Australia and New Zealand Intensive Care Society
Paediatric Study Group
Terms of Reference

Version 4.3
09/10/2024

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List of Abbreviations

Abbreviation	Definition
ANZICS	Australia and New Zealand Intensive Care Society
ANZPIC	Australia and New Zealand Paediatric Intensive Care
ARCAC	ANZPIC Registry Clinical Advisory Committee
CORE	Centre for Outcome and Resource Evaluation
CTG	Clinical Trials Group
PICU	Paediatric Intensive Care Unit
PSG	Paediatric Study Group
SMC	Study Management Committee

Version History

Version Number	Date	Changes
1.0	2016	Initial version
2.0	18/10/2018	Formatting updated
3.0	18/08/2021	Inclusion of allied health representatives; inclusion of researchers affiliated, but not employed, with an ANZ PICU; expansion of working groups *(Working version; not endorsed)*
3.1	09/11/2022	Updated following Committee and PIRCIG Review
4.3	09/10/2024	Update Governance, Committee, working groups, study endorsement, formatting

1. Mission

To promote excellence in paediatric intensive care medicine through collaborative research focused on improving patient-centred outcomes.

2. Aims

- Undertake multicentre research in the field of Paediatric Intensive Care. Wherever possible, the ANZICS Paediatric Study Group (PSG) will aim to undertake research that is inclusive of children admitted to all Intensive Care Units in Australia and New Zealand.
- Provide a point of contact and facilitate collaboration and participation of paediatric units in selected trials proposed by the ANZICS Clinical Trials Group (CTG).
- Provide a point of contact and facilitate participation of Australian and New Zealand units in international paediatric intensive care trials.
- Foster research that will improve the quality and safety of paediatric intensive care in Australia and New Zealand.
- Provide education, training and mentorship relating to research design, conduct and translation of research outcomes into clinical practice.
- Liaise closely with the ANZICS Centre for Outcome and Resource Evaluation (CORE) registry of children admitted to intensive care units in Australia and New Zealand (the Australian and New Zealand Paediatric Intensive Care [ANZPICR] Registry) to undertake combined research with the ANZPIC Registry.

3. Vision

- Facilitate and promote investigator-initiated, collaborative clinical research in paediatric critical illness throughout Australia and New Zealand.
- Foster and promote multidisciplinary and international paediatric research collaboration.
- Foster and promote continuous education to elevate research design, conduct and translation of research outcomes into clinical care.
- Foster the development of sustainable infrastructure and expertise across Australia and New Zealand to enable paediatric intensive care research.
- Co-ordinate the timing and prioritisation of PSG projects.

4. Values

- Foster and facilitate patient-centred research to improve outcomes for paediatric patients and their families.
- Innovation, creativity and intellectual development of scientific thought.
- Respectful and collegiate relationships within our group, the broader paediatric intensive care community, and with collaborators.
- Integrity, responsibility and accountability to ourselves, our patients, and the community.

5. Structure and Governance

5.1 Relationship with ANZICS

The Australian and New Zealand Intensive Care Society (ANZICS) Paediatric Study Group (PSG) committee is a working group of the ANZICS Clinical Trials Group (CTG).

The PSG reports to the ANZICS Board via ANZICS CTG through a Paediatric Co-Chair. A PSG Co-Chair sits as the paediatric representative on the ANZICS CTG Committee.

Administration of the ANZICS PSG is supported by annual ANZICS CTG membership subscriptions received from Intensive Care Units, as per the ANZICS CTG Terms of Reference. Full, affiliate, and honorary memberships are possible.

5.2 PSG Member Units

Any paediatric intensive care service or mixed adult/paediatric ICU facility in Australia or New Zealand that is an ANZICS CTG Member Unit (i.e. contributes the yearly membership subscription) is considered a PSG Member Unit.

5.3 PSG Members

An individual can become a PSG Member if they meet any of the following criteria:

- Employed within a PSG Member Unit; or
- Employed within an affiliated organisation (eg. university) that is collaborating with a PSG Member Unit in the field of paediatric intensive care research.

Medical members must be ANZICS financial members.

5.4 PSG Governance

The PSG governance structure encompasses three primary groups -

- Office Bearers;
- Committee; and
- Working Groups.

5.4.1 PSG Office Bearers

The PSG Office Bearers consists of the following positions:

- Two Co-Chairs (1xmedical, 1xnon-medical researcher [PhD qualified]); and
- Two Vice Co-Chairs (1xmedical, 1xnon-medical researcher [research higher degree in progress or completed]).

The PSG Office Bearers must include representation from at least two regions.

The PSG Office Bearers will be responsible for administrative, strategic, and operational oversight of the PSG. Specific duties will include:

Co-Chairs:

- Oversee the governance and strategic plan of the ANZICS PSG.
- Oversee all endorsement applications unless conflicted.

- Sit on the ANZICS CTG Committee and reports all ANZICS PSG activity to the ANZICS CTG (written & verbal).
- Convenor of ANZICS PSG Scientific Meetings in conjunction with PSG Committee Members.

Vice Co-Chairs:

- Act as proxy in the absence of the Co-Chairs.
- Review and approve all external correspondence (mailing list, social media).
- Oversee endorsement applications when Co-Chairs are conflicted.

5.4.1.1 Election Process

The PSG Co-Chairs and Vice Co-Chairs are elected by anonymous vote (using the preferential method if three or more nominations are received) for a term of two years as follows:

1. Applicants for Co-Chair and Vice Co-Chair positions will occur every two years. Applicants will self-nominate and be elected every second year in February by the PSG Committee. In order to stand for election, the individual must be a current member of the PSG Committee with at least the preceding 18 months experience on the PSG Committee, or have made a strong and active contribution to the PSG in the preceding 18 months (as determined by the ANZICS PSG Immediate Past Chair/s and the Paediatric Chair on the ANZICS Board). ANZICS, through the ANZICS Board Paediatric Chair, must approve all non-full member applications for Office Bearer positions prior to the election. Tenure is renewable once (i.e. a total of four years in one role). Once tenure is completed, members may stand for election in an alternate position.
2. If a PSG Co-Chair or Vice Co-Chair vacates their position mid-term, a replacement will be appointed as described above, as soon as practical to serve the remainder of the term. For all replacements that occur within the last 12 months of a term, the appointment will be for the remaining term (not included in the maximum term limit) and the following two years.

5.4.2 PSG Committee

The PSG Committee shall comprise:

- Two Co-Chairs;
- Two Vice-Co-Chairs;
- Immediate Past Chair/s;
- Director of the Australian and New Zealand Paediatric Intensive Care (ANZPIC) Registry or an appropriate delegate;
- ANZICS Board Paediatric Chair;
- Chair of each PSG Working Group; and
- Representation from each member unit if not already represented above.

The Immediate Past Chair/s will remain for the tenure of their immediate replacements. In the event that the Past Chair/s resign or vacate the position, the Past Chair/s will remain vacant for the remaining tenure of the Co-Chair.

Per fiscal year, PSG Committee Members are required to attend at least two-thirds of Committee meetings and review at least two studies or manuscripts for endorsement. If Committee members do not meet this threshold, their tenure on the Committee will be reviewed.

5.4.3 PSG Working Groups

To progress the vision and achieve the aims of the PSG, the PSG Committee can establish Working Groups in areas deemed to be high priority. The Working Groups will comprise of a Chair, Vice Chair, and interested PSG Members, who commit to supporting the activities of the Working Group and uphold the PSG Terms of Reference. The Working Group Chair will be appointed as per the Working Group Terms of Reference, or by direct invitation by the PSG Office Bearers, approved by the PSG Committee. Working Group/s will be reviewed every two years by the PSG Committee to determine if the Working Group is still required.

5.5 Meeting Structure

5.5.1 PSG Committee

- The PSG Committee have quarterly videoconference meetings and make all reasonable efforts to meet face-to-face bi-annually at ANZICS scientific meetings, including the ANZICS Annual Scientific Meeting, ANZICS CTG Scientific Meetings. In the event that a face-to-face meeting is not achievable, it will be replaced with a videoconference.
- A quorum at the PSG Committee meetings is two members of the PSG Office Bearer group (including at least one of the Co-Chairs) and fifty percent of the Committee members.
- The meeting arrangements and minuting is undertaken by an ANZICS staff member.

5.5.2 PSG Working Groups

- PSG Working Groups will have regular meetings and make all reasonable efforts to meet face-to-face at ANZICS scientific meetings, including the ANZICS Annual Scientific Meeting, ANZICS CTG Scientific Meetings.
- Each Working Group has a Terms of Reference. These are required to be endorsed by the PSG Committee upon any changes.

5.5.3 Scientific Meetings

The PSG conducts scientific meetings each year. PSG scientific meetings aim to provide a forum for education, research related discussions, and the development of study proposals. Other key aspects of these conferences include the development of position papers and operating procedures relating to intensive care research.

Members of the intensive care community are encouraged to submit study proposals or discussion papers for presentation at a PSG meeting. Where feasible, the PSG Committee and Office Bearers should endeavour to promote early career investigators to present study proposals, or study findings. A closing date for submission of presentations will apply. All submissions should be sent to the ANZICS CTG Office or the meeting convener. The PSG Committee will decide which submissions are accepted for presentation.

6. Communication

Communication among the PSG Office Bearers, PSG Committee, and PSG Members is facilitated by a closed mailing list for each, maintained by the ANZICS Office. It is the responsibility of the PSG Committee members to ensure PSG communications are shared with their local unit teams as appropriate.

The PSG Members mailing list is a resource that may be accessed by PSG members for opinion, discussion, and circulation of proposed protocols, and other communication deemed appropriate by the PSG Office Bearers. This provides a peer review forum for

developing studies, facilitates communication between Investigators and PICUs and fosters a network of support and interaction for the large number of individuals contributing to paediatric intensive care research in Australia and New Zealand.

The PSG distributes an annual report detailing research activity and achievements which is included in the ANZICS CTG annual report and published on the ANZICS website.

The PSG is committed to raising the profile of paediatric intensive care research. As such, the PSG may investigate other means of dissemination, including, but not limited to, LinkedIn, Instagram, X, and Facebook. These channels will be administered by a PSG Office Bearer in conjunction with support from the PSG Office Bearers and ANZICS staff.

7. Terms of Reference

The ANZICS Office maintains the PSG Terms of Reference which are reviewed annually. Changes to PSG Terms of Reference are endorsed by the PSG Committee (by majority of votes), then by the ANZICS CTG, and the ANZICS Board.

8. Conflict Resolution

In the event of a conflict within the PSG, parties are encouraged to engage in open and respectful communication to resolve the issue at the earliest stage. If resolution cannot be reached, the matter will be escalated to the PSG Co-Chairs and Immediate Past-Chair/s for review and mediation, with the proposed actions to achieve resolution communicated to the ANZICS CTG Chair for endorsement.

9. Review of studies

The PSG aims to promote studies where the PSG contributes substantially to study design and/or conduct and/or analyses and interpretation. Priority will be given to studies endorsed by ANZICS PSG, or supported by ANZICS PSG, which contribute to the track record and visibility of the ANZICS PSG.

Not all surveys/studies sent to ANZICS PSG for distribution require PSG endorsement or support; there are three different types of review outcomes (Figure 1):

1. Endorsed after appropriate review (Section 9);
2. Supported after appropriate review (Section 10); and
3. Disseminated without detailed review (Section 11).

Studies for review are submitted through the ANZICS PSG website. It is the role of an ANZICS PSG Co-Chair to confirm suitability for the review pathway nominated by the applicant. The review process is overseen by by a Co-Chair. This is delegated to Vice Co-Chair in the event of a conflict of interest for both Co-Chairs, then delegated to the first non-conflicted member PSG Committee member on the following hierarchical list: Past-Chair/s, PIRCIG representative, ANZPICR representative, remaining voting members of the PSG Committee in chronological order of current appointment to the PSG Committee.

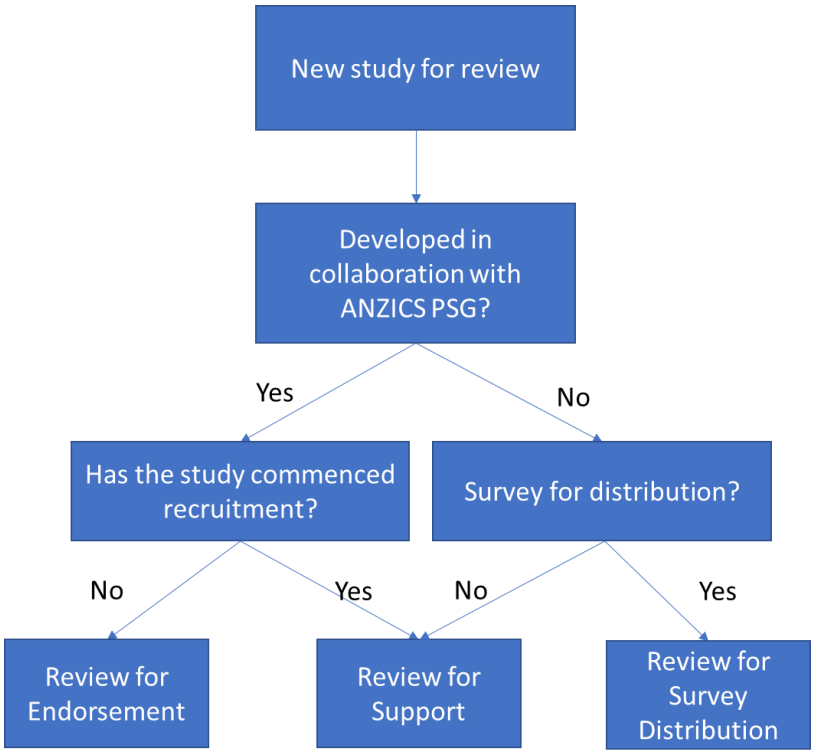

Figure1. Decision tree for level of PSG review

ANZICS staff are responsible for maintaining documentation of conversations and reviews, and provides the final decision to the respective study leads.

10.Review for study endorsement

Studies conducted in association with the ANZICS PSG need to be submitted for consideration as 'PSG Endorsed' studies. The purpose of PSG endorsement is to ensure a consistently high standard of study design, conduct, analysis and dissemination for studies being undertaken in Australian and New Zealand intensive care units involving paediatric patients. The ANZICS PSG endorsement process will ensure that PSG Committee members have had the opportunity to comment on the study, that the study meets requirement for the specific context of paediatric intensive care, that the study has support from the PSG community, and that the study is not competing or conflicting with already endorsed studies.

10.1 Study endorsement criteria

1. Studies must accord with the ANZICS PSG Mission, Vision, and Values statements and must conform to these Terms of Reference and all other relevant PSG policies.
2. Study Chief Investigator A/Co-ordinating Principal Investigator is a PSG Member.
3. Study will involve patients or staff from at least one PSG Member Unit.
4. The PSG Committee will only endorse studies prior to commencement; for studies recruiting participants, they must not have commenced recruitment.
5. The Study Management Committee (SMC) comprises at least two of four of the following positions: intensivist, nurse, allied health professional, and non-clinical researcher (i.e. none mandatory on an individual level, but at least two of those roles must be included). The inclusion of at least one early career investigator, one research co-ordinator, and one consumer on the SMC is expected.

6. New and revised study proposals are encouraged to be presented at a PSG scientific meeting. If this is not possible then the study documentation should be circulated to the PSG mailing list for feedback prior to endorsement submission.
7. An Expression of Interest to participate or collaborate in the study (including ANZPICR-based studies) must be sent to PSG Members via the PSG Committee prior to, or during, the endorsement process.

10.2 Considerations for development of new studies

1. Multicentre collaborative studies are preferred. In certain circumstances PSG may endorse single-centre studies such as pilot studies where PSG members have provided substantial input into study design. In this case, demonstration of benefit to the PSG and alignment with mission and values will be required and reviewed by the PSG Committee.
2. Study proposal development should take into account any potential competition for recruitment with existing PSG endorsed studies.
3. Study proposals must be developed in accordance with ICH-GCP Guidelines[1] and should include:
    a. Nominated Study Management Committee (SMC);
    b. Nominated administering institution(s) (if applicable);
    c. A detailed protocol including a hypothesis, rationale and study aim(s)/objective(s);
    d. Evidence of feasibility including proposed budget, funding strategy, and/or a demonstration of in-principle support from sites;
    e. Consideration of all relevant ethical issues;
    f. Where appropriate, applicants are encouraged to consider the issues of knowledge translation in their proposal; and
    g. For interventional trials, details on the construction, purpose, and membership of a Data and Safety Monitoring Board.
4. Relationship between ANZICS PSG Endorsement and grant applications:
    a. Investigators may not indicate in a grant application that the study is endorsed by the PSG unless formal endorsement has been provided by the PSG.
    b. Investigators may only indicate in a grant application that they have submitted, or intend to submit, the study for PSG endorsement, with the approval of the PSG Co-Chairs.
    c. Obtaining funding for a study is neither a requirement for, nor a guarantee of, PSG endorsement.
5. Relationship between ANZICS PSG Endorsement and commercial entities:
    a. The majority of funding for ANZICS PSG research comes from competitive grants. However, industry may be approached to provide products for investigation or funding support.
    b. Funding or in-kind support from commercial entities may be acceptable but only if the study is investigator initiated and the SMC retains complete and enduring scientific independence including, but not limited to, the design, conduct and reporting of the study, and ownership of data and intellectual property. This must be established in a contract or research agreement (referred to here-in as a contract).
    c. Where a study is presented for endorsement with a clear intention to obtain commercial support the proposed contract should be included in the application. It is recommended that the contract between the SMC (or institutions acting on

[1] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Harmonised Guideline: Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2). 2016.

behalf of, or in conjunction with, the SMC) and the commercial entity is not signed prior to the endorsement process. If no contract is provided ongoing endorsement of the study will be dependent on the PSG Committee approving the contract prior to signing.

d. Submission of a study for PSG endorsement after a contract has been agreed for commercial support is strongly discouraged and may preclude endorsement. Where it is planned that a study will both seek PSG endorsement and commercial support it may be acceptable for commercial negotiations to commence and proceed prior to submission for PSG endorsement but it is strongly encouraged that the PSG be made aware of and have the opportunity to comment on any contract prior to its finalisation. Where a study is submitted for endorsement with a signed commercial support contract already in place endorsement is only possible if the contract is consistent with the PSG principles of interaction with commercial entities. The PSG Office Bearers may require modification of the contract for endorsement to proceed.
e. Where a PSG endorsed study subsequently seeks new or additional commercial support, continued PSG endorsement is dependent on the proposed contract being approved by the PSG prior to signing.
f. Contracts between a management committee and a commercial entity for the provision of supplies and services for the trial at a commercial rate do not need to be approved by the PSG.

10.3 PSG endorsement process

The PSG endorsement process is independent from the ANZICS CTG and the ANZPIC Registry Clinical Advisory Committee (ARCAC). The PSG Office Bearer will work with ARCAC to facilitate streamlining of the ARCAC review process in relation to ANZPICR based multicentre research which is on behalf of PSG and ARCAC.

The following principles apply to the PSG endorsement process:

1. Engagement with the PSG research community is an essential component of the endorsement process. Presentation at an early stage of development is strongly encouraged.
2. Where there is a known deadline for obtaining PSG endorsement of a study proposal (such as for major grant submissions), applications need to be submitted allowing sufficient time for review and revision if recommended. For this reason cut-off dates for submission of endorsement applications will be six weeks prior to major funding round deadlines.
3. Endorsement applications can be built around a grant application or a study protocol or both but must provide a detailed rationale and research plan for the study.
4. The study may be conducted in association with one or more collaborating institutions. If collaboration has been formed at the time of submission for endorsement, these arrangements must be disclosed.
5. The study may be conducted in association with one or more other partner trials or research groups but this must be disclosed at the time of submission for endorsement, or thereafter when collaboration is formed. If a Memorandum of Understanding or other document outlining the relationship between the management committee and a partner research group already exists this should be provided at the time of endorsement or when subsequently developed. The PSG Committee may require the drafting of a Memorandum of Understanding that is acceptable to the PSG Committee, the management committee and the partner research group.

6. Proposals will be endorsed on merit, considering whether the study accords with the Mission, Vision and Values, Terms of Reference, research strategy and research capacity of the PSG.
7. Applications for endorsement must be made using the PSG application for endorsement form (available online: https://www.anzics.org/psg/) and a declaration of any relevant potential conflicts of interest of all investigators. The Study Chief Investigator A/Co-ordinating Principal Investigator may take responsibility for reporting the conflicts of interest for all members of the management committee by providing a signed conflict of interest disclosure on behalf of all investigators. Where one or more members of the investigator team have a conflict of interest, these must be reported for each individual with a conflict of interest. It is the responsibility of the Study Chief Investigator A/Co-ordinating Principal Investigator to update the PSG of any changes to the most recent declaration of conflicts of interest.
8. A PSG Co-Chair, or a delegate from within the PSG Committee, will supervise the review of each submitted study. Members of the PSG Committee who have an established conflict of interest will not be involved in either the supervision or the conduct of a review of an endorsement application.
9. Applications for endorsement may be returned to the SMC without review if they are deemed by a PSG Co-Chair to be incomplete.
10. A PSG Co-Chair will identify at least three individuals to undertake a review of the study. At least one reviewer must be a voting member of the PSG Committee and one reviewer must be an ICU Research Coordinator.
11. All reviewers will be asked to comment on the scientific merit, significance, and feasibility of the proposed study. Assessment of study feasibility will include the resources required to conduct the study at the site level and proposed site payments. Large-scale studies, such as those proposed for NHMRC/MRFF funding, must budget for sufficient resources to cover all reasonable site costs. With respect to site payments, SMCs may propose to provide no payment or payment that is considered below that required to cover site costs but this must be disclosed to prospective sites. If feasibility is considered to be questionable, the PSG Committee may require demonstration of informed, in-principle support from the number of sites deemed necessary to successfully complete the study.
12. If the proposed study is based on ANZPICR data, the PSG Co-Chair overseeing the review should contact ARCAC. It is recommended that, for ANZPICR-based studies, reviewers provide feedback to both ARCAC and PSG, to avoid duplication of review processes.
13. A majority vote of non-conflicted voting members of the PSG Committee will be used to determine the outcome where conflicting opinions exist.
14. Prior to the final outcome being determined additional information or a response to suggested modifications may be requested from the SMC.
15. If a submission for endorsement is rejected the SMC may appeal this decision. Appeals will be heard by the PSG Office Bearers and, where appropriate and by mutual agreement, one or more external reviewers may be engaged to provide an opinion. However, the PSG Office Bearers will make the final decision on endorsement.
16. The PSG Office Bearers aim to ensure that all endorsement applications are reviewed in a thorough and timely manner as such, most endorsement application outcomes will be available within 6 weeks. Under exceptional conditions the PSG Office Bearers will consider requests to undertake an expedited review process.

10.4 Conditions of endorsement

Once endorsed by the PSG, the conditions outlined in Supplement 1 apply for the duration of the study and for all prospectively defined sub-studies. The Principal Investigator will be responsible for ensuring that these conditions are fulfilled.

10.5 Sub-studies of PSG endorsed studies

Sub-studies of an ANZICS PSG Endorsed study are encouraged. A sub-study is a nested study that involves additional aims and collects additional data and/or additional study procedures in some or all of the participants in the parent study. Post-hoc or secondary analysis of data from the parent study is not regarded as a sub-study and does not require submission for endorsement as a project but will require submission for endorsement prior to being submitted for publication.

1. Sub-studies must have the written support of the SMC.
2. The PSG Co-Chairs must be informed of all sub-studies. A PSG Co-Chair will determine whether or not submission for PSG endorsement is required.
3. A sub-study that does not require PSG endorsement may proceed under the guidance of the SMC; however the PSG Committee must be notified of all non-endorsed sub-study manuscripts prior to submission to a journal.

10.6 Sharing of data from PSG endorsed studies

The ANZICS PSG encourages sharing of data, for example, to allow the conduct of individual patient data meta-analyses or other secondary analyses.

1. SMC`s that propose to share data with another group need to obtain approval from a PSG Co-Chair before providing any data to a third party.
2. The PSG reserves the right to require that manuscripts derived from data shared with another group be submitted for review and endorsement prior to publication.
3. Manuscripts derived from data obtained from a PSG Endorsed study that has been shared with another group must acknowledge the role of the PSG in the original study.
4. A copy of the published manuscript is to be provided to the ANZICS Office.

10.7 Management of conflicts of interest during the review process

The PSG is committed to providing a fair and transparent process of review for all endorsement applications.

1. A member of the PSG Committee is regarded as conflicted with respect to an endorsement application if that person is a member of the SMC or a confirmed site Principal Investigator or Site Research Coordinator for that study.
2. Members of the PSG Committee who are conflicted will not participate in the assessment and evaluation of endorsement applications, although they should be available for discussion at the discretion of a PSG Co-Chair. Where all PSG Committee members have an affiliation with a study, the person responsible for supervising the endorsement application will be agreed by majority vote among voting members of the PSG Committee.
3. All members of the PSG Committee, including conflicted members, should be informed of the proposed outcome of endorsement during the endorsement pathway prior to notification of the SMC.

4. Individuals who are not members of the PSG Committee who are invited to review studies and manuscripts on behalf of the PSG Committee must not be involved in the design or conduct of the study.

11.Review for supported studies

11.1 Supported studies eligibility criteria

A study may apply to be formally recognised as a 'PSG Supported Study' if all of the following criteria are met:

a. the study is a collaboration between an ANZ paediatric intensive care research group and other research groups in countries outside Australia and New Zealand;
b. the study is a collaboration of three or more trials groups or organisations;
c. researchers who are based in Australia and New Zealand are not leading the study;
d. it is anticipated that recruitment in Australia and New Zealand will not comprise a plurality of all recruited participants; and
e. in all other respects the study accords with the Mission, Vision, and Values of the ANZICS PSG.

Studies that meet the criteria for endorsement however have already begun recruitment can also be considered to be recognised as a 'PSG Supported Study'.

11.2 PSG review process for supported studies

The following principles apply:

1. PSG supported studies must comply with all criteria and conditions of PSG endorsement set out in the current published version of the Terms of Reference unless otherwise specified in this section.
2. It is the responsibility of the SMC to include at least one researcher from Australia or New Zealand. This individual will have the designated responsibility of ensuring that the conduct of the study and all sub-studies, as well as the sharing of data with third parties, complies with the ANZICS PSG's published Terms of Reference. This individual will also be responsible for liaison with the ANZICS PSG and must be a member or have the opportunity to be a member of the writing committee responsible for manuscripts that are derived from data collected for the study.
3. It is strongly encouraged that the SMC includes at least one study site PICU Research Coordinator.
4. There are three possible outcomes following submission of a study to be recognised as a PSG Supported Study:
    - Approved as a PSG Supported Study;
    - Not approved as a PSG Supported Study although this does not preclude informal assistance such as utilisation of the PSG List and encouragement to the research group to allow sites in Australia and New Zealand the opportunity to participate in the study; or
    - Recommended to be submitted for formal PSG endorsement.
5. The component of a PSG Supported Study that is conducted in Australia and New Zealand must comply with the PSG`s Competing Studies Policy.
6. The ANZICS PSG makes no claim of ownership of data collected by a PSG Supported Study.
7. The ANZICS PSG reserves the right to withdraw the designation of a PSG Supported Study at any time.

8. It is strongly encouraged that a Memorandum of Understanding or some other document, such as a contract, specifies the roles and responsibilities of different groups of researchers or trials groups or both. Any document of this type must be submitted to the PSG Office Bearers for review and approval prior to being signed.

11.3 Conditions of endorsement

Once supported by the PSG, the conditions outlined in Supplement 2 apply for the duration of the study and for all prospectively defined sub-studies. The Principal Investigator will be responsible for ensuring that these conditions are fulfilled.

12. Review for endorsement of clinical guidelines

A clinical guideline may apply to be formally endorsed by ANZICS. As the paediatric interest group within ANZICS, the PSG will review clinical guidelines submitted for ANZICS endorsement that relate to practices undertaken on paediatric patients and make recommendation on the outcome of endorsement application.

12.1 Principles of PSG review process for guideline endorsement

1. The following criteria must be met for guidelines submitted for ANZICS endorsement:
   a) Guidelines must accord with the ANZICS mission, vision and values statements and must conform to all relevant ANZICS policies.
   b) The guidelines have not yet been implemented into clinical practice.
   c) The guidelines will be made available to all ANZ ICUs.
2. The guideline authorship group is strongly encouraged to include at least one (1) individual employed as an ICU nurse and at least one (1) practising intensivist from an Australia and New Zealand PICU.
3. Guidelines for endorsement must be submitted for review using the designated form available online and to the ANZICS CTG Executive Officer.
4. A PSG Co-Chair will oversee the process of review. Two individuals will be identified to undertake a review of the study. At least one reviewer must be a voting member of the PSG Committee and one reviewer must be an ICU Research Coordinator.
5. The PSG Office Bearers will discuss the reviews and come to agreement on recommendation for endorsement, or otherwise. If endorsement is proposed, the guideline will be circulated, along with the reviews, to the PSG Committee for final feedback.
6. A PSG Co-Chair will communicate the outcome of endorsement to ANZICS.

13. Distribution of study information not seeking PSG endorsement or support

If a study or survey was designed and started prior to seeking PSG endorsement, if there is no ANZICS PSG contribution other than dissemination of a survey/expression of interest, or if a study did not meet the requirements for endorsement or support, then a PSG Co-Chair (delegation to other Office Bearer if appropriate) and agreed on by the Office Bearers, can disseminate study material such as survey links and EOI to the PSG Committee or PSG Members, if requested by the respective study lead.

The ANZICS staff is responsible for maintaining documentation of conversations and reviews, and provides the final decision to the respective study leads.

14.Publication policy

1. All manuscripts that report results obtained from ANZICS PSG Endorsed studies (including PSG Endorsed sub-studies) or from post-hoc analyses of a PSG Endorsed study, must be submitted for review and endorsed by the PSG Committee prior to submission for publication. Manuscripts should comply with the uniform requirements for manuscripts submitted to Biomedical Journals published by the International Committee of Medical Journal Editors[2] and with guidelines for reporting of specific study types such as CONSORT[3] and STROBE[4]. Theses that report results from ANZICS PSG Endorsed studies (including PSG Endorsed sub-studies) must be submitted for review by the PSG Co-Chairs prior to submission for examination.
2. All manuscripts that describe aspects of the conduct (e.g. protocols or statistical analysis plans) or secondary discussion papers of a PSG Endorsed study must be submitted for review and endorsed by the PSG Committee prior to submission to a journal for publication. This review may be undertaken by a Co-Chair or another PSG Office Bearer who will determine whether external review is required or whether the Co-Chair or another PSG Office Bearer should recommend endorsement to the PSG Committee without external review.
3. An Expression of Interest from the Study Co-ordinating Principal Investigator will be circulated, via the PSG Committee, for PSG members to nominate as members of the writing group for a manuscript reporting on a PSG endorsed study. Members of the writing group must meet minimum requirements for contribution to maintain authorship.
4. All other manuscripts that are proposed to be published in the name of the group study investigators or the SMC of a PSG Endorsed study (e.g. editorials or review articles) must be submitted for review and endorsed by the PSG Committee prior to submission to a journal for publication. Such manuscripts proposed to be published in individual name(s) that do not include study data do not require PSG endorsement.
5. If the study manuscript is based on ANZPICR data, PSG strongly recommends that the responsible PSG Co-Chair supervising the review contacts the ANZPIC Registry Clinical Advisory Committee (ARCAC). It is recommended that, for ANZPIC Registry based studies, reviewers provide feedback to both ARCAC and PSG, to avoid duplication of review processes. The ultimate decision on endorsement from PSG however will be independent of ARCAC.
6. The default authorship for all PSG Endorsed study manuscripts is:
    - "The X Study Investigators on behalf of the ANZICS Paediatric Study Group" or
    - "Listed individuals and the X Study investigators on behalf of the ANZICS Paediatric Study Group" or
    - "Listed individuals, the X Study investigators, and the X Institution on behalf of the ANZICS Paediatric Study Group"
7. Other arrangements may be acceptable but must be approved by the PSG Office Bearers.
8. The default listing of individuals on lists of investigators or study sub-committees is the Chair followed by in alphabetical order, unless prospectively agreed by the management committee and approved by a PSG Co-Chair.
9. Identification of contributors on study sub-committees, such as steering, data and safety monitoring, statistical and writing committees, who qualify for authorship, will

[2] http://www.icmje.org/recommendations/
[3] http://www.consort-statement.org/
[4] https://www.strobe-statement.org/

be listed in accordance with the respective journal's policy and the PSG Authorship Guidelines (Supplement 3). The nomination and appointment of people to these sub-committees will be determined by the SMC. These sub-committees will comprise of a Chair and other members with the appropriate expertise.

10. All hospitals that participated in the study must be listed in the manuscript or on-line appendix. Individuals who contributed to the conduct of the study at each participating hospital must be listed, and where possible, as collaborators. It is usually the case that this will comprise one or more Site Research Coordinator(s) and the Site Investigator(s). Variations to this requirement may be proposed by journals and may be acceptable with approval from a PSG Co-Chair. Participating institutions will be listed alphabetically; individual(s) will be listed alphabetically within each institution, unless agreed by the SMC otherwise as required by the journal.
11. Manuscripts submitted to the PSG for publication endorsement will be reviewed by at least two persons, at least one of whom is a voting member of the PSG Committee. Manuscripts reporting protocols will be reviewed by one reviewer only. All other aspects of the review process for manuscripts are as described for study proposal endorsements above.
12. Prior to submission to a journal, a copy of the final manuscript must be sent or made available to all participating site Principal Investigators who should be given a reasonable period of time to voice any major concerns to the writing committee.
13. The outcome of submission of a PSG endorsed manuscript to a journal must be disclosed to the ANZICS CTG Office. If a PSG endorsed manuscript is neither submitted for publication, nor accepted at any journal for publication, this must be disclosed to the ANZICS CTG Office. A copy of all ANZICS PSG endorsed manuscripts that are published must be sent to the ANZICS CTG Office.
14. The PSG Office Bearers reserve the right to withdraw endorsement for publication at any stage of the submission for publication process should the scientific quality of a manuscript be deemed substandard or if conflicts cannot be resolved.
15. Studies not endorsed by the PSG should not mention the PSG in applications for funding or publications. This includes non-endorsed sub studies of endorsed studies. The Principal Investigator(s) own the study data. Publications and presentations of these studies must make no reference to the PSG or ANZICS, except for acknowledgments where appropriate (for example, "This study is a sub study of XXX study which was ANZICS PSG endorsed").

Supplement 1: Conditions of Endorsement

1. It is the responsibility of the SMC to obtain resources and conduct the proposed study in accordance with the PSG Terms of Reference and relevant policies applicable at the time of PSG endorsement, and where practical with future revisions. Studies must be conducted with high professional standards and in compliance with codes of research conduct such as the Australian Code for the Responsible Conduct of Research produced by the NHMRC.
2. The SMC will nominate a member, usually the Chair, who is responsible for liaising with the PSG Office Bearers and it is the responsibility of the SMC to update the PSG with respect to any major design or administration changes that occur after endorsement is conferred.
3. The Data and Safety Monitoring Board (DSMB) members for the study must not be currently or historically linked to the study design or SMC.
4. The study will be listed on a clinical trials registry (where applicable).
5. A study progress report, using the standard PSG template, will be submitted to the ANZICS office annually, and additionally as required by the PSG Committee. The ANZICS office should receive study updates that are sent to participating sites.
6. The PSG Committee reserves the right to withdraw endorsement at any stage should the study not progress adequately, if it is not being conducted in accordance with the PSG Terms of Reference, or if irresolvable conflicts of interest arise.
7. Manuscripts arising from the study will comply with the PSG Publication Policy.
8. Results of the primary study must be presented at a PSG Scientific Meeting, and it is preferred that this is the first presentation outside of the study investigators. A verbal presentation or written communication of the results must be provided to all participating sites before or within one month of first presentation, with appropriate confidentiality procedures if required.

Supplement 2: Conditions of Supported Studies

1. Any manuscript that utilises data collected by the study must be submitted to the ANZICS PSG committee prior to submission for publication. A PSG Co- will determine if peer review is required but comments provided by or on behalf of the PSG committee to the management committee will be advisory and non-binding. The PSG committee estimate 14 calendar days to undertake the review of the manuscript.
2. Rules for authorship of manuscripts that report data collected by the study will be determined by the study management committee but if at least one other trials group is named within the author list then ANZICS PSG must also be named. The ANZICS PSG committee must be notified of the proposed author list prior to submission for publication. If the ANZICS PSG is not listed as an author its contribution must be recognised within the acknowledgements section of the manuscript by indicating "This study was supported by the Australian and New Zealand Intensive Care Society Paediatric Study Group (ANZICS PSG)."
3. The PSG Committee must be informed of the forum at which the first public release of results from the primary study analysis will take place.

Supplement 3: Authorship Guidelines

Authorship guide
Each journal will have prescribed guidelines regarding authorship in publications based on International Committee of Medical Journal Editors (ICMJE)[5]. This guide supports the identification of potential authors based on the initial criteria of substantial contributions to the work. It recommends, where possible, that an authorship plan is established prior to the study commencement either through inclusion of contributors as investigators or as part of a writing group. The individuals who conduct the work are responsible for identifying who meets these criteria and ideally should do so when planning the work, making modifications as appropriate as the work progresses.

Authorship
ICMJE states that authors should have made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data. All individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript.

Investigators should be included as authors when they have made substantial contributions to protocol design, including database design, data collection and data cleaning. Data collection and ethics completion alone does not necessarily meet criteria but may need to be discussed with study team. In the event there are multiple data collectors or collaborators meeting criteria, discussion should occur to identify a site representative to contribute to writing of manuscript. All other contributors should be given acknowledgement.

For short projects expected to be completed in less than a year it is anticipated that all named investigators on protocol are invited to be authors. Any researcher contributing to design, data collection, cleaning and analysis should be included on the protocol.

For large multi-site studies it is recommended a representative from each site is included as authors, including site PI and/or a research coordinator. The investigators on the protocol may not meet authorship criteria due to contribution over the life cycle of the project and confirmation of manuscript authorship with the site study team should be undertaken prior to commencing the manuscript preparation. The number of authors should be reflective of the number of participants recruited at the site. Each site study team should confirm key contributors at the site prior to commencing writing; representatives who do not meet contribution criteria should be considered for acknowledgement.

Where possible opportunities should be identified to increase contribution of early career researchers, nurses, and allied health practitioners to the study process including authorship.

Publication
Any person who has made significant contributions to the study should be invited to co-author the publication. All members of the group named as authors should meet all criteria for authorship, as per ICMJE recommendations.

[5] http://www.icmje.org/recommendations/

Contributorship (Acknowledgement)

Contributors who do not meet criteria for authorship should not be listed as authors, however they should be acknowledged. Examples of activities that alone (without other contributions) do not qualify a contributor for authorship are acquisition of funding; general supervision of a research group or general administrative support; and writing assistance, technical editing, language editing, and proofreading. Those whose contributions do not justify authorship may be acknowledged individually or together as a group under a single heading (e.g. “Clinical Investigators” or “Participating Investigators”), and their contributions should be specified (e.g. “served as scientific advisors”, “critically reviewed the study proposal”, “collected data,” “participated in writing or technical editing of the manuscript”). As acknowledgment may imply endorsement of the manuscript, corresponding authors are advised to obtain written permission to be acknowledged from all acknowledged individuals.