



ENDORSEMENT OF STUDIES BY THE ACEM CLINICAL TRIALS NETWORK (ACEM CTN)

1. PURPOSE OF POLICY

- 1.1 The ACEM CTN is a Section of the Australasian College for Emergency Medicine, operating in accordance with the ACEM CTN Terms of Reference and with the ACEM Policy on Sections.
- 1.2 The mission of the ACEM CTN is to promote excellence in emergency medicine through collaborative, multi-centre clinical research focused on production of high quality trial evidence that translates into safe and effective practice and improves patient outcomes.
- 1.3 The purpose of this Policy is to ensure that ACEM CTN endorsement is synonymous with a consistently high standard of study design, conduct, analysis, publication and dissemination, and with optimal research capacity and study feasibility. Maintenance of such high quality will ensure that ACEM CTN endorsement of a study and its outputs is considered a 'gold standard'.
- 1.4 The Policy applies to both applicants and ACEM Fellows acting in an official capacity on behalf of the College as members of the ACEM CTN Executive. It outlines the prerequisites, review process, and conditions of endorsement. Endorsement is contingent upon the study steering committee fulfilling and maintaining these terms as outlined below.

2. PRECONDITIONS FOR ENDORSEMENT

- 2.1 A new study proposal is developed by a group of individuals who normally form the study steering/management committee.
- 2.2 The research project must be a clinical research project or clinical audit (not necessarily a clinical trial) that is primarily related to an aspect of emergency medicine. Surveys will not be considered.
- 2.3 Multi-centre collaborative studies are preferred, although single-centre studies may be endorsed.
- 2.4 Programs of research proposing more than one individual study will not be endorsed collectively. Each component of a proposed program must be submitted separately for endorsement.
- 2.5 Unless exceptional circumstances exist, the ACEM CTN Executive will only endorse studies prospectively, that is before they commence recruitment. Presentation of studies at an early stage of development is strongly encouraged.
- 2.6 Study proposals must be developed in accordance with ICH Good Clinical Practice Guidelines and include:
 - Nominated steering committee.
 - Nominated lead institution.
 - A detailed protocol including a hypothesis, rationale, aim(s)/objective(s) and study methodology.
 - Evidence of feasibility, and/or a demonstration of in-principle support from some sites.
 - Consideration of all relevant ethical issues.
 - Where appropriate, applicants should consider the issues of knowledge translation in their proposal.

- 2.7 The study steering committee must include at least two ACEM CTN members.
- 2.8 The inclusion of at least one early career investigator on the study steering committee, and on any related grant applications, is strongly recommended. Collectively the investigators must have a reasonable track record of clinical research.

3. ENDORSEMENT AND GRANT APPLICATIONS

- 3.1 Investigators may not indicate in a grant application that the study is endorsed by the ACEM CTN unless formal endorsement has been approved by the ACEM CTN Executive.
- 3.2 Indication in a grant application of submission (or intention to submit) for ACEM CTN endorsement requires the approval of the ACEM CTN Executive.

4. ENDORSEMENT PROCESS

- 4.1 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.
- 4.2 If the study is to be performed in conjunction with another research group or network this must be made clear in the application.
- 4.3 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 ACEM CTN. The specific criteria to be addressed are outlined in the ACEM CTN Application for Endorsement Form. Applications for endorsement must be made using this Form.
- 4.4 The Chair of the ACEM CTN Executive or a Chair-delegate will supervise the review of each submitted study. Members of the Executive who have an established conflict of interest (for example a member of the steering committee) will not be involved in either the supervision or the conduct of a review of an endorsement application. If the Chair is conflicted, the Executive will appoint a delegate.
- 4.5 The ACEM CTN Chair or Chair-delegate will identify at least two individuals to undertake a review of the study. At least one reviewer must be a voting member of the Executive.
- 4.6 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 the likelihood of recruiting the required patient numbers.
- 4.7 The Chair or Chair-delegate will coordinate the reviews. A majority vote of non-conflicted voting members of the ACEM CTN Executive will be used to determine the outcome where conflicting reviews exist. Endorsement or non-endorsement of a trial will be reported to CAPP who may request a review of the decision. All CAPP members involved in this process shall be subject to the same conflict policy as outlined in Section 6.
- 4.8 Applicants will be notified of the outcome in a timely manner. Review of any decision (appeal) will be made in accordance with the College review and appeals processes.

5. CONDITIONS OF ENDORSEMENT

- 5.1 Once endorsed by the ACEM CTN Executive, the following conditions apply for the duration of the study and for all prospectively defined sub-studies. The chair of the trial steering committee will be responsible for ensuring that these conditions are fulfilled.
 - Studies must be conducted in compliance with codes of research conduct such as the Australian Code for the Responsible Conduct of Research produced by the NHMRC.
 - Trials must be registered with a recognised trial registry authority, preferably the Australian and New Zealand Clinical Trials Registry
 - The steering committee will nominate a member, usually the Chair, who is responsible for liaison with the ACEM CTN Executive, and it is the responsibility of the steering committee to update the ACEM

CTN with respect to any major design or administration changes that occur after endorsement is conferred.

- The steering committee should meet and maintain records of their meetings (for example, minutes or action points) with sufficient frequency to ensure good governance of the study. The records of steering committee meetings will be made available to the ACEM CTN Executive if requested.
- A study progress report will be submitted to the ACEM CTN Executive twice yearly upon request. The ACEM CTN Executive Officer should receive study updates that are sent to participating sites.
- The ACEM CTN Executive reserves the right to withdraw endorsement at any stage should the study not progress adequately, or if irresolvable conflicts of interest arise.
- Manuscripts arising from the study will comply with the ACEM CTN *Publication Policy* (Section 7 below).

6. MANAGEMENT OF CONFLICTS OF INTEREST DURING THE REVIEW PROCESS

- 6.1 The ACEM CTN Executive is committed to providing a fair and transparent process of review for all endorsement applications. A member of the ACEM CTN Executive is regarded as conflicted with respect to an endorsement application if that person is a member of the steering committee or a proposed or confirmed site principal investigator for that study.
- 6.2 Members of the ACEM CTN Executive who are conflicted will not participate in the assessment and evaluation of endorsement applications.
- 6.3 Individuals who are invited to review studies and manuscripts on behalf of the ACEM CTN Executive must not be involved in the design or conduct of the study.

7. PUBLICATION POLICY FOR ENDORSED STUDIES

- 7.1 All manuscripts and theses that report processes of, or results obtained from ACEM CTN-endorsed studies, or from post-hoc analyses of an ACEM CTN-endorsed study, must be submitted for review and endorsed by the ACEM CTN Executive prior to submission for publication or examination.
- 7.2 The default authorship for all ACEM CTN-endorsed study manuscripts must include 'on behalf of the Australasian College for Emergency Medicine Clinical Trials Network (ACEM CTN)' as part of the author line.
- 7.3 Other arrangements may be acceptable but must be approved by the CAPP on the recommendation of the ACEM CTN Executive.
- 7.4 All hospitals that participated in the study must be listed in the manuscript or online appendix. Individuals who contributed to the conduct of the study at each participating hospital must be listed, and where possible, as collaborators.
- 7.5 Manuscripts submitted to the ACEM CTN for publication endorsement will be reviewed in a timely manner by at least two persons, at least one of whom is a voting member of the ACEM CTN Executive.
- 7.6 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.
- 7.7 A copy of all ACEM CTN-endorsed manuscripts that are published must be sent to CAPP via the ACEM CTN Executive Officer.
- 7.8 CAPP reserves 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 on the recommendation of ACEM CTN Executive.

8. DOCUMENT REVIEW

Timeframe for review: Every year, or earlier if required.

8.1 Responsibilities

Document authorisation: Council for Advocacy, Practice and Partnerships (CAPP)
Document implementation: ACEM CTN Executive
Document maintenance: ACEM CTN Administrator

8.2 Revision History

Version	Date of Version	Pages revised / Brief Explanation of Revision
V.1		First version

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