



ANZCA
FPM

**ANZCA
CLINICAL
TRIALS
NETWORK**

Guidelines for endorsement Version 5.0

February 2026

Purpose of document:

This guideline articulates the expectations of the Australian and New Zealand College of Anaesthetists (ANZCA), including the Faculty of Pain Medicine (FPM), and the associated conditions relating to ANZCA Clinical Trials Network (CTN) endorsement of documents related to clinical trials in anaesthesia, perioperative medicine and pain medicine. This endorsement process provides an important imprimatur of quality and reflects the highest standards of research. A register of endorsed documents and the associated trials will be maintained and tabled at each CTN executive meeting.

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ANZCA Clinical Trials Network

Guidelines for endorsement

Version 5.0

1. Purpose

This guideline articulates the expectations of the Australian and New Zealand College of Anaesthetists (ANZCA), including the Faculty of Pain Medicine (FPM), and the associated conditions relating to ANZCA Clinical Trials Network (CTN) endorsement of documents related to clinical trials in anaesthesia, perioperative medicine and pain medicine. This endorsement process provides an important imprimatur of quality and reflects the highest standards of research. A register of endorsed documents and the associated trials will be maintained and tabled at each CTN executive meeting.

2. Introduction

The CTN does not sponsor trials or provide ethical approval. The CTN does not provide trial monitoring unless it is delivered by the CTN Office as a specific service. The CTN does not, and cannot, endorse a trial in its entirety. The CTN does not wish to provide extra regulatory burden on applicants above that required by the government regulators, ethics committees and sponsors.

The CTN can, however, endorse documents presented for review. The types of documents that can be endorsed include, but are not limited to:

- Grant applications for trials.
- Trial protocols, including appendices.
- Letters to any third party from an investigator describing a trial, including the concept of a trial.
- Protocols or grant applications for pilot or feasibility studies directly related to a future trial.
- Master protocols or grant applications for platforms that support trial activity, or appendices or protocols describing platform domains.
- A document describing a research question or idea.

Note that the endorsement pertains to the document presented and may not be relevant to further versions of the document, any later modifications to the document or any other aspect or documents of the trial.

The ANZCA CTN aims to be a world leader in delivering high-quality trial evidence that translates into safe and effective practice in anaesthesia, perioperative and pain medicine.

The purposes of the ANZCA CTN endorsement process are to:

- Support and promote a high standard of clinical trial design, conduct, analysis and reporting.
- Increase the competitiveness of grant applications of endorsed clinical trials.
- Strengthen the brand of the ANZCA CTN and its endorsed clinical trials.

- Create a process which serves as a testament to the validity of a clinical trial's principal question, the robustness of the trials design, the feasibility of the trial processes and the ability of the trial team to deliver the trial.
- Facilitate engagement between the trial team, the CTN Office and ANZCA CTN-affiliated sites.

Endorsement by the ANZCA CTN is a powerful badge of quality, adding to the competitiveness of studies in peer-reviewed grant processes, the acceptability of protocols among ethics committees, investigators and study participants, and the attractiveness of completed projects to journal editors and scientific meeting convenors. A rigorous process is therefore essential to ensure that CTN-endorsed trial protocols are of the highest standard and that the evidence resulting from these trials is robust and trustworthy. The endorsement process also poses a reputational risk to the CTN, hence the need for rigour and thorough vetting of applications. When a trial protocol is revised during the course of a trial, the CTN Executive may, at its discretion, require the revised protocol to undergo re-endorsement if the changes are significant. Investigators will need to inform the CTN Office of changes.

3. Body of guidelines

3.1. Endorsing a research idea or question

The ANZCA CTN may offer endorsement at the concept stage, recognising the value of a well-defined research question and the proposed approach to addressing it, even before a full protocol is developed. This is particularly relevant when the research question addresses unmet needs or targets underrepresented populations, including Indigenous, rural, or vulnerable groups, and when the concept aligns with a strategic funding call or national/international priority area.

Early endorsement of the research idea supports the development of competitive grant applications and fosters collaborative input from the CTN network. The research question or idea must be presented in a clearly dated document. The provisional endorsement of a research idea or question does not mean subsequent endorsement of related protocols or grant applications.

Final decisions about the eligibility or appropriateness of an application will be made by the CTN Executive Chair. The CTN will only endorse a trial that has commenced recruitment in exceptional circumstances. The CTN will not endorse a trial after recruitment has been completed.

3.2. The applicants

A corresponding person (who will usually be the applicant) must be named on the document. They will be responsible for all communication with the CTN manager.

They should:

- be fellows and/or trainees of the college.
- be named as a chief investigator on the trial protocol.
- be members of trial committees and/or named investigators on peer-reviewed grant applications.

It is recognised that trial governance and titles of roles within the trial governance structure vary. If the role of the applicant is unclear, then the Chair of the CTN will decide if the applicant has a sufficiently substantive role in the trial governance to be a legitimate applicant.

Documents from ANZCA/FPM trainees who apply for CTN endorsement must identify a supervisor among the investigator list who is considered by the CTN Executive to be an eligible supervisor or mentor. Applications from investigators who are not ANZCA or FPM fellows or trainees will be considered at the discretion of the CTN Executive Chair. Suitable applications include those that foster collaboration between the ANZCA CTN and other trial networks locally and internationally, and promote multidisciplinary and cross-specialty collaboration.

3.3. The application

An endorsement application requires that sufficient detail is presented to enable a proper assessment of the application.

In some cases, endorsement may require referral to appropriate ANZCA staff or committees, such as the CEO, President, Council or Research Committee. This will be at the discretion of the Chair and also guided by the level of sign-off required by applicants.

Such details might include:

- Membership of the Trial Steering Committee and identification of the Australian or New Zealand study sponsor.
- Study aims and the hypotheses to be tested.

- A comprehensive literature review with relevant references.
- A detailed research plan, including methodology and data collection strategy.
- A comprehensive budget, including:
 - Appropriate per-patient payments.
 - Funding for direct trial-related support from the CTN Office.
- A funding strategy, including sources and grant applications.
- Assessment of sample size, statistical power, project timeline, and feasibility.
- Letters or statements of in-principle support from proposed participating sites.
- Consideration of all ethical issues, including consent and participant safety.
- For multinational trials:
 - Countries and sites involved.
 - Principal Investigator's name, institution, and location.
 - Details of any international sponsors.
 - Status of contracts and insurance arrangements.
- If the trial has already commenced, include:
 - Number of participants recruited to date.
 - List of currently active sites.
 - Grants.

Endorsement decisions will also take into account the following:

- Whether or not the required detail is included in the document (see above).
- Alignment of the research question with the CTN's strategic priorities.
- Inclusion of emerging researchers in key leadership roles.
- Evidence of consumer involvement in study design or oversight.
- Involvement of a research coordinator on the management committee.
- Regional and rural site representation.
- New Zealand–Australia reciprocity, where applicable (e.g. NZ investigator involved in an Australian-led trial and vice versa).
- Inclusion of paediatric populations, where relevant.
- Demonstrated access to expert statistical support.
- Peer review feedback received at ANZCA CTN workshops or forums.

3.4. The review process

The CTN Executive Chair or their nominee will identify at least two individuals to undertake a review of the document, including at least one reviewer who is a member of the CTN Executive. A third reviewer who may be a member of the ARCNS Sub-committee or a senior research coordinator in the network may be assigned if any proposed activity could benefit from operational and logistical feedback, such as on operational feasibility.

The reviewers will provide a written report that may include questions, comments and/or suggestions for improvement. The turnaround time for the initial review is 20 working days from receipt of a completed application. Applicants will have two weeks to respond to the reviewers' reports. The reviewers then provide a written recommendation to the CTN Manager regarding endorsement of the document. In the case of a disagreement between the reviewers, the application will be considered by the full CTN Executive.

Trial investigators seeking CTN endorsement prior to applications for grant funding, ethics approvals or other deadlines, are expected to provide adequate notification of intention to submit, with due consideration for issues such as the impact of holiday periods or periods close to national grant deadlines on the availability of suitable reviewers prior to submission deadlines. Requests for expedited review may be considered but cannot be guaranteed. Investigators are strongly advised to seek CTN endorsement before the initial grant application rather than during the grant review process or after the trial has commenced.

If a submission for endorsement is rejected, the applicant may seek reconsideration or review of the decision, or appeal the decision, under ANZCA regulations.

4. Presentation at an ANZCA CTN Strategic Research Workshop

Applicants are strongly encouraged to present proposals at an ANZCA CTN Strategic Research Workshop prior to seeking endorsement. Initial presentation at an early stage of development and re-presentation of refined proposals at subsequent meetings are strongly encouraged. Presentation at an ANZCA CTN Strategic Research Workshop is not an alternative to a written application.

The CTN Executive reserves the right to withdraw endorsement at any stage for any reason. The ANZCA CTN executive may choose to advise any relevant institutions, journals or other bodies if endorsement is withdrawn.

4.1. Involvement of the CTN

It is not mandatory for the CTN executive to be involved in the management or delivery of trials related to endorsed documents. It is, however, preferable for a member of the CTN Executive either to be named as a chief investigator on an approved trial protocol or to serve as the designated liaison with the trial management committee for the purpose of oversight and protection of the integrity of the endorsement process. This is particularly important when a trial is proposed for broad implementation across CTN-affiliated sites.

5. ANZCA partnership letters

Requests for formal partnership require additional review and approval by ANZCA.

5.1 Process and timelines

1. Executive review

- CTN Executive Chair or their delegate will review the request with focus on:
 - Scientific merit (may already be vetted at endorsement).
 - Resource implications for ANZCA, the CTN and the CTN Office.
 - Strategic alignment with ANZCA and CTN priorities.
 - Whether adequate lead time is available to prepare, review and issue the letter.

2. Drafting

- Draft partnership letter is prepared by the CTN Office and forwarded to an authorised College delegate.

3. Review and Approval

- Final approval must be obtained from the ANZCA President or the Chief Executive Officer, as only they can commit College resources to external partnerships.

4. Issuing the letter

- Partnership letter is issued on official ANZCA letterhead, signed by the President or Chief Executive Officer (or delegated authority, if applicable).

6. Letters of support

Requests for letters of support will be assessed by the CTN Chair or delegated to another Executive member and will be provided on a case-by-case basis.

7. Contact

If you need help or further advice, please contact the ANZCA CTN at
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