANZIC-RC
4. The Deputy Directors of the ANZIC-RC (3)
5. The Chair of the Australian and New Zealand Intensive Care Society Clinical Trials Group (ANZICS-CTG)
6. The Immediate Past Chair of the ANZICS-CTG
7. The Immediate Past Chair of the ANZICS-CTG from New Zealand
8. The Chair of the Australian and New Zealand Intensive Care Society Centre for Outcome and Resource Evaluation (ANZICS-CORE)
9. A co-opted representative from the New Zealand intensive care research community

### CHAIR

The Chair of the Advisory Board is the Monash University Director of the Centre.

### TERMS OF OFFICE

The terms of office are as follows:

- Head of SPHPM: term continues whilst the ANZIC-RC is affiliated with the SPHPM
- The Monash University Director and Co-Director of the ANZIC-RC: term is until that member steps down from their role, and
- Representatives of organisations: term is until that member steps down from their role within that organisation.

The number and composition of members of the Advisory Board will be reassessed as necessary. Any changes to the number and composition of members of the Advisory Board will be decided by the Monash University Director and Co-Director.

### DUTIES AND RESPONSIBILITIES

The Advisory Board is responsible for advising the Director and Co-Director on the following:

- Overseeing the Centre's general operations and activities
- Providing guidance on the Centre's strategic plan and future direction
- Monitoring the Centre's accounts and financial concerns
- Overseeing all grants and projects administered by the Centre including issues of scientific integrity and research conduct
- Providing ongoing review of staffing levels
- Ensuring adherence to the Centre's Mission Statement (Appendix 1), and
- Establishing Sub-Committees as required, and determining the composition, duties, responsibilities, limitations and operating procedures of those Sub-Committees.

### MEETINGS

The Advisory Board meets two times each year (typically April and September). Senior members of the ANZIC-RC staff are invited to attend Advisory Board meetings as Guests when appropriate.

## CONFLICT OF INTEREST

This section is to be read in conjunction with *Appendix 2* and the following Monash University procedures and guidelines:

*Conflict of Interest Procedure*
https://www.monash.edu/__data/assets/pdf_file/0009/792297/Conflict-of-Interest.pdf

*Conflict of Interest Examples and Actions Guideline*
https://www.monash.edu/__data/assets/pdf_file/0009/1248489/Conflict-of-Interest-Examples-and-Actions-Guideline.pdf

The term 'conflict of interest' refers to a situation where a conflict arises for an individual between two competing interests. These are often, but not exclusively, interests of public duty versus private interests. This refers to a reasonably perceived, potential or actual conflict of interest. Conflicts of interest can involve financial or non-financial interests of the staff member and the interests of a business partner or associate, family member, friend or person in, or who has had, a close personal relationship with the staff member.

### EXAMPLES OF CONFLICT OF INTEREST IN RESEARCH

The following scenarios are illustrative of the wide range of situations that constitute a conflict of interest:

- A researcher solicits benefits or largesse in exchange for using their position and reputation to unfairly advance the interests of a particular organisation.
  For example, the researcher speaks in favour of treatment X as if they were 'scientifically neutral' but in fact they have received inducements – or are accused of have receiving inducements – from a commercial organisation that stands most to gain from adoption of treatment X.
- A grant reviewer writes an unfavourable review of a grant application without disclosing that they are conducting research in the same area.
- A researcher uses University resources without permission or recompense to the University to participate on an external committee.
- A researcher is conducting a clinical trial of a medical device that shows great promise. A family member of the researcher buys shares in the medical device company before the results of the trial are made public.
- A researcher represents themselves as a University employee pursuing contract research opportunities for their research group at the University but in fact deliberately 'siphons off' the major projects as contracts for a private consulting company owned by that researcher.
- A researcher accepts substantial (non-token) 'gifts' from a third party with whom they interact (e.g. pharmaceutical company involved with the research) and favours – or is accused of favouring – that company.

## CONFLICT OF INTEREST MANAGEMENT

It is the responsibility of each ANZIC-RC Staff, Adjunct, Board Member, Management Committee Member or DSMC Member to:

- Declare any actual, perceived or potential conflicts of interest in the past two years regarding the person's role at the ANZIC-RC.
- Provide an update whenever there is a change in circumstances that requires disclosure.
- Declare any conflicts on the first slide (after the title slide) of any ANZIC-RC related study presentation.

**Staff or Adjuncts:** If an ANZIC-RC staff or adjunct has a conflict of interest, they must declare the conflict using the Monash University *Conflict of Interest Disclosure and Management Form* (https://www.monash.edu/eforms-resources/frevvo-forms/hr/conflict-of-interest-disclosure-and-management-plan - Note: You must be logged in to your Monash account to access this form).

**Advisory Board Members:** At the first Board meeting on or after 1 July each year, the Chair will remind the ANZIC-RC Advisory Board Members to ensure that they have a current *ANZIC-RC Disclosure of a Conflict of Interest Form (Form 1)* on file with the ANZIC-RC Research Manager. The *Form* must either declare any current conflicts or state that there are no conflicts to declare. Any actual, perceived or potential conflict of interest will be assessed by the Management Committee. If applicable, a management plan to mitigate or remove the conflict of interest will be developed by the Board in conjunction with the individual who has the conflict of interest.

**ANZIC-RC Investigators (Management Committee Members):** Project Managers must ensure that each of their study's Management Committee Members has a current *ANZIC-RC Disclosure of a Conflict of Interest Form (Form 1)* on file with the ANZIC-RC Research Manager. At the first Management Committee meeting on or after 1 July each year, the relevant study Project Manager will remind their Management Committee Members that:

- Participation on ANZIC-RC Study Management Committees is contingent upon the timely completion of the *ANZIC-RC Disclosure of a Conflict of Interest Form (Form 1)*.
- They must have a current *Form* (separate form for each study) on file with the ANZIC-RC Research Manager. (For Monash Staff/Adjuncts, even if they have declared the conflict using the Monash form, they must also complete a separate ANZIC-RC *Form* for each study Management Committee they are a member of.)
- The form must either declare any current conflicts or state that there are no conflicts to declare.
- Whenever there is a change in circumstances that requires disclosure, an updated *Form* must be provided.
- Any actual, perceived or potential conflict of interest will be assessed by the Management Committee.
- If applicable, a management plan to mitigate or remove the conflict of interest will be developed in conjunction with the individual who has the conflict of interest. The proposed management plan must be stated on the *Form* and submitted to the ANZIC-RC Director. The Director will either endorse the management plan or, if the proposed plan is deemed to be insufficient, refer it to the Advisory Board for further development.

**Data and Safety Monitoring Committees (DSMC)**:

- The DSMC Charter for each ANZIC-RC study must include a clause that requires each DSMC Member to declare any actual, perceived or potential conflicts of interest in the past two years relating to their role on the DSMC of an ANZIC-RC study; and to provide an updated form whenever there is a change in circumstances that requires disclosure.
- Project Managers must ensure that each of their study's DSMC Members has signed a copy of the Charter and that it is on file with the ANZIC-RC Research Manager.

## SUB-COMMITTEES

The Advisory Board will establish Sub-Committees as necessary, to provide information and recommendations to the Board in order for it to function effectively. Final decisions on all advice received remains the prerogative of the Advisory Board. The Advisory Board, in consultation with the Research Manager, will determine the composition, duties, responsibilities, limitations and operating procedures of all Sub-Committees established.

## DIRECTOR – DUTIES AND RESPONSIBILITIES

The ANZIC-RC Director is ultimately responsible to Monash University, through the Head of the SPHPM, for all activities of the Centre including:

- Research integrity
- Compliance with policies and procedures of the University, Faculty and School
- Financial management
- HR matters
- Supervision of the Research, Business and Administration Managers
- Oversight and approval of each academic staff member's performance plan annually, and
- Attendance at faculty and department meetings as required.

## PhD Scholars

The ANZIC-RC is a national teaching centre for doctoral researchers in critical care medicine. To search for relevant PhD projects and supervisors, please go to the SupervisorConnect website.

For information on how to apply, please go to:
https://www.monash.edu/medicine/research/grad-research/how-to-apply

For further information on graduate research, please contact the SPHPM Graduate Research Administrator by email sphpm-doctoral-admin@monash.edu or telephone +61 3 9903 0276.

Prospective international students should consult Monash University Admissions.

**Important Notes:**

1. If the PhD project is a sub-study of a main study, all outcome data and the thesis itself will be quarantined until the main study is published. Papers arising from each sub-study may be written, but will not be submitted for publication until the main study has been completed and published. This will not prevent the Applicant from being awarded their PhD provided they have satisfied the PhD assessment criteria.
2. To meet the requirements of the University's Intellectual Property (IP) Statute and Regulations, all ANZIC-RC PhD Scholars, together with their supervisor, must complete the *Monash University Institute of Graduate Research Intellectual Property and Confidentiality Declaration* at the time of enrolment and whenever there is a change in the research program or surrounding circumstances that has intellectual property implications. The intellectual property implications of the candidate's research project should be reviewed annually. The reason for assigning IP is that in most cases PhD Scholars work on collaborative projects where the input of multiple individuals is involved. If there is a reason why the PhD Scholar considers it inappropriate to assign IP, they should discuss the matter with the ANZIC-RC's Director before commencing.

## Access to Service Policy

### Access Policy – Request for Assistance Process

The request for assistance process is as follows:

- The investigator completes the two page "Request for Assistance" pro forma (Form 2) available on the ANZIC-RC website (www.anzicrc.monash.org), together with any supporting documentation such as the grant application and budget, and submits it to the ANZIC-RC via email (anzicrc@monash.edu).
- Requests for assistance to the Centre for new studies will be assessed by the Director, in conjunction with the Leadership and Management Teams, using the criteria on page 11.
- If an investigator wants to name the ANZIC-RC as the coordinating centre in their grant application, the application must be reviewed and approved in writing by the Director prior to submission of the grant application to the funding organisation.
- As the ANZIC-RC Director is ultimately responsible for all activities of the Centre, the final decision whether to proceed with a grant application will be made by the Director.
- Any agreement for the ANZIC-RC to be the coordinating centre for a NHMRC or MRFF trial is conditional on the Chief Investigators delegating authority to the ANZIC-RC for the day-to-day responsibility of running the trial and its budget, and managing the trial staff; the CIA on the grant must have their organisational affiliation in the application submission systems (NHMRC RGMS / NHMRC SAPPHIRE / Monash PURE) set to the School of Public Health and Preventive Medicine at Monash University; and the entire funding-related RSP must be assigned to the SPHPM immediately on approval of the funding.
- Obtaining funding is neither a requirement for, nor a guarantee of, ANZIC-RC assistance.
- For Industry funding / sponsorship please refer to the Conducting Research with Industry Funding Bodies Policy (Appendix 2).
- If the grant is approved, a Memorandum of Understanding or other legal agreement will be formalised, including requirements for further funding. Then the project will proceed according to the workload of the relevant ANZIC-RC staff members.

### Sub-Studies

All sub-studies of NHMRC project grants must be conducted at the ANZIC-RC, unless otherwise agreed by the ANZIC-RC Board. Sub-studies need to be appropriately budgeted, and additional FTE needs to be provided to support the Project Manager.

## NEW STUDY ASSESSMENT CRITERIA

Each request for the ANZIC-RC to assist with a new study will be assessed on the following criteria:

1. Importance of the research question: Does the study address a clinically important question? For example, in areas of crucial evidence gaps, or areas of controversy or high variation in clinical care.
2. Need for the research: Does the evidence base demonstrate that the research is needed? For example, a formal review of relevant RCTs.
3. Relevance: Is it relevant to the Australian and New Zealand population?
4. Feasibility:
    - Recruitment within timeframe: Many RCTs fail to proceed in line with expectations, in particular failing to recruit and retain the required number of participants within an acceptable timeframe.
    - Ability to recruit patients described in study cohort.
    - Research team: The research team will be assessed for the correct blend of talent, enthusiasm, experience and clinical credibility.
    - Study assumptions: The assumptions behind the study would be critically reviewed, with evidence sought upfront that these assumptions are reasonable. If no such reassurance is possible, then it will be sought from a pilot study or early returns as the study commences.
5. Methodologically sound: The optimal scientific design, with the best and most appropriate analysis, with suitable methods of managing and conducting the trial, including procedures for early termination for safety or efficacy reasons, will be required, along with trial registration and a full commitment to publish the results in peer reviewed journals.
6. Financially viable and the cost and likelihood of obtaining funding: Our involvement with a study must be appropriately financed, with a minimum expectation that the ANZIC-RC recovers the true cost of its engagement in a study (in terms of its expense of staff costs and consumables).
7. Fits in with the aims of the ANZIC-RC: The trial should enhance and confirm the ANZIC-RC's reputation as the deliverer of high quality, clinically relevant, methodologically excellent RCTs.
8. Ethically sound: The risks and benefits have been considered, awareness that there is a need for high ethical standards in research.
9. Quality assured: All trials conducted as part of the ANZIC-RC must adhere to the ANZIC-RC's relevant Standard Operating Procedures.
10. The likely benefits for the ICU community in Australia and New Zealand, and
11. The resources available at the Centre.

## ACKNOWLEDGEMENT AND AUTHORSHIP

Researchers using ANZIC-RC facilities and/or services must acknowledge the contribution of the Centre to their research in publications and presentations.

### STUDY PROTOCOL MUST STATE THE PUBLICATION POLICY

The publication policy for each study must be clearly stated in the study protocol. It is recommended that a writing committee be established "a priori". If a nominated author is required by a journal, nominated person(s) will be identified before submission of the manuscript and approved by the Management Committee of the study.

Correspondence

- Correspondence will be addressed to the nominated author.
- If no nominated author is required, the default person for correspondence will be the Chair of the study's Management Committee.

Sub-committees and Other Contributors

- Identification of study sub-committee participants, such as Study Management, Data and Safety Monitoring, Statistical, and Writing Committees will be listed in accordance with the respective journal's policy.
- Sub-committee membership will appear in alphabetical order following the Chair of the appropriate committee. Non-alphabetical listing of members of sub-committees may be considered where individuals have made a significant contribution to a sub-committee.
- Other contributors such as follow-up assessors or adjudication panel members will be listed in accordance with the respective journal's policy.

Institution Contributor List

- Each institution may nominate contributors for inclusion in the contributors' list, generally the Principal Investigator and Research Coordinator.
- Where another craft group has been significantly involved in the study, additional contributors may be nominated.
- The number of contributors from each institution and each craft group must be clearly documented in the protocol.
- Additional contributors will be considered on application to the study Management Committee.
- Contributing institutions will be listed alphabetically; individual(s) will be listed alphabetically within each institution.

### MINOR COLLABORATIONS – ACKNOWLEDGEMENT

For minor collaborations:

- Recognition will appear in the acknowledgement section of the manuscript.
- The exact wording will vary according to the nature of assistance provided.
- An example may include the following: "The authors wish to acknowledge the Australian and New Zealand Intensive Care Research Centre and <staff member's name> for their assistance with statistical advice and study design".

### MAJOR COLLABORATIONS – AUTHORSHIP

For major collaborations:

- Entitlement to authorship will be similar to those outlined in the section entitled "Editorial Policies for Authors: Authorship Criteria and Contributions" of the Journal of the American Medical Association (JAMA) website (available at http://jama.ama-assn.org/cgi/content/full/293/14/1788).
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.
- ANZIC-RC staff and investigators will only be entitled to authorship in projects where they have made a significant contribution to the study.
- All Chief Investigators on a grant should be given the opportunity to be a member of the Management Committee of that project.
- Management Committees must have a fair and transparent process regarding decisions on authorship and ongoing membership of the Management Committee.
- Research conducted in collaboration with the ANZICS-CTG must also adhere to its publication policy (ANZICS-CTG Terms of Reference CTG 1a (2011) http://www.anzics.com.au/ctg/ctgdocuments).

### BY-LINING THE ANZIC-RC AS AUTHOR AFFILIATION

For publications relating to their ANZIC-RC research, ANZIC-RC staff, adjunct staff, affiliates and PhD students must by-line the Centre as an affiliation as follows:

- "Australian and New Zealand Intensive Care Research Centre (ANZIC-RC), School of Public Health and Preventive Medicine, Monash University"

### FUNDING ACKNOWLEDGEMENT

If appropriate for the journal, funding sources of the research project will be acknowledged. Research conducted by ANZIC-RC staff will include acknowledgement of the support of the relevant funding body/ies.

## DATA OWNERSHIP

All data obtained through collaboration with other bodies and structured groups of investigators is assumed to be conjointly owned, unless negotiated otherwise prior to commencement. All such arrangements will be documented accordingly in the form of a Memorandum of Understanding or Clinical Trial Agreement. For the release of data or data sharing, please refer to the Data Sharing Policy (Appendix 3).

## HUMAN RESEARCH ETHICS COMMITTEE APPROVALS

All studies and investigations undertaken by the ANZIC-RC and its collaborators will comply with Human Research Ethics Committee (HREC) requirements at participating sites. Each participating site will be responsible for obtaining HREC approval prior to commencing the study, and a copy of this approval must be provided to the ANZIC-RC to be kept on file. HREC approval must also be obtained from Monash University. Studies involving database analysis will be undertaken following notification or formal application to the appropriate ethics committees, including Monash University.

## INTELLECTUAL PROPERTY

The ANZIC-RC will align itself with and abide by the intellectual property regulations of Monash University, as outlined in the Monash University calendar at:

http://www.monash.edu.au/pubs/calendar/statutes/statute11.html

All intellectual property developed by the ANZIC-RC remains the property of Monash University as outlined in the Monash University Intellectual Property Framework at:

http://intranet.monash.edu.au/research/forms/intellectual-property-framework.html

# APPENDICES

## APPENDIX 1

## MISSION STATEMENT

The mission of the Australian and New Zealand Intensive Care Research Centre (ANZIC-RC) is to:

- Conduct high impact, large-scale, investigator-initiated clinical trials designed to determine best and most cost-effective practice in Intensive Care Medicine (ICM)
- Increase the quality of clinical trial design and biostatistical analysis in this field
- Be readily accessible to all Australian and New Zealand clinician-researchers in critical care
- Expand the national and international reach of large Australian and New Zealand led trials
- Introduce systems to integrate research results into clinical practice by promulgating research-based practice guidelines
- Develop integrated clinical research programs that provide the training ground for future clinical trialists in the field of ICM
- Encourage and support clinician researchers in research theory, study design, study conduct, data analysis and scientific writing

# APPENDIX 2

## CONDUCTING RESEARCH WITH INDUSTRY FUNDING BODIES – POLICY

Background

This policy outlines the relationship between the ANZIC-RC and industry funding bodies including but not limited to the pharmaceutical industry and manufacturers of therapeutic, monitoring or diagnostic devices. This section is to be read in conjunction with the "Conflict of Interest" section of the ANZIC-RC's *Terms of Reference* and the following Monash University procedures and guidelines:

*Conflict of Interest Procedure*
https://www.monash.edu/__data/assets/pdf_file/0009/792297/Conflict-of-Interest.pdf

*Conflict of Interest Examples and Actions Guideline*
https://www.monash.edu/__data/assets/pdf_file/0009/1248489/Conflict-of-Interest-Examples-and-Actions-Guideline.pdf

For the purposes of this document, the pharmaceutical industry and manufacturers of therapeutic, monitoring or diagnostic devices will be referred to as "industry" and commercial/industry funding may take the form of monetary support and/or supply of therapeutic agents and devices at reduced or no cost.

Purpose

The purpose of this policy is to ensure that all ANZIC -RC investigators and staff members have an understanding of the:

- Implications of receiving funding from industry bodies
- Potential or perceived conflicts of interest in dealings with any industry funding body, and
- Process involved when dealing with an industry funding body.

Policy

**Board assessment of a potential funding opportunity:**

Prior to agreeing to accept industry funding for research, the ANZIC-RC Advisory Board must assess the risk of undertaking the industry research activity taking into account:

- Legal risks
- Risks to reputation, and
- Business risks.

**Conditions of accepting industry funding:**

1. When industry funding is obtained for a specific project, the protocol must document that the funding has been obtained from industry.
2. The appropriate HREC submission for the industry funded research project must include details of the industry funding in the application.
3. Industry funding for research will only be accepted on the basis that whilst the industry funding body may offer suggestions regarding research design, study management, data analysis, report writing or publication, all final decisions will rest with the study Management Committee.

4. The industry funding body will be advised of the detailed study results at an agreed time before publication but it will not restrict or place limitations on the publication of research results.
5. All industry funded research publications and presentations must state that, "Funding has been received from <Name of commercial entity> in the form of an unrestricted grant to Monash University".
6. No money will be paid directly to individual staff members, adjuncts or affiliates from the industry funding body for performance of the research project.
7. A formal contractual arrangement between the industry funding body and Monash University must be executed prior to commencing the industry funded research.
8. A budget including the Monash University Department of Epidemiology and Preventive Medicine's levy must be included with the contract.
9. Any funds from industry sources must be paid into a Monash University fund and be solely used for the purpose of the research activity.
10. ANZIC-RC investigators and staff members should not allow their names or the name of the ANZIC-RC to be associated with any form of direct advertising, unless the commercial nature of their involvement is clearly stated and there has been prior approval by the ANZIC-RC Board. An association between the ANZIC-RC and any product does not imply endorsement of the product. A disclaimer to this effect should be included in any industry advertising material relating to the study.
11. In any commercial arrangement between an ANZIC-RC investigator or staff member and industry, if the ANZIC-RC is directly or indirectly involved, the final agreement must be subject to ANZIC-RC Advisory Board approval. If negotiations are conducted in a personal capacity, no mention of the ANZIC-RC may be made.

## Partnership Grants With Industry Funding Bodies

Collaboration with industry funding bodies may offer sources of research support with either NHMRC partnership grants or ARC linkage grants. In these circumstances it may be appropriate for a representative from the industry funding source to join a research Management Committee. In this case, the industry funding body will be asked to nominate a representative. Agreement must be obtained from a quorum of the existing Management Committee members prior to the industry representative joining the Management Committee.

## Industry Funding / Sponsorship – Procedure

1. Sponsorship funding for educational meetings / conferences may be sought from industry funding bodies, however, both the ANZIC-RC and the industry funding body must comply with the Medicines Australia Code of Conduct (Edition 16). http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/
2. Prior approval from the ANZIC-RC Advisory Board must be sought before accepting sponsorship from an industry funding body.
3. A formal contract or exchange of letters outlining the terms of sponsorship will be required.
4. Sponsorship must never be contingent on changes to any part of the meeting.
5. Funding support for the costs of a visiting speaker will be acceptable provided that such support is acknowledged at the meeting. If the industry funder nominates a speaker, then the presentation will not contain product promotion.
6. Other industry financial support in the form of venues or refreshments is acceptable.
7. All support must be acknowledged in any promotional materials and at the commencement of the conference.

# APPENDIX 3

## DATA SHARING POLICY

Background

The Australian and New Zealand Intensive Care Research Centre (ANZIC-RC) is a Centre within the School of Public Health and Preventive Medicine (SPHPM) in the Faculty of Medicine, Nursing and Health Sciences at Monash University (FMNHS). The ANZIC-RC strongly supports the view that:

- Publicly funded research data are a public good that should be made available with as few restrictions as possible
- Greater data sharing could enhance public well-being by maximising utilisation of gained knowledge, reducing redundant research and facilitating scientific innovation, and
- The approach to scientific data sharing must be responsible and must recognise legal, regulatory, ethical and commercial constraints.

For this reason, the ANZIC-RC has formulated a policy and process to allow appropriate and responsible sharing of its research data for scientific research. This *Data Sharing Policy* (**Policy**) covers **all** studies conducted by the ANZIC-RC including prospective and completed studies. This Policy was guided by the following principles for responsible sharing of clinical trial data formulated by the Institute of Medicine, while recognising that these principles extend to a broader range of study designs:

- Maximise the benefits of clinical trials while minimising the risks of data sharing
- Respect individual participants whose data are shared
- Increase public trust in clinical trials and the sharing of trial data
- Conduct the sharing of trial data in a fair manner, and
- Appropriately manage conflicts of interest.

Definitions

| | |
|---|---|
| ***Collection*** | • A research dataset, including summary datasets, or set of human samples with associated data, in respect of a study conducted by the ANZIC-RC. |
| ***Custodian*** | • Has responsibility for the relevant *Collection*.<br>• The Chair of the relevant Management Committee is the *Custodian*.<br>• If the Chair of the relevant Management Commitment no longer has an affiliation with the ANZIC-RC or is uncontactable, the *Data Sharing Committee* will designate an appropriate senior scientist at the ANZIC-RC to act as the *Custodian*. |
| ***Data Sharing Agreement*** | • A formal agreement between Monash University and a *Requester*, setting out the terms on which the University agrees to the ANZIC-RC providing access to certain data in a *Collection* for the purposes set out in the relevant approved *Data Sharing Request*. |
| ***Data Sharing Committee*** | • The ANZIC-RC Committee that oversees *Data Sharing Requests*.<br>• Where the study no longer has an active *Custodian*, the *Data Sharing Committee* will designate an appropriate senior scientist at the ANZIC-RC to act as the *Custodian*.<br>• Membership of the Committee is determined by the Director of the ANZIC-RC. It currently includes two Deputy Directors, the Research Manager and the Senior Biostatistician.<br>• The Committee meets as required, and reports to the Director.<br>• Decisions will be made if ≥3 members are in favour.<br>• If the Committee is unable to reach agreement, the matter will be referred to the Director, who will decide. |
| ***Data Sharing Coordinator*** | • An individual responsible for updating the Policy, providing ANZIC-RC staff with guidance on the Policy and related procedures, coordinating the *Data Sharing Committee*, and liaising with Monash University's Office of the General Counsel (responsible for the University's legal matters) regarding *Data Sharing Agreements*.<br>• The role is held by the ANZIC-RC's Research Manager. |
| ***Data Sharing Request*** | • Must be submitted on the ANZIC-RC's pro forma to anzicrc@monash.edu and in accordance with this Policy. |
| ***Data Sharing Statement*** | • A plan outlining whether data and related documents will be shared, and if so, what data in particular, when the data will become available and for how long, and the access criteria. |
| ***Requester*** | • An individual, or a group of researchers, seeking access to data from a *Collection*. |

Responsibilities of ANZIC-RC's Investigators – Data Sharing Statement

The ANZIC-RC's Investigators are required to:

- Design research studies and manage research data with the expectation that data will be shared.
- Have in place a *Data Sharing Statement* for **all** research proposals where the primary goal is to create a database resource. The generation of datasets have scope for wider research use and can hold significant long-term value, including datasets that could be shared for added value, for example, those where the data has clear utility for research questions beyond those that the data generators are seeking to address.
- Typically, conceive such a *Data Sharing Statement* in the planning stage, and ensure it is in place once the project becomes either active or funded.
- Although the ANZIC-RC's researchers can structure their *Data Sharing Statement* in a manner most appropriate to their research, they are asked to answer the following questions in considering their approach to data sharing:
    - What data outputs will your research generate and what data will have value to other researchers?
    - Where will you make the data available?
    - What documentation will you provide to describe your data?
    - How will other researchers outside the study be able to access the data?
    - Are any limits to data sharing required, for example, to either safeguard research participants or to gain appropriate intellectual property protection?
    - How will you ensure that key datasets are preserved to ensure their long-term value?
    - What resources will you require to deliver your plan?
- Sharing of Data from ANZICS-CTG Endorsed Studies:
    - Management committees that propose to share data with another group need to obtain approval from the CTG Chair or Chair-delegate before providing any data to a third party.
    - The CTG reserves the right to require that manuscripts derived from data shared with another group be submitted for review and endorsement prior to publication.
    - Manuscripts derived from data obtained from a CTG Endorsed study that has been shared with another group must acknowledge the role of the CTG in the original study.
    - A copy of the published manuscript is to be provided to the CTG committee Office.
- Abide by the International Committee of Medical Journal Editors' (ICMJE) requirements that:
    - As of 1 July 2018 manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a *Data Sharing Statement* (see Appendix A)
    - Clinical trials that begin enrolling participants on or after 1 January 2019 must include a *Data Sharing Statement* in the trial's registration. If the *Data Sharing Statement* changes after registration, this should be reflected in the statement submitted and published with the manuscript, and updated in the registry record.
- Share data from research activities in accordance with this Policy and the terms and conditions of applicable grants and contracts.
- Take into consideration local / regional requirements and regulations regarding data sharing.

Data Sharing Statement: ICJME Requirements

The ANZIC-RC adopts ICMJE requirements regarding ***Data Sharing Statements***. In particular, we adopt the view that ***Data Sharing Statements*** must indicate the following:

- Whether individual de-identified participant data (including data dictionaries) will be shared
- What data in particular will be shared
- Whether additional, related documents will be available (e.g., study protocol, statistical analysis plan, data dictionary, etc.)
- When the data will become available and for how long
- By what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism).

Examples of ***Data Sharing Statements*** that fulfil ICMJE requirements.
Note: These examples illustrate a range of, but not all, data sharing options.

| | Example 1 | Example 2 | Example 3 | Example 4 |
|---|---|---|---|---|
| **Will individual participant data be available (including data dictionaries)?** | Yes | Yes | Yes | No |
| **What data in particular will be shared?** | All of the individual participant data collected during the trial, after de-identification | Individual participant data that underlie the results reported in this article, after de-identification (text, tables, figures, and appendices) | Individual participant data that underlie the results reported in this article, after de-identification (text, tables, figures and appendices) | Not available |
| **What other documents will be available?** | Study protocol, statistical analysis plan, informed consent form, clinical study report, analytic code | Study protocol, statistical analysis plan, analytic code | Study protocol | Not available |
| **When will data be available (start and end dates)?** | Immediately after publication. No end date | Beginning 3 months and ending 5 years after article publication | Beginning 9 months and ending 36 months after article publication | Not applicable |
| **With whom?** | Anyone who wishes to access the data | Researchers who provide a methodologically sound proposal | Investigators whose proposed use of the data has been approved by an independent review committee ("learned intermediary") identified for this purpose | Not applicable |
| **For what types of analyses?** | Any purpose | To achieve aims in the approved proposal | For individual participant data meta-analysis | Not applicable |
| **By what mechanism will data be made available?** | Data are available indefinitely at (*Link to be included)*. | Proposals should be directed to xxx@yyy. To gain access, data requesters will need to sign a data access agreement.<br>Data are available for 5 years at a third party website. (*Link to be included)* | Proposals may be submitted up to 36 months following article publication. After 36 months the data will be available in our university's data warehouse but without investigator support other than deposited metadata.<br>Information regarding submitting proposals and accessing data may be found at (*Link to be provided*). | Not applicable |

Data Sharing: Eligibility, Terms Of Sharing, Period Of Data Unavailability, and Limits On Data Sharing

**Eligibility:**

- Data sharing will only be for the purposes of health and medical research and within the constraints of the consent under which the data were originally gathered.
- The Custodian of the Collection will not consider any Proposals for data sharing that unblind, or potentially unblind, randomised comparisons in active / ongoing trials.
- Requesters should be employees of a recognised academic institution, health service organisation, commercial research organisation or from the pharmaceutical industry. Requesters must have experience in medical research.
- Requesters must be able to demonstrate through their peer review publications in the area of interest their ability to carry out the proposed use of the requested dataset.
- Conflicts of Interest and Funding Sources:
    - The Requesters must not have a conflict of interest that may potentially influence their interpretation of any analyses.
    - Requesters must declare all actual or potential conflicts of interest in relation to the requested dataset or to previous research conducted by the Requesters.
    - Requesters must also declare funding sources for the requested work for which the requested dataset will be used, and update the ANZIC-RC about subsequent funding sources that are secured after the data are shared with them. All such conflicts of interest and funding sources must also be declared in all publications and presentations resulting from the shared dataset.
    - The ANZIC-RC reserves the right to refuse sharing its data in the face of potential adversarial conflicts of interest.

**Terms of Sharing**:

- The *Requester(s)* will be required to enter into a *Data Sharing Agreement* with Monash University that meets the ANZIC-RC's and Monash University's data sharing requirements.
- Data supplied from a *Collection* may be transferred only to the *Requester(s)* named in the original *Data Sharing Request* and as specified in the relevant *Data Sharing Agreement*. Data from the *Collection* may not be transferred to individuals outside the *Requester*'s research group.
- Supplied data must only be used for the purpose described in the *Data Sharing Request* as stipulated in the *Data Sharing Agreement*.
- All data provided to the *Requester(s)* will be de-identified, and identifying data will not be made available to *Requesters*. The processes for de-identification will be as stated by the relevant study *Custodian* or the *Data Sharing Committee*.
- The *Requester* and individuals within their research group must not attempt to identify any individual from the data provided. Should the *Requester* or individuals within their research group believe that they have inadvertently identified any individual, they must not record such identifiable data, or share the identification with any other person or attempt to contact the individual. Such identification must be promptly reported to the ANZIC-RC.
- Recipients must agree not to link the de-identified data provided with any other dataset without the permission from the *Custodian* or *Data Sharing Committee*.

**Period of Data Unavailability**:

It is the ANZIC-RC's policy that the full data package (comprising the full analysable data set, the full protocol, the full statistical analysis plan, and the analytic code) may be shared with eligible *Requesters* after a reasonable period following study publication, as defined by the *Custodian* or *Data Sharing Committee*. The decision on whether or not to share such data will remain with the *Custodian*, *Data Sharing Committee* and the ANZIC-RC's Director, taking into account any legal, regulatory and ethical considerations.

**Limits on Data Sharing**:
For some research, delays or limits on data sharing may be necessary and appropriate to:

- Safeguard research participants, in particular for research involving samples or information pertaining to human subjects, data must be managed and shared in a way that is fully consistent with the terms of the consent under which samples and data were provided by the research participants
- Allow appropriate opportunity to exploit the dataset for additional pre-specified hypotheses, gain intellectual property protection or to the further development of a technology for public benefit
- Protect against clear conflicts of interest, where analyses may be requested to support commercial aims rather than those related to the broader public good; or
- Meet other legal (including contractual), regulatory, or ethical obligations.

The *Data Sharing Committee* will carefully consider the potential implications of sharing data with a third party, if the third party may derive commercial benefits from the data sharing. Delays or limits on data sharing may be necessary in such circumstances. The *Data Sharing Committee* and the *ANZIC-RC's Director* retain absolute discretion to decide whether access is provided to commercial entities or parties associated, or perceived to be associated with such entities.

**Note:** For prospective studies, consent procedures should include provision for data sharing in a way that maximises the value of the data for wider research use, while providing adequate safeguards for participants. As part of the consent process, proposed procedures for data sharing should be clearly set out. Current and potential future risks associated with this should be explained to research participants. In designing studies, researchers must ensure that they have appropriate systems to protect the confidentiality and security of data pertaining to human subjects, and minimise any risks of identification by data users. This can be achieved through the use of appropriate anonymisation procedures and managed data sharing processes. Such systems should be sufficient to safeguard participants, but proportionate to the level of sensitivity of the data and associated risk. They should not unduly inhibit responsible data sharing for legitimate research uses.

<u>Dissemination of Research Results and Transparency</u>
The ANZIC-RC reserves the right to publish the title, the name(s) and affiliation(s) of the PI(s), a lay summary and a scientific abstract of each piece of collaborative research for which access to the data in a *Collection* has been granted, before identification or publication of results. *Requesters* who do not wish details of their study to be openly available should state this in their *Data Sharing Request Form* and give reasons.

The ANZIC-RC's staff will usually have significant insight into shared data and would usually be able to add value to publications utilising the data in a *Collection*. It would be expected that an ANZIC-RC representative of the original study would be involved as a collaborator on studies resulting from the shared data and be offered co-authorship on resulting publications or presentations. It may be appropriate to acknowledge members of the original study staff who have contributed directly to the original study in order that they may claim authorship as members of the study team.

Each paper to be submitted for publication by collaborators must be forwarded to the relevant *Custodian* for consideration at least 28 days before submission.

<u>Policy Review</u>
To keep abreast of the rapidly developing ideas around data sharing globally, the ANZIC-RC's policy and process on data sharing will be reviewed periodically (at least every twelve months) by the ANZIC-RC Advisory Board.

References

Institute of Medicine. 2015. Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk. Washington, DC: The National Academies Press. https://doi.org/10.17226/18998.

National Health and Medical Research Council. Principles for accessing and using publicly funded data for health research. Canberra: National Health and Medical Research Council. 2016. (ISBN: 978-1-925129-53-3).

Taichman DB, Backus J, Baethge C, Bauchner H, de Leeuw PW, Drazen JM, Fletcher J, Frizelle FA, Groves T, Haileamlak A, James A, Laine C, Peiperl L, Pinborg A, Sahni P, Wu S. Sharing clinical trial data: a proposal from the International Committee of Medical Journal Editors. Lancet 2016;387:e9-e11.

Taichman DB, Sahni P, Pinborg A, Peiperl L, Laine C, James A, Hong ST, Haileamlak A, Gollogly L, Godlee F, Frizelle FA, Florenzano F, Drazen JM, Bauchner H, Baethge C, Backus J. Data sharing statements for clinical trials: a requirement of the International Committee of Medical Journal Editors. Lancet 2017;389:e12-e4.

Wellcome Trust. Policy on data, software and materials management and sharing. Available from: https://wellcome.ac.uk/funding/guidance/policy-data-software-materials-management-and-sharing

## DATA SHARING REQUEST PROCESS

Step 1: Requester Informally Approaches Custodian

- In the first instance, the potential *Requester* is strongly encouraged to informally approach the relevant *Custodian* to discuss the feasibility of data sharing.

Step 2: Data Sharing Request (on pro forma) emailed to ANZIC-RC

- The *Requester* submits a *Data Sharing Request* (using the pro forma, maximum 3 pages – see Form 3) to the ANZIC-RC by email to anzicrc@monash.edu including an outline of the proposed study with a clear statement of the background to the proposed data use, the objectives and details of the methodology proposed, and relevant references.
- The *Requesters* must demonstrate, through their peer review publications in the area of interest, their ability to carry out the proposed study.

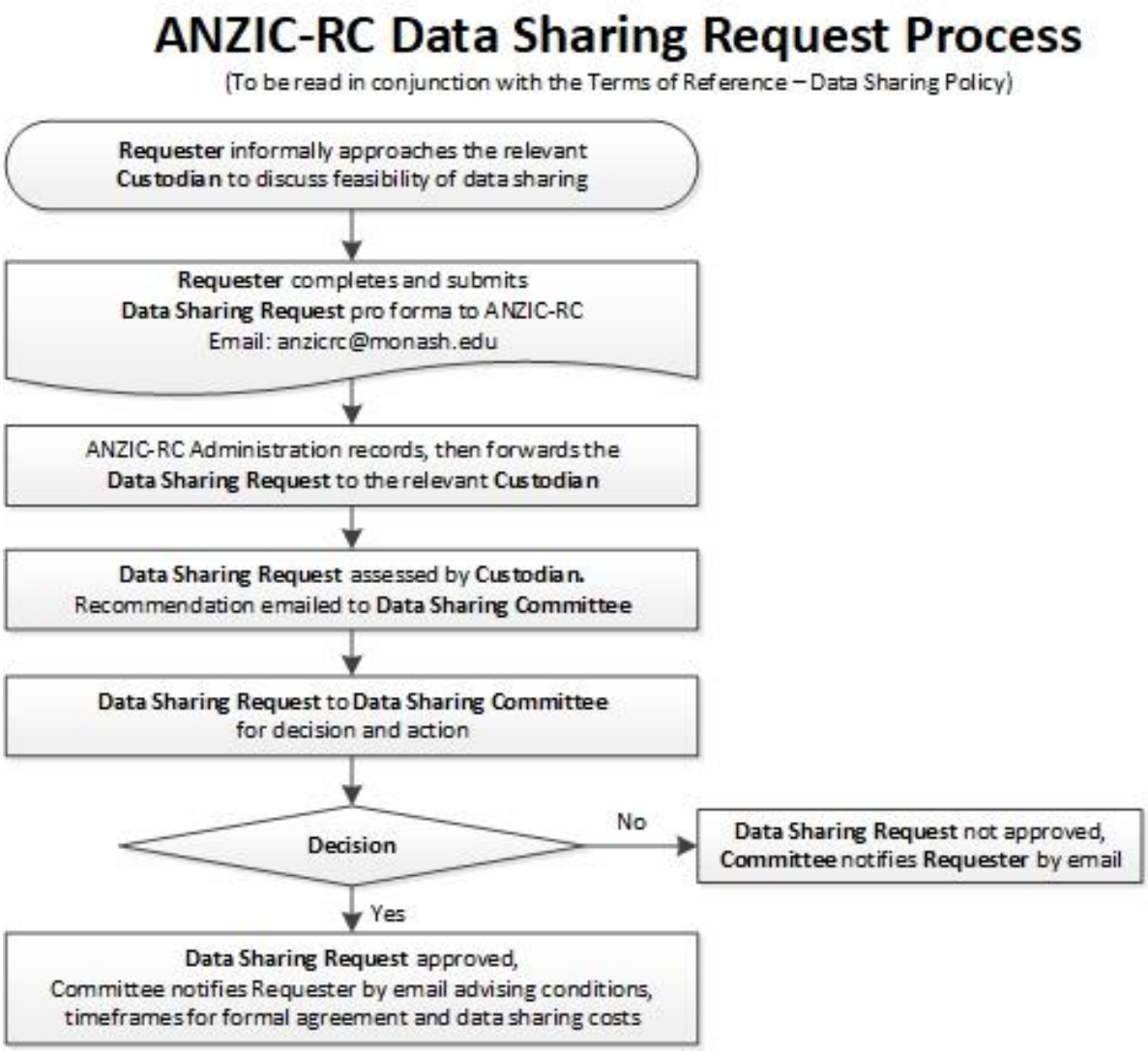
Step 3: Data Sharing Request forwarded to Custodian for recommendation

- The ANZIC-RC Administration records, then forwards the *Data Sharing Request* to the *Custodian*.
- If there is no active *Custodian*, the Chair of the *Data Sharing Committee* will designate an appropriate senior scientist at the ANZIC-RC to act as the ANZIC-RC's *Custodian*.
- The *Custodian* will liaise with the *Requester* to ensure that the *Data Sharing Request* is scientifically sound and achievable. The *Custodian* will email their recommendation to the *Data Sharing Committee* as to whether or not to approve the *Data Sharing Request*.

Step 4: Data Sharing Request to Data Sharing Committee for decision and action

- If approved by the *Data Sharing Committee*, access to data in the *Collection* will only be permitted under a formal *Data Sharing Agreement* with Monash University.
- Where demand exceeds availability of staffing resources to make the data available, access will be prioritised on scientific merit by the *Data Sharing Committee*.
- *Requesters* will be required to cover the costs of administering the data sharing (including legal fees, if applicable), retrieving, processing and sending the data. The estimated costs for a particular request will be provided after initial review of the application.
- Ethics Committee approval from the *Requester's* ethics committee is the *Requester's* responsibility. The *Requester* may also need to obtain approval from the Research Ethics Committee responsible for the existing ANZIC-RC study.
- The *Data Sharing Committee* will:
    - Review and make a decision on the *Data Sharing Request*.
    - Advise the *Requester(s)* of the outcome of the *Data Sharing Request* by email including the conditions of access to the data, the timeframe for the preparation of the *Data Sharing Agreement*, the estimated costs involved in the request.
- The *Data Sharing Coordinator* will be the liaison with Monash University's Office of the General Counsel regarding *Data Sharing Agreements*.
- A *Requester* whose *Data Sharing Request* was not approved may appeal by emailing the ANZIC-RC's Director at anzicrc@monash.edu, outlining why they disagree with the *Custodian's* refusal. The decision of the ANZIC-RC's Director's is final and not subject to further review.

**Figure 1: Data Sharing Request Process**



anzic research centre

# DISCLOSURE OF A CONFLICT OF INTEREST FORM

(This form should be read in conjunction with the ANZIC-RC's Terms of Reference)

MONASH University

## DISCLOSURE

I, (Insert full name) ....., hereby declare that:

☐ I have no conflicts of interest

or

☐ I have disclosed below any actual, perceived or potential conflicts of interest in the past two years regarding my role on the .....

| Category of Interest | Conflict of Interest (Please tick all applicable boxes) | | | Please provide organisation names and amounts |
|---|---|---|---|---|
| | Actual | Perceived | Potential | |
| Grants from industry sources (including research or travel grants) | ☐ | ☐ | ☐ | |
| Industry sponsorship / fellowship (salary) | ☐ | ☐ | ☐ | |
| Honoraria / speaking fees | ☐ | ☐ | ☐ | |
| Conference expenses paid by industry sources | ☐ | ☐ | ☐ | |
| Hospitality or gifts from industry sources (including but not limited to travel, accommodation, meals, entertainment or events) | ☐ | ☐ | ☐ | |
| Industry employment / consultancies | ☐ | ☐ | ☐ | |
| Industry financial interest (includes shares, equity) | ☐ | ☐ | ☐ | |
| Other (intellectual or other relevant interests that, broadly viewed, could be construed as constituting a conflict of interest or the appearance thereof) | ☐ | ☐ | ☐ | |
| Does any immediate family member have any personal or financial interest (including shares) in the outcome of your ANZIC-RC related research projects? | ☐ | ☐ | ☐ | |

I agree to provide the ANZIC-RC with an updated Disclosure of a Conflict of Interest Form whenever there is a change in circumstances that requires disclosure.

*Signature:* ..... *Date:* ...../...../.....

## ARRANGEMENTS PROPOSED TO RESOLVE/MANAGE THE CONFLICT OF INTEREST

The ..... Management Committee has discussed and agreed the following plan to resolve/manage the conflict (attach additional pages if necessary).

.....

.....

.....

.....

*Name of Management Committee Chair:* ..... *Signature:* ..... *Date:* ...../...../.....

## ENDORSEMENT BY THE ANZIC-RC DIRECTOR:

I, (Insert full name) ..... have reviewed the disclosure (and plan where applicable) and:

- ☐ As there is no declared conflict of interest, no further action is necessary in relation to this matter.
- ☐ Believe that a plan to manage the conflict of interest is not required and that no further action is necessary in relation to this matter.
- ☐ Believe that the proposed arrangements outlined in this disclosure will mitigate or remove the conflict of interest but I will continue to monitor the situation.
- ☐ Believe that the proposed arrangements outlined in this disclosure are insufficient and a detailed management plan to mitigate or remove the conflict of interest needs to be developed by the ANZIC-RC Advisory Board in conjunction with the individual who has the conflict of interest.

*Signature ANZIC-RC Director:* ..... *Date:* ...../...../.....

## IF APPLICABLE, MANAGEMENT PLAN DEVELOPED IN CONJUNCTION WITH THE ANZIC-RC ADVISORY BOARD

☐ Agreed management plan attached *Date:* ...../...../.....

## FORM 2 – REQUEST FOR ASSISTANCE FORM


Australian and New Zealand
Intensive Care Research Centre
(ANZIC-RC)

# REQUEST FOR ASSISTANCE FORM

| | |
|---|---|
| Name: | |
| Date: | |
| Institution/Hospital: | |
| Mobile Telephone: | |

### HYPOTHESES

Please list the study hypotheses (maximum 5)

| | |
|---|---|
| 1. | |
| 2. | |
| 3. | |
| 4. | |
| 5. | |

### AIMS

Please list the study aims (maximum 5)

| | |
|---|---|
| 1. | |
| 2. | |
| 3. | |
| 4. | |
| 5. | |

### BACKGROUND

Please outline the background literature to the study being proposed

Email to: anzicrc@monash.edu or Fax to: +61 3 9903 0071
Please note: Referral must not exceed 2 pages (Font size Calibri 12)

| |
|---|
| **ETHICS SUBMISSION AND APPROVAL**<br>Please outline whether ethics approval has been sought and obtained and details of the HRECs who have approved the study. |
| |
| **METHODOLOGY AND PROTOCOL** |
| |
| **IMPORTANCE AND SIGNIFICANCE**<br>Why does the study need to be done? |
| |
| **ASSISTANCE SOUGHT**<br>What specific assistance is being sought from the ANZIC-RC? |
| |

Email to: anzicrc@monash.edu or Fax to: +61 3 9903 0071
Please note: Referral must not exceed 2 pages (Font size Calibri 12)

## FORM 3 – DATA SHARING REQUEST FORM


Australian and New Zealand
Intensive Care Research Centre
(ANZIC-RC)

# DATA SHARING REQUEST FORM

| | |
|---|---|
| Name(s): | |
| Date: | |
| Institution/Hospital: | |
| Email: | |
| Mobile Telephone: | |

### OUTLINE OF THE PROPOSED STUDY

### BACKGROUND TO THE PROPOSED DATA USE

### OBJECTIVES

### METHODOLOGY

### DEMONSTRATE ABILITY TO CARRY OUT PROPOSED STUDY

The Requesters must demonstrate, through their peer review publications in the area of interest, their ability to carry out the proposed study.

### REFERENCES

Email to: anzicrc@monash.edu

Please note: Request **must not exceed 3 pages** (Font size Calibri 12)