Australasian College
for Emergency Medicine

Endorsement of research projects

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Document Review

Timeframe for review:	Every three years, or earlier if required
Document authorisation:	Council of Advocacy, Practice and Partnerships
Document implementation:	ACEM Research Committee
Document maintenance:	Department of Policy, Research and Partnerships

Revision History

Version	Date	Pages revised / Brief Explanation of Revision
01	May 2014	Procedure created
02	Mar 2016	Minor edits
3	Sep 2016	Edits to criteria – [1.-2nd para] surveys not considered; and [2.2(a)] projects to be completed prior to completion of data collection
4	May 2018	Major revisions to coincide with establishment of ACEM Clinical Trials Network
05	Mar 2020	Major revisions to recognise: • Change in Policy name • Submission of clinical research projects (for endorsement by ACEM Clinical Trials Network) • Submission of epidemiological research projects (for endorsement by the ACEM Emergency Department Epidemiological Network) • Streamlining of all endorsement applications through the Research Committee, who will assign appropriate Executive members for review and decision of a submitted application • Addition of reference articles
6	April 2020	Edits to section 3.2 to remove reference to clinical audit project and study designs that are qualitative
7	May 2021	Further minor edits on governance processes.
8	Sep 2022	Further minor edits.

1. Purpose

The Research Committee oversees the College's research networks, providing strategic direction with regards to the co-ordination, facilitation, endorsement and monitoring of emergency medicine (EM) research.

The purpose of this document is to outline the criteria to be used by the Research Committee in determining whether or not a research proposal is suitable for endorsement by ACEM. This process will ensure that 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 endorsement of a research study and its outputs is considered a 'gold standard'.

The Policy applies to both applicants and ACEM Fellows acting in an official capacity on behalf of the College as members of the ACEM Research Committee, the ACEM Clinical Trials Network (CTN) Executive, and the ACEM Emergency Department Epidemiology Network (EDEN) Executive. It outlines the prerequisites, review process, and conditions of endorsement for clinical and observational research and research projects using large-scale routinely collected health data or registry-based research. Endorsement is contingent upon the study steering committee fulfilling and maintaining these terms as outlined below.

2. Endorsement and grant applications

Investigators may not indicate in a grant application that the study is endorsed by ACEM unless formal written endorsement has been provided by the ACEM Research Committee.

Indication in a grant application of submission (or intention to submit) for ACEM endorsement requires the approval of the ACEM Research Committee.

3. Conditions for endorsement

A new study proposal is developed by a group of individuals who normally form the study steering/ management committee (where applicable).

The research project must be clinical or observational research (not necessarily a clinical trial), or a project using large-scale routinely collected health data or registry-based research that is primarily related to an aspect of emergency medicine. Study designs where the sole component is a survey will not be considered for endorsement. In these instances, applicants are to refer to Standard Operating Procedure No. 262 Advertisement of requests for research project participation, which details ACEM's process for advertising participation in surveys to ACEM members and trainees.

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.

Unless exceptional circumstances exist, the ACEM Research Committee will only endorse studies prospectively, that is before they commence recruitment or data request/extraction/linkage at Australasian sites. Presentation of studies at an early stage of development is strongly encouraged.

3.1 Clinical and observational research study proposals

For clinical and observational research study proposals, it is recommended that the guidelines outlined in the Standard Protocol Items: Recommendations for International Trials (SPIRIT) 2013 Statement[1] are followed. Specifically, the following criteria should be apparent within the study protocol:

Introduction

- Background and rationale, describing the justification for undertaking the trial
- Specific objectives and/or any prespecified hypotheses
- Trial design, including type of trial, allocation ratio, and framework

Methods

Participants, interventions, and outcomes

- Study settings, including references to where a list of study sites can be obtained
- Eligibility criteria (inclusion and exclusion) for participants and study centres (if applicable)
- Intervention(s), including criteria for discontinuing or modifying interventions (if applicable), and any relevant concomitant care and interventions that are permitted or prohibited during the trial
- Primary, secondary, and other outcomes including the specific measurement variable(s), analysis metric, aggregation method, and time point for each outcome (explanation of clinical relevance of chosen outcome is strongly recommended)
- Participant timeline (schematic diagram is highly recommended)
- Sample size, including recruitment strategy for achieving adequate enrolment to reach target sample size

Methods

Assignment of interventions (for controlled trials)

- Sequence generation method, and list of any factors for stratification
- Allocation concealment mechanism
- Blinding (if applicable), including circumstances under which unblinding is permissible and the procedure for revealing a participant's allocated intervention during the trial

Data collection, management, and analysis

- Data collection methods, including any related process(es) to promote data quality, a description of study instruments and the reliability and validity of study instruments (if known)
- Data management
- Data Linkage plans where relevant
- Statistical methods for analysing primary, secondary, and other outcomes, any additional analyses, and any methods to handle missing data

Monitoring

- Data monitoring, including composition of data monitoring committee or an explanation of why such a committee is not needed, and description of who will have access to any interim results and make the final decision to terminate the project
- Harms, including management plans for solicited and spontaneously reported adverse events and other unintended effects
- Auditing procedures and frequency, and whether the process will be independent from project investigator(s) and/or sponsor(s)

Ethics and dissemination

- Research ethics approval
- Protocol amendments, including plans for communicating any important protocol modifications
- Consent or assent
- Patient confidentiality
- Declarations of interest
- Access to data, and data linkage including disclosure of any confidentiality agreements that limit such access for investigators;
- Ancillary and post-trial care provisions (if any);
- Dissemination policy with regards to participants, healthcare professionals, the public, and other relevant groups

3.2 Research study proposals

For research study proposals that involve the use of large-scale routinely collected health data or registry-based research, it is recommended that the guidelines outlined in the Reporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement[2] are followed. Specifically, the following criteria should be apparent within the study protocol.

Introduction

- Background and rationale, describing the justification for undertaking the project
- Specific objectives and/or any prespecified hypotheses

Methods

Participants, interventions, and outcomes

- Study design and setting, including the setting, locations, and any relevant dates (including periods of recruitment, exposure, follow-up, and data collection)
- Participants, including methods of study population selection. Where codes or algorithms will be used to identify subjects, any validation studies of such codes or algorithms should be referenced. If the project will involve linkage of databases, a flow diagram or other schematic representation is recommended to demonstrate the data linkage process and the number of anticipated individuals with linked data at each stage
- Variables, including a complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers. If these cannot be reported, an explanation should be provided
- Statistical methods, including those used to control for confounders, examination of any subgroups and interactions, and those that will address missing data. If applicable, an explanation of how loss to follow-up (for Cohort studies) or how matching of cases and controls (for Case-control studies) will be addressed

Data collection, management, and analysis

- Data sources and methods of assessment for each variable of interest
- Any efforts to address potential sources of bias should be described
- Explanation of how the study size was determined
- Explanation of how quantitative variables will be handled in the analysis including (if applicable) which groupings will be chosen and why
- Data linkage plans where relevant

Monitoring

- Data access and cleaning methods, including the extent to which investigators will have access to the database population used to create the study population
- Linkage and methods of linkage quality evaluation, including a statement of whether the project will include personal-level, institutional level, or other data linkage across two or more databases

Ethics and dissemination

- Research ethics approval
- Protocol amendments, including plans for communicating any important protocol modifications
- Consent or assent
- Patient confidentiality
- Declarations of interest
- Access to data, and data linkage including disclosure of any confidentiality agreements that limit such access for investigators
- Dissemination policy with regards to participants, healthcare professionals, the public, and other relevant groups

4. Endorsement process

Applications can be built around a grant application or a study protocol (or both).

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 Research Committee and CTN or EDEN Networks. The specific criteria to be addressed are outlined in the ACEM Application for Endorsement Form. Applications for endorsement must be made using this form.

- If the study is to be performed in conjunction with another research group or network this must be made clear in the application.
- The Chair of the ACEM Research Committee or a Chair-delegate will supervise the review of each submitted study. Members of the Research Committee 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 Research Committee will appoint a delegate.
- Clinical and observational research projects submitted for endorsement will be assigned to and reviewed by a minimum of three (3) members of the ACEM CTN. Research using large-scale routinely collected health data or registry-based research that is submitted for endorsement will be assigned to and reviewed by a minimum of three (3) members of the ACEM EDEN. At least one reviewer must be a voting member of the Executive. Studies that do not clearly fit within the terms of reference of either the CTN or EDEN will be reviewed by the Research Committee, with external ACEM Fellow reviewers approached as needed.
- All reviewers will be asked to comment on the scientific merit, significance and feasibility of the proposed study. This includes but is not limited to investigator(s) track record in the area of clinical and/or epidemiological research; the ability of the proposed study to enhance the development of EM; the ability of the proposed study to generate results that are of importance to a regional, national or international level;; and the ability of the proposed study to generate novel data and information as opposed to replicating previous or ongoing research studies. Assessments will be made on the prescribed ACEM Application for Endorsement Form.
- The Chair or Chair-delegate will coordinate the reviews. A majority vote of non-conflicted voting members of the ACEM CTN Executive (for clinical and observational research) or ACEM EDEN Executive (for research using large-scale routinely collected health data or registry-based research) or the Research Committee for other projects will be used to determine the outcome where conflicting reviews exist. In instances where there is not one (1) non-conflicted member of the ACEM CTN Executive (for clinical research projects) or the ACEM EDEN Executive (for research projects using routinely collected health data), Executive members of the alternate Network and/or Research Committee will be used.
- Endorsement or non-endorsement of a trial will be reported to the Council of Advocacy, Practice and Partnerships (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.
- 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.

Notification will include the conditions of endorsement (Section 5) and require an acceptance of these conditions by the applicant for endorsement to be effective.

5. Conditions of endorsement

Once endorsed by ACEM, 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.
- Clinical trials must be registered with a recognised trial registry authority, preferably the Australian and New Zealand Clinical Trials Registry.
- The steering committee (where applicable) will nominate a member, usually the Chair, who is responsible for liaison with the ACEM Research Committee, and it is the responsibility of the steering committee to update the ACEM Research Committee 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 Research Committee if requested.
- The steering committee must complete and return the ACEM Endorsed Projects Annual Reporting Form yearly upon request. The ACEM Research Coordinator should receive study updates that are sent to participating sites.
- The steering committee should present an update on the study at the annual ACEM Research Network Symposium.
- The ACEM Research Committee 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 Publication Policy (Section 7 below).

6. Management of conflicts of interest during the review process

The ACEM Research Committee is committed to providing a fair and transparent process of review for all endorsement applications. A member of the ACEM Research Committee, ACEM CTN, or ACEM EDEN 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.

Members of the ACEM Research Committee, ACEM CTN, or ACEM EDEN who are conflicted will not participate in the assessment and evaluation of endorsement applications.

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

7. Publication of endorsed studies

All manuscripts and theses that report processes of or results obtained from ACEM-endorsed studies, or from post-hoc analyses of an ACEM-endorsed study, must be submitted for review and endorsed by the ACEM CTN or EDEN Executive prior to submission for publication or examination.

The default authorship for all ACEM-endorsed study manuscripts must include 'on behalf of the Australasian College for Emergency Medicine Clinical Trials Network (ACEM CTN)' or 'on behalf of the Australasian College for Emergency Medicine Emergency Department Epidemiology Network (ACEM EDEN)' as part of the author line.

Other arrangements may be acceptable but must be approved the Research Committee.

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 acknowledged, and where possible, listed as collaborators.

Manuscripts submitted to ACEM 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 or EDEN Executive.

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.

A copy of all ACEM-endorsed manuscripts that are published must be provided to the Research Committee (and reported to CAPP).

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 Research Committee

References

1. Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin JA et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ. 2013;346:e7586. Available from: https://www.bmj.com/content/346/bmj.e7586

2. Benchimol EI, Smeeth L, Guttman A, Harron K, Moher D, Petersen I et al. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement. PLoS Med. 2015;12:e1001885. Available from: https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001885

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