

Terms of Reference

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Mission

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

Vision

- To facilitate and promote investigator-initiated, collaborative clinical research in intensive care throughout Australia and New Zealand.
- To develop high-quality programs addressing clinically relevant research questions.
- To advance the education and understanding of research methodology and critical analysis.

Values

- Innovation, creativity and intellectual development of scientific thought.
- Respectful and collegiate relationships within our group, the intensive care community and with collaborators.
- Integrity, responsibility and accountability to ourselves, our patients and the community.

Research Strategy

- To develop programs of research directed at patient-centred outcomes expressed as epidemiological studies and large-scale multi-centred trials.
- To validate questions posed by emerging and established research.
- To develop longitudinal programs examining the translation of research into clinical practice.
- To develop and enhance the education, development and training of clinical researchers

Structure and Governance

The Clinical Trials Group (CTG) is accountable to the Board of the Australian and New Zealand Intensive Care Society (ANZICS).

An Executive Committee that is a sub-committee of the ANZICS Board administers the CTG. In addition to a Chair, Vice-Chair, Secretary and Treasurer, this committee consists of a representative from each Australian state and territory, and New Zealand (nominated by the ANZICS Regional Committees), and representatives from the ANZICS Paediatric Study Group (PSG), ANZICS Centre for Outcomes and Resource Evaluation (CORE) and the Intensive Care Research Coordinators Interest Group (IRCIG). Other members, who are co-opted, include the Immediate Past Chair, the CTG Executive Officer, the CTG Executive Assistant, and research strategy leaders as required.

Each ANZICS regional committee will be asked to nominate a representative every two years. Regional representatives may serve consecutive two-year terms if re-nominated by their region. If a regional representative resigns mid-term, the regional committee will be asked to nominate a replacement to serve the remainder of the term.

Elections for CTG Executive office bearers (Chair, Vice-Chair, Secretary and Treasurer) will be held every two years. Office bearers are elected by the CTG Executive Committee. In order to stand for election, the individual must be a current member of the Executive Committee with at least two years experience as either a regional representative or as an office bearer. Tenure for Treasurer and Secretary is two years and is renewable. Tenure for Chair and Vice-Chair is two years, renewable to a maximum of four years in the same position. Once tenure is completed, members may stand for election in a different office bearing position.

The Chair of the CTG is a standing member of the ANZICS Board and the ANZICS Audit, Risk and Finance Committee.

The CTG employs an Executive Officer and administrative staff based at ANZICS House in Melbourne to coordinate the activities of the group. The Executive Officer reports to the CTG Chair and Executive and the ANZICS General Manager and Board.

Executive Committee meetings are held three times per year and business meetings are held in conjunction with the CTG's scientific meetings.

The CTG distributes an annual report detailing research activity and achievements.

Membership

Administration of the CTG is supported by annual membership subscriptions received from Intensive Care Units.

Full Membership

Any public or private Intensive Care Unit in Australia or New Zealand is eligible to subscribe to become a full member of the CTG. Membership fees are payable on 1 July each year from 2011.

Affiliate Membership

Intensive Care Units outside Australia and New Zealand are eligible to subscribe to become an affiliate member of the CTG, providing at least one practitioner working in the unit is a financial member of ANZICS (either Full or Associate).

Affiliate members do not have regional representation on the CTG Executive Committee.

Honorary Membership

Honorary membership may be offered, at the discretion of the CTG Executive, to institutions with whom the CTG has a close and valuable relationship.

Membership Benefits

- Participate in world-class multi-centre research.
 - Participation in CTG endorsed studies is encouraged and welcomed from all suitable ICUs, however where site selection for individual studies is competitive, additional weighting will be given to member units.
- Develop and conduct world-class multi-centre research.
 - Practising Intensivists from Australia and New Zealand on a CTG Endorsed study management committee must be appointed to at least one CTG member unit.
- Demonstrate a program of research and quality assurance for accreditation by training colleges and other certifying bodies.
- A published Annual Report of CTG activity.
- Membership signage to display in your unit.
- Member unit staff are entitled to:
 - Discount registrations at CTG meetings.
 - Automatic access to the CTG Mailing List.
 - Access to the Members' Area of the CTG Website.
 - Access the CTG's Mentor Program for early-career researchers.
 - Apply for study development support subject to the terms and conditions of the CTG's seed funding policy (full members only).
 - Be awarded any prizes given at CTG meetings (full members only).

Policy and Procedure Documents

The CTG maintains policy and procedure documents. These are amended from time-to-time and published on the CTG website (www.anzics.com.au/clinical-trials-group). All references made here-in to terms outlined in policy documents, including these Terms of Reference, will be considered to relate to the current published version.

CTG Endorsed Studies

Prior to April 2007, studies conducted in association with the CTG were classified as 'CTG Owned' or 'CTG Endorsed' studies. The classification of 'CTG Owned' studies ceased to be used in April 2007 after which all studies were submitted for consideration as 'CTG Endorsed' studies.

Current 'CTG Owned' studies and related sub-studies will continue to operate under the original criteria. CTG Endorsed studies must comply with the current requirements of CTG policies and procedures.

A. Development of New Studies

1. A new study proposal is developed by a group of individuals who form the study management committee.
2. Multicentre collaborative studies are preferred, although single-centre studies may be endorsed.
3. Programs of research proposing more than one individual study will not be endorsed collectively. Instead, each component of a proposed program must be submitted for endorsement, separately.
4. Study proposal development should take into account any potential competition for recruitment with existing CTG endorsed studies and comply with the CTG *Competing Studies Policy*.

B. Study Endorsement Criteria

1. Studies must accord with the CTG's mission, vision and values statements and must conform to these Terms of Reference and all other relevant CTG policies.
2. The CTG Executive will only endorse studies prospectively, that is before they commence recruitment.
3. Study protocols must be developed in accordance with ICH GCP Guidelines and should include:
 - Nominated management committee and administering institution(s).
 - Hypothesis, rationale and study aim(s)/objective(s)
 - A detailed research plan
 - Evidence of feasibility including proposed budget, funding strategy, and / or a demonstration of in-principle support from sites.
 - Consideration of all relevant ethical issues
4. The study management committee must include at least one individual employed as an ICU Research Coordinator for the duration of the study.
5. The inclusion of at least one early career investigator on the study management committee and on related grant applications is strongly recommended.
6. Practising Intensivists from Australia and New Zealand on the study management committee must be appointed to at least one Intensive Care Unit that is a CTG member unit.

C. Relationship between CTG Endorsement and Grant Applications

1. Investigators may not indicate in a grant application that the study is endorsed by the CTG unless formal endorsement has been approved by the CTG Executive.
2. Investigators may only indicate in a grant application that they have submitted, or intend to submit, for CTG endorsement with the approval of the CTG Executive.
3. Obtaining funding for a study is neither a requirement for, nor a guarantee of CTG endorsement.

D. Relationship Between CTG Endorsement and Commercial Entities

The majority of funding for CTG research comes from competitive grants. However, industry may be approached to provide products for investigation or funding support.

1. Funding or in-kind support from commercial entities may be acceptable but only if the management committee 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).
2. 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 management committee (or institutions acting on behalf of, or in conjunction with, the management committee) 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 CTG executive approving the contract prior to signing.
3. Submission of a study for CTG 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 CTG endorsement and commercial support it may be acceptable for commercial negotiations to commence and proceed prior to submission for CTG endorsement but it is strongly encouraged that the CTG 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 CTG principles of interaction with commercial entities. The CTG Exec may require modification of the contract for endorsement to proceed.
4. Where a CTG endorsed study subsequently seeks new or additional commercial support, continued CTG endorsement is dependent on the proposed contract being approved by the CTG Executive prior to signing.
5. 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 CTG Executive

E. CTG Endorsement Process

The purpose of CTG endorsement is not only to ensure a consistent high standard of study design, conduct, analysis and dissemination but also to ensure that research capacity and study feasibility is optimised.

1. Engagement with the CTG research community is an essential component of the endorsement process. To be eligible for endorsement, new and revised study proposals must be presented at CTG scientific meetings and presentation at an early stage of development is strongly encouraged. Even if earlier versions of a proposal have been presented previously, the essential elements of the current research plan must be presented at a CTG scientific meeting prior to submission for endorsement.
2. Where there is a known deadline for obtaining CTG 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, the CTG Executive will advertise a cut-off date for submission of endorsement applications prior to major funding round deadlines. These closing dates will be approximately 1 month after the Spring Research Forum for applications to the NHMRC and ANZCA the following year, and 1 month after the Annual Meeting (Noosa) for applications to the Intensive Care Foundation in the same year
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, describe the feasibility and resources required to complete the study and include a study budget and an indicative schedule of payments to participating sites.
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 CTG Executive may require the drafting of a Memorandum of Understanding that is acceptable to the CTG Executive, the management committee and the partner research group.
6. Endorsement applications for studies to be conducted as part of the CTG Point Prevalence Program (PPP) will be submitted to and reviewed by the PPP management committee. Please refer to *Guidelines for investigators accessing the CTG Point Prevalence Program*. Publications arising from PPP studies must comply with the CTG Publication Policy outlined below.
7. 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 CTG.

8. Applications for endorsement must be made using the standard CTG application for endorsement form and be accompanied by a declaration of any relevant potential conflicts of interest of management committee members
9. The Chair of the CTG Executive or a Chair-delegate will supervise the review of each submitted study. Members of the CTG Executive who have an established conflict of interest (e.g. a member of the management 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 Chair-delegate will be the first non-conflicted member on the following hierarchical list: Vice-Chair, Secretary, Treasurer, remaining voting members of the CTG Executive in chronological order of current appointment to the committee.
10. Applications for endorsement may be returned to the management committee without review if they are deemed by the Chair or Chair-delegate to be incomplete.
11. Following acceptance of the application for endorsement a synopsis of the project will be circulated on the CTG Mailing List. This will include contact details of a named member of the management committee who is available to provide additional information about the proposed study directly to members of the CTG research community, and the name and contact details of the CTG Chair or Chair-delegate supervising the review who can be contacted with feedback by any member of the CTG research community.
12. The CTG Chair or Chair-delegate will identify at least three individuals to undertake a review of the study. At least one reviewer must be a voting member of the CTG Executive and one reviewer must be an individual employed as an ICU Research Coordinator.
13. 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 to the NHMRC, must budget for sufficient resources to cover all reasonable site costs. With respect to site payments, management committees 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 CTG Executive may require demonstration of informed, in-principle support from the number of sites deemed necessary to successfully complete the study.
14. The Chair or Chair-delegate will coordinate the reviews and follow the CTG endorsement pathway (see Appendix A). A majority vote of non-conflicted voting members of the CTG Executive will be used to determine the outcome where conflicting opinions exist.
15. Prior to the final outcome being determined additional information or a response to suggested modifications may be requested from the management committee.

16. If a submission for endorsement is rejected the management committee may appeal this decision. Appeals will be heard by the CTG Executive and, where appropriate and by mutual agreement, one or more external reviewers may be engaged to provide an opinion. However, the CTG Executive will make the final decision on endorsement.
17. Most endorsement application outcomes will be available within 3 to 6 weeks. Under exceptional conditions the CTG Executive will consider requests to undertake an expedited review process.

F. Conditions of Endorsement

Once endorsed by the CTG Executive, the following conditions apply for the duration of the study and for all prospectively defined sub-studies.

1. It is the responsibility of the study management committee to obtain resources and conduct the proposed study in accordance with the CTG Terms of Reference and relevant policies. 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 management committee will nominate a member, usually the Chair, who is responsible for liaison with the CTG Executive and it is the responsibility of the management committee to update the CTG with respect to any major design or administration changes that occur after endorsement is conferred.
3. The management committee should meet and maintain records of their meetings (e.g. minutes or action points) with sufficient frequency to ensure good governance of the study. The records of management committee meetings will be made available to the CTG Executive if requested.
4. The study will be listed on a clinical trials registry (where applicable).
5. A study progress report, using the standard CTG template, will be submitted to the CTG Executive Officer twice yearly, and additionally as required by the CTG Executive. The CTG Executive Officer should receive study updates that are sent to participating sites.
6. A study update must be presented at a CTG scientific meeting at least once per year, or more frequently if required by the CTG Executive.
7. The CTG Executive 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 CTG Terms of Reference, or if irresolvable conflicts of interest arise.

8. Study data will be co-owned by the CTG and the study management committee, and, where appropriate, by collaborating institutions. Release of data to third parties may only occur with the agreement of the CTG Executive, the management committee, and, where appropriate, collaborating institutions or partner research groups.
9. Manuscripts arising from the study will comply with the CTG *Publication Policy* outlined below.
10. The forum that will provide the first public release of results from the primary study analysis outside the study investigators must be approved by the CTG Chair or Chair-delegate prior to presentation and a copy of the material (e.g. abstract, poster, slide set) provided for archiving by the CTG office.
11. Results of the primary study must be presented at a CTG 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.

G. Sub-studies of CTG Endorsed Studies

Sub-studies of a CTG Endorsed study are encouraged. A sub-study is a nested observational or interventional study that involves new additional aims and collects additional data and / or additional study procedures in some or all of the subjects 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 study management committee.
2. The CTG Executive must be informed of all sub-studies. The CTG Chair or Chair-delegate will determine whether or not submission for CTG endorsement is required. Circumstances where submission for endorsement will be required include, but are not limited to:
 - Where the sub-study is the subject of a grant application.
 - Where the sub-study will have a different management committee to the primary study.
 - Where the sub-study is to form part of a Higher Degree (please refer to *Conditions Researchers to Conduct Higher Degrees through the CTG*).
3. A sub-study that does not require CTG endorsement may proceed under the guidance of the management committee; however the CTG Executive must be notified of all non-endorsed sub-study manuscripts prior to submission to a journal. Authorship of non-endorsed sub-studies must not include the CTG or group authorship in the name of the primary study, but CTG endorsement of the primary study must be acknowledged in the manuscript.

H. Sharing of Data from CTG Endorsed Studies

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

1. 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.
2. 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.
3. 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.
4. A copy of the published manuscript is to be provided to the CTG Executive Office.

I. Management of Conflicts of Interest During the Review Process

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

1. A member of the CTG Executive is regarded as conflicted with respect to an endorsement application if that person is a member of the management committee or a confirmed site principal investigator for that study.
2. Members of the CTG Executive 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 the Chair or Chair-delegate. Where all CTG executive 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 Executive.
3. All members of the CTG Executive, including conflicted members, should be informed of the proposed outcome of endorsement during the endorsement pathway prior to notification of the study management committee.
4. If the CTG Executive is convened to discuss an endorsement for which the Chair is conflicted, the Chair-delegate will chair the discussion of that endorsement.
5. Individuals who are not members of the CTG Executive (non-executive) who are invited to review studies and manuscripts on behalf of the CTG Executive must not be involved in the design or conduct of the study. This includes members of the study management committee, confirmed site principal investigators or employees of methods centres co-ordinating the study.
6. A Research Coordinator (RC), for the purpose of conducting an RC review of a study on behalf of the CTG Executive, is considered to be an individual currently employed as a Research Coordinator in an intensive care unit.

CTG Supported Studies

1. A study may apply to be formally recognised as a 'CTG Supported Study' if all of the following criteria are met:
 - The study is a collaboration between an ANZ intensive care research group and other research groups in countries outside Australia and New Zealand,
 - the study is a collaboration of three or more trials groups or organizations,
 - researchers who are based in Australia and New Zealand are not leading the study,
 - it is anticipated that recruitment in Australia and New Zealand will not comprise a plurality of all recruited participants,
 - in all other respects the study accords with the mission, vision and values of the ANZICS CTG.
2. CTG supported studies must comply with all criteria and conditions of CTG endorsement set out in the current published version of the Terms of Reference unless otherwise specified in this section.
3. The study management committee must include at least one researcher from Australia or New Zealand approved by the CTG Executive Committee. 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 CTG's published Terms of Reference. This individual will also be responsible for liaison with the ANZICS CTG Executive 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.
4. It is strongly encouraged that the management committee includes at least one Research Coordinator but this is not mandated.
5. The component of a CTG Supported Study that is conducted in Australia and New Zealand must comply with the CTG 'Competing Studies Policy'.
6. Any manuscript that utilises data collected by the study must be submitted to the ANZICS CTG Executive prior to submission for publication. The CTG Chair or Chair-delegate will determine if peer review is required but comments provided by or on behalf of the CTG Executive to the management committee will be advisory and non-binding. The CTG Executive will not take longer than 14 calendar days to undertake the review of the manuscript.
7. 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 so must the ANZICS CTG be named. The ANZICS CTG Executive must be notified of the proposed author list prior to submission for publication. If the ANZICS CTG 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 Clinical Trials Group (ANZICS CTG).

8. The CTG Executive must be informed of the forum at which the first public release of results from the primary study analysis will take place.
9. The ANZICS CTG makes no claim of ownership of data collected by a CTG Supported Study.
10. The ANZICS CTG reserves the right to withdraw the designation of 'CTG Supported Study at any time.
11. There are three possible outcomes following submission of a study to be recognised as a CTG Supported Study:
 - Approved as a CTG Supported Study
 - Not approved as a CTG Supported Study although this does not preclude informal assistance such as utilisation of the CTG List and encouragement to the research group to allow sites in Australia and New Zealand the opportunity to participate in the study
 - Recommended to be submitted for formal CTG endorsement.
12. 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 CTG Executive for review and approval prior to being signed.

Publication Policy

1. All manuscripts and theses that report results obtained from CTG Endorsed studies (including CTG endorsed sub-studies) or from post-hoc analyses of a CTG Endorsed study, must be submitted for review and endorsed by the CTG Executive prior to submission for publication or examination. Manuscripts should comply with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals published by the International Committee of Medical Journal Editors and with guidelines for reporting of specific study types such as CONSORT and STROBE.
2. All manuscripts that describe aspects of the conduct of a CTG Endorsed study (e.g. protocols or statistical analysis plans) must be submitted for review and endorsed by the CTG Executive prior to submission to a journal for publication.
3. All other manuscripts that are proposed to be published in the name of the group study investigators or the management committee of a CTG Endorsed study (e.g. editorials or review articles) must be submitted for review and endorsed by the CTG Executive 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 CTG endorsement.
4. The default authorship for all CTG Endorsed study manuscripts is:
 - “The X Study Investigators and the ANZICS Clinical Trials Group” or
 - “Listed individuals, the X Study investigators and the ANZICS Clinical Trials Group” or
 - “Listed individuals, the X Study investigators, the X Institution and the ANZICS Clinical Trials Group”

Other arrangements may be acceptable but must be approved by the CTG Executive.

5. The default listing of individuals on lists of investigators or study sub-committees is the Chair followed by alphabetical order, unless prospectively agreed by the management committee and approved by the CTG Chair or Chair-delegate.
6. Identification of contributors on study sub-committees, such as steering, data and safety monitoring, statistical and writing committees will be listed in accordance with the respective journal’s policy. The nomination and appointment of people to these sub-committees will be determined by the study management committee. These sub-committees will comprise of a Chair and other members with the appropriate expertise.

7. 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. 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 the CTG Chair or Chair-delegate. Participating institutions will be listed alphabetically; individual(s) will be listed alphabetically within each institution, unless agreed by the Management Committee or otherwise as required by the journal.
8. Manuscripts submitted to the CTG for publication endorsement will be reviewed by at least two persons, at least one of whom is a voting member of the CTG Executive. All other aspects of the review process for manuscripts are as described for study proposal endorsements above.
9. 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.
10. The outcome of submission of a CTG endorsed manuscript to a journal must be disclosed to the CTG Executive Office. Where submission to an alternative journal is planned the name of the new target journal must be provided to the CTG Executive Office. If a CTG endorsed manuscript is neither submitted for publication, nor accepted at any journal for publication, this must be disclosed to the CTG Executive Office. A copy of all CTG endorsed manuscripts that are published must be sent to the CTG Executive Office.
11. The CTG Executive 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.
12. 'Non-CTG' studies should not mention the CTG in applications for funding. The Principal Investigator(s) own the study data. Publications and presentations of these studies must make no reference to the CTG or ANZICS, except for acknowledgments where appropriate.

CTG Mailing List

The CTG Mailing List is a resource that may be accessed by members of the intensive care research community for opinion, discussion and circulation of proposed protocols. This is a closed email list with access restricted from the general public and commercial entities. The list is regulated by a person nominated by the CTG Executive and is audited at least once per year to maintain security.

For further details on access to the list and its appropriate use, please refer to the *CTG Mailing List Guidelines*.

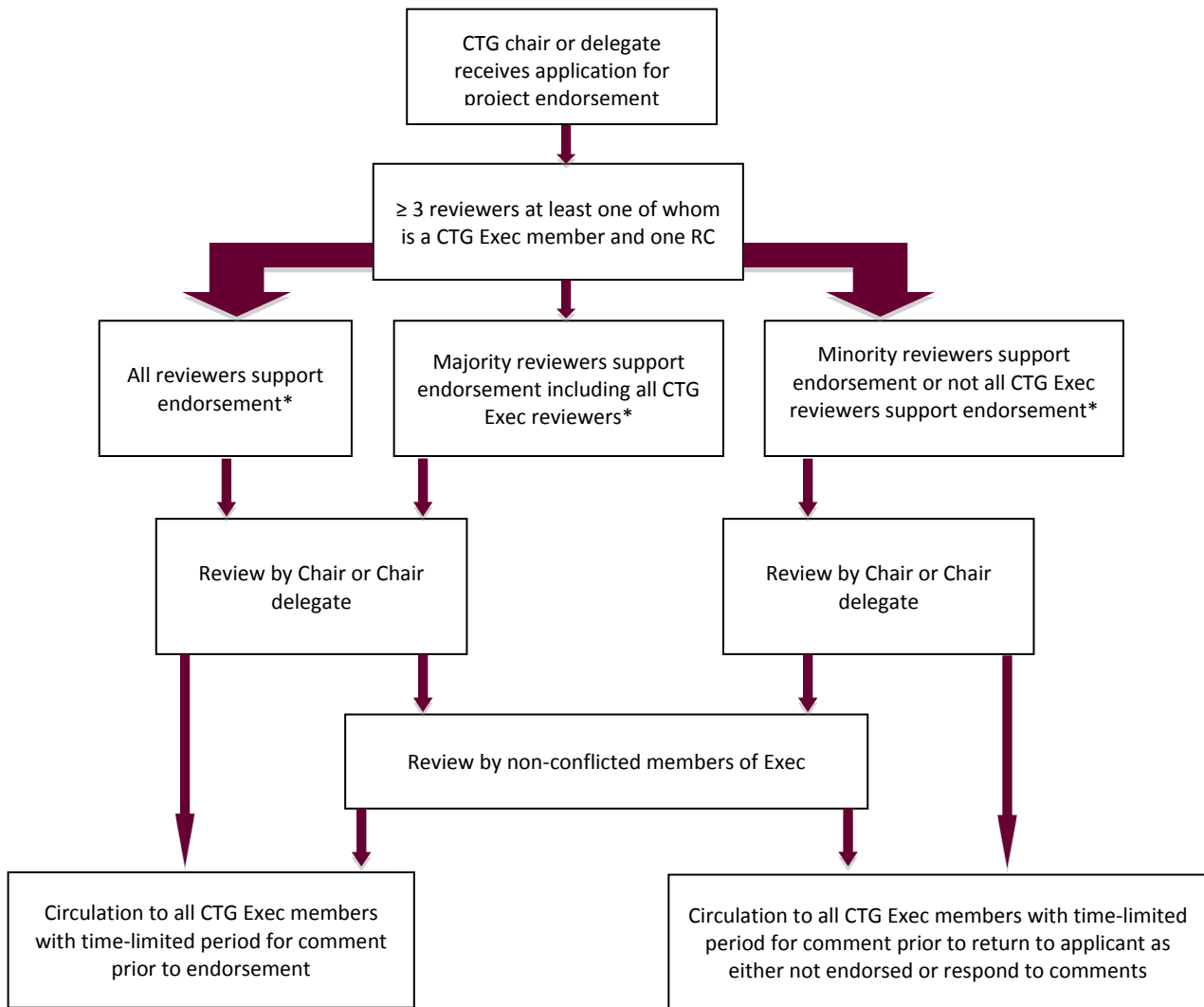
Scientific Meetings

The CTG conducts three major scientific meetings each year. The Annual Meeting on Clinical Trials in Intensive Care is held over three days in March, the Spring Research Forum is held in association with the ANZICS/ACCCN ASM in October and the Winter Research Forum is held in August. CTG meetings aim to provide a forum for research related discussions and particularly the development of study proposals. Other key aspects of these conferences include educational sessions and 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 to be presented at a CTG meeting. A closing date for submission of presentations will apply. All submissions should be sent to the CTG Executive Officer. The conference organising committee will decide which submissions are accepted for presentation.

Presentation of a protocol or proposal at the CTG conference does not alone confer endorsement of the study by the CTG. Studies that have been developed or completed through the CTG email list or conferences, but not officially endorsed as CTG studies, are independent of the CTG ('non-CTG' studies).

Appendix A. Application process for CTG endorsement of a study.



*Applicants may be asked to submit a revised application in response to reviewers' comments or provide justification for comments with which they don't agree before a final decision is made by the Executive.