



**Australian
Clinical
Trials
Alliance**

COMMITTEE TERMS OF REFERENCE

Guidance for CTNs

MAY 2019

*ACTA gratefully acknowledges operational funding from the
Australian Government's Medical Research Future Fund*

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PURPOSE OF DOCUMENT

This document is intended to assist clinical trial networks (CTNs) in establishing Terms of Reference (ToR) for CTN committees.

ROLE OF ACTA IN DEVELOPING TERMS OF REFERENCE

The Australian Clinical Trials Alliance (ACTA) is providing advice to assist CTNs to establish Terms of Reference for CTN committees. The generic advice provided by ACTA should be considered and applied by each CTN taking into account the specific individual circumstances and needs of the network. The following principles are integral to successful CTN operations.

- Decisions should reflect good governance practices, including transparency, identification and management of conflicts of interest, and rules that are applied consistently.
- The CTN Governance structure should recognise the diversity of roles in potential membership and their contributions to a successful CTN.
- The CTN governance structure should be both representative of and responsible to its members.

ACKNOWLEDGEMENTS

We acknowledge the contributions of ACTA CTN members and members of ACTA's Efficient and Effective CTNs Reference Group in the preparation, development and review of this document.

USE OF THIS DOCUMENT

ACTA requests that the following acknowledgement is included in any CTN operational processes that are developed and documented using knowledge gained from this document. This will assist ACTA in identifying the usefulness and impact of this document in creating efficient and effective processes for CTNs.

“[name of CTN] acknowledges the contribution of ACTA to the development of operational processes within our network (reference: Terms of Reference).”

An editable version of this document can be obtained by contacting acta@clinicaltrialsalliance.org.au

DISCLAIMER

The information in this document is for general guidance only. ACTA does not make any representations or warranties (expressed or implied) as to the accuracy, currency or authenticity of the information provided.

DOCUMENT HISTORY

Version	Date	Changes made to document	Author
1.0	14 May 2019	Initial	ACTA Project team, AB, MS ACTA Reference Group A KG, MM, MG, KL, ABo

TABLE OF ABBREVIATIONS

ACTA	Australian Clinical Trials Alliance
CTN	Clinical Trial Network
ToR	Terms of Reference

WHY ARE TERMS OF REFERENCE IMPORTANT TO CLINICAL TRIAL NETWORKS?

A key component of membership engagement in networks is transparent decision-making processes and communication by governance committees. The ToR is a document that outlines the purpose, structure and operating rules of each governance committee. The ToR provides a foundation for the shared expectations and accountabilities of the committee, defines the roles of each committee member, outlines the decision-making process of the committee, and describes the accepted methods of communication to and from the governance committee. Depending on the organisational and business structure adopted by the CTN, the CTN may need to develop a formal constitution. Similar principles as are outlined in the ToR will need to be used in the constitution, although constitutions are normally developed on 'model rules' provided by a regulator. Ideally, the ToR document for governance committees should be accessible to all CTN members e.g on the website.

WHAT MAKES AN EFFECTIVE TERMS OF REFERENCE?

A ToR should be developed collaboratively and approved by the committee. It should be a clear and concise document that can be adapted as the work of the CTN evolves.

The purpose of the governance committee should describe how the committee brings value to the CTN. The responsibilities of the governance committee should be clearly outlined and align with the vision and mission on the CTN. The ToR should clearly state whether the committee has been empowered to carry out certain acts, or whether the remit of the committee is advisory only in nature. The relationship with the other CTN committees and the wider membership should be described, as well as the acceptable methods of communication between these groups. Consideration should be given to whether deliberations of the committee should remain confidential, which will influence whether communications arising from the committee take the form of distribution of the minutes, or a shorter summary of decisions and/or preparation of letters or emails to assign action items to those outside the committee.

A description of the process for becoming a committee member should be detailed, including election, nomination or other method, the required expertise, skills or attributes, a description of the length of term and how many consecutive terms can be served. Any requirement for diversity of the committee (e.g. gender, geographical representation, sub-disease expertise) should be detailed. A process for a committee position that is attainable by all members greatly facilitates membership engagement and confidence within the governance committee. However, it is important that this process also retains corporate knowledge within the committee when key leaders reach the end of their term. Initially, terms for committee members should be staggered, with a proportion of the committee serving a shorter term, so that not all committee members require re-election or re-appointment at the same time. Some committees institute retirement by rotation, where a defined proportion of committee members that have served the longest terms retire from their position and seek re-election or re-appointment.

Office-bearing positions should be named including the process for taking up one of these roles, including election, nomination or other method, and the expected responsibilities of office bearers and other committee members. It may be preferable for office-bearing positions to only be available to members who have already served on the committee. If liaison with particular stakeholders is an expected duty of committee members, this should be stated in the ToR. The ToR should describe

whether co-opted members will be allowed on the committee, and whether they will have voting rights. Co-opted members are usually appointed for a shorter term to fulfil the need for a particular skill set or expertise. The term of the co-opted position should be defined in the ToR. An 'ex officio' committee member has membership by virtue of his/her position or office and voting rights of this position should be stipulated in the ToR. If any positions are to be excluded from attainment of quorum for any meeting, this should be stated in the ToR.

Secretariat support and the process for submitting an item for the agenda should be outlined. CTNs may wish to consider whether items raised from a CTN member will be tabled at meetings of the committee. The process for meeting conduct, including frequency, who can call a meeting, expected preparation prior to meetings and the timeframes and responsibilities for dissemination of any meeting agendas and minutes should be described. Processes for dealing with conflict of interest should be detailed. Among other options, potential conflicts or interests could be declared by submission of an annual form that is assessed confidentially, and form a regular agenda item prior to the commencement of committee business. Whether proxies are allowed and the process for decision-making in the committee and the quorum should be outlined. Regular attendance and collaborative discussion at meetings enable the goals of the committee to advance. The committee may also include in the ToR a process for regular evaluation of committee performance. This may be done by a survey of committee members.

If the committee is to receive a budget for its activities, the committee members that have the delegated authority to commit to expenditure within budget and the process for out of budget expenditure approval should be detailed in the ToR or in a separate finance policy. This section should also detail any payments or reimbursements for committee members.

Lastly, the committee members are generally regarded as representatives of the CTN, and thus their conduct contributes to the maintenance of the brand and reputation of the CTN. It should be considered if it is appropriate for the ToR to include expected conduct of members in dealings of the CTN. It may also be prudent to outline a grievance procedure if a CTN member disagrees with a decision made by the governance committee.

APPENDIX 1 TERMS OF REFERENCE TEMPLATE

1. PURPOSE OF COMMITTEE

This [Committee] was established by [Title and Name] on [date] for the purpose of [Purpose].

2. FUNCTIONS AND RESPONSIBILITIES

The main roles and responsibilities of the Committee are to:

[detail responsibilities]

[The responsibilities of the Committee that have been delegated from the parent Committee include:]

[detail responsibilities]

3. COMPOSITION

The Committee will be composed of [number] members. Members should meet at least one of the following requirements:

CTN Full members

Consumer

Specialist expertise

Diversity requirement of the Committee

Ex officio

Members are nominated to serve on the Committee by a CTN member and elected by the CTN membership. In the case of more nominations than open Committee positions, members will be elected by a process of secret ballot. All elected members are voting members of the Committee.

The Committee may also appoint up to [number] co-opted members or ex officio who contribute a particular skill that is required within the Committee. Co-opted members and ex officio members [do] OR [do not] have voting rights.

Proxies are [allowed] OR [not allowed].

The CTN Executive Officer will attend meetings but does not have voting rights.

3.1 TERMS OF OFFICE

Members elected to the Committee can serve on the Committee for up to [number] consecutive terms of [number] years each. If a member resigns from the Committee prior to the end of their term, new nominations will be requested from the membership. If the new nominee is elected and there is less than 12 months remaining of the replacement term, the elected member will serve an additional term without the requirement for re-election.

Co-opted members will serve on the Committee for as long as their expertise is required, or for [number] years, whichever is shorter.

Members who fail to attend [number] Committee meetings in a row, without adequate explanation, may be replaced, at the discretion of the [Committee] OR [Chair].

3.2 OFFICE-BEARERS

Office-bearing positions of the Committee are the Chair, Deputy Chair [and Treasurer]. Nominations will be accepted from Committee members and agreed by majority vote of the remaining Committee.

The Office-bearers shall serve for a term of office of [number] years, with the option to serve a consecutive term in the position, provided that the term of the Office-bearer falls within their remaining term on the Committee.

The Chair is expected to conduct meetings and is responsible for approving the agenda and minutes and for any reporting that is required. The Chair will also fulfil [specific duties of the CTN].

The Deputy Chair is expected to fulfil the duties of the Chair if he/she is unavailable and fulfil [specific duties of the CTN].

The Treasurer is expected to oversee the financial administration of the [organisation] OR [Committee] and [advise the Committee on financial strategy for the CTN] OR [OTHER].

4. ADMINISTRATION

4.1 MEETINGS

Committee meetings may be held face-to face, by teleconference, videoconference or other electronic means.

Committee meetings shall be held at least [[number] times per year] OR [every [number] months] OR [every [number] weeks]. The Chair may call additional meetings or alter meeting dates and frequency as necessary to address any matters arising.

Committee members are required to be fully prepared for each meeting, having read the documents, and to make every reasonable effort to attend and contribute to each meeting.

4.2 AGENDAS AND MINUTES

All papers must be submitted to the Executive Officer no later than [number] working days prior to the forthcoming meeting for consideration by the Chair. Except with the express permission of the Chair, late papers and tabling of papers will not be accepted.

Agendas and associated documentation will be distributed [number working days] prior to the meeting] OR [forwarded to members in sufficient time to enable consideration prior to meetings, where practicable]. Alternatively, Committee members will be notified by email of the location and availability of material.

The draft minutes including actions arising from each meeting are to be reviewed and approved by the Chair and circulated to all Committee members by the Executive Officer [as soon as practicable] OR [within [number working days] of meeting] OR [by placing on next Committee agenda].

A copy of the minutes, once the Chair has reviewed them, will be included in the agenda papers for the next Committee meeting for ratification.

Responsibility for ensuring appropriate records management for the Committee rests with the Executive Officer under the direction of the Chair of the Committee.

4.3 CONFIDENTIALITY

All deliberations of the Committee are confidential, and all recommendations must be considered confidential.

All new members to the Committee will sign written confidentiality agreements [annually] OR [when first elected to the Committee]. See APPENDIX 2.

4.4 CONFLICTS OF INTEREST

New members to the Committee need to sign a [conflict declaration] OR [declaration of interests]. Each member will sign a [conflict declaration] OR [declaration of interests] annually. See APPENDIX 3 for an example conflict declaration form.

Any potential conflict that arises during the year is to be declared prior to the start of a meeting.

[The Chair] OR [Committee excluding member with conflict] OR [Executive Officer] or [other] will determine whether any declared interest gives rise to a conflict and requires mitigation to ensure appropriate continuation of Committee business and decision-making.

5. CONDUCT

5.1 QUORUM

A quorum for the Committee is defined as [% of the voting members] OR [majority of voting members].

If at any time during a Committee meeting the number of members present is less than a quorum, [the meeting may be adjourned until such time as the Chair may determine], OR [the Committee may meet for discussion purposes only].

5.2 DECISIONS

In general, the Committee will adopt a consensus approach to decision-making, where a majority of members agree, with the remainder content to give way. Any objections are to be noted in the minutes.

Where consensus cannot be achieved, decisions will be made by majority vote. In the event of a tie, [the Chair has the casting vote] OR [the Committee shall escalate issues to [parent Committee]] for a decision. Escalation of issues shall be through the Chair or another invited Committee member as appropriate.

If a decision is required outside of a meeting, this can be conducted [by electronic means] OR [as a circular resolution]. Outside of meeting decisions and any action that has occurred following that decision shall be placed on the agenda of the next meeting [for ratification by the full Committee] and recorded in the minutes of that meeting.

[Include any limitations on exercise of power e.g. The Committee will then report to [XX], and [XX] will be responsible for making the final decision/endorsement.]

6. REPORTING OF COMMITTEE BUSINESS

Committee business will be reported to the wider membership by [distribution of minutes] OR [summary presentation by the Chair at the Annual General Meeting/ Annual Scientific Meeting] OR [letter including detailing specific action items to be undertaken by non-Committee members] OR [communique].

Meeting outcomes will be reported to a parent Committee by [tabling of the minutes at parent Committee meeting] OR [communication by Committee chair to parent Committee].

When the originator of a submission is not a member of the Committee or parent Committee, the outcome of the submission will be reported to the originator of the submission by [letter] OR [verbal communication by Chair or nominated Committee member].

7. RELATIONSHIP WITH EXTERNAL STAKEHOLDERS

The [Committee] OR [specific Committee positions] are required to liaise with the designated external stakeholders:

[list stakeholders, for example, parent Committee or sub-Committee]

8. GRIEVANCE PROCEDURE

Complaints in relation to the activities and operation of the Committee should be made in writing to the Chair or, where the Chair is considered to have a conflict of interest, to the Deputy Chair or the Executive Officer. The complaint will be considered by three nominated Committee members. The decision whether to table the complaint at a Committee meeting will be at the discretion of these three nominated Committee Members. Where the complaint is resolved out of meeting, minutes of the discussion and decision should be recorded, and the outcome of the deliberations communicated to the complainant by letter.

9. [EVALUATION OF COMMITTEE PERFORMANCE]

[Committee performance will be evaluated by survey to be completed by each voting Committee member annually (See APPENDIX 4). Prior to administration of the survey, it should be placed on the agenda to enable the entire Committee to consider its content. The Executive Officer should distribute the survey, collate responses and report aggregate results back to the Committee, together with options for improving performance.

The Committee should consider the results and options for improving performance.]

10. REVIEW AND APPROVAL OF TERMS OF REFERENCE

The Terms of Reference should be approved by the [Chair of Committee] OR [entire Committee] OR [parent Committee].

Amendments to the Terms of Reference need to be approved by the [Chair of Committee] OR [entire Committee] OR [parent Committee].

This Committee shall review these Terms of Reference every [number] years.

Name of the document	[Committee] Terms of Reference
Version	
Reviewed	
Approved	
Next review	
CHAIR	
CHAIR SIGNATURE	
DATE	

APPENDIX 2 CONFIDENTIALITY AGREEMENT

I, _____ (name),

_____ (position) of,

_____ (organisation)

_____ (address),

acknowledge the confidential nature of all activities of the Committee, including all discussions, whether by verbal, written or electronic and all associated documents.

I agree that I will not supply details or copies of documents to any third party outside the Committee except as outlined in the Committee Terms of Reference or agreed to in writing by the Committee.

I understand that my obligations under this agreement continue to have full force and effect when I am no longer a member of the Committee.

Signature _____ Date: ___/___/___

SIGNED on behalf of the [administering CTN] by _____

Position: _____

Signature _____ Date: ___/___/___

APPENDIX 3 CONFLICT DECLARATION

NAME (please print) _____

COMMITTEE NAME _____

PERIOD COVERED BY DECLARATION _____

Once each year, all members of the Committee must provide signed declaration forms describing any arrangements that have been entered into, or have been active, over the previous 12-month period that may give rise to a conflict, including, but not limited to, any financial benefits. These declarations will be recorded in the minutes of the appropriate Committee meeting. It is understood that information provided by the relevant members is for the purposes of disclosing potential conflicts of interest within the group, will not be put to any other purpose, and will be viewed only by the relevant committee. Where in the opinion of the Committee, members are required to lodge a conflict of interest statement and fail to do so within a reasonable period of time, such members will become ineligible to hold any office within the group.

Description of interest	Actions taken by the individual to address the conflict	Steps taken by the Committee for dealing with the conflict

I certify that I have disclosed all interests relevant to my role and will disclose any further interest arising during the year at Committee meetings.

Signed _____ Date: _____

APPENDIX 4 EVALUATION SURVEY

			[Date of issue]
In my opinion, the Committee	Yes:	No:	Needs work:
• safeguards the name and values of the CTN	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• understands and complies with the CTN's governing document (e.g. ToR)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• understands their responsibilities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• is the appropriate <ul style="list-style-type: none"> ○ mix of skills and expertise, ○ mix of personalities ○ degree of diversity to undertake its purpose	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
• appropriately manages conflicts of Interest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• has developed a strategy that <ul style="list-style-type: none"> ○ aligns with the mission and vision of the organisation ○ is proportionate to the capabilities, resources, financial, intellectual property and other resources available to the CTN 	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
• monitors the political and regulatory environment for potential changes to its remit and strategy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• aligns with the organisation's risk expectations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• ensures that all potential risk is assessed and dealt with	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• receives reliable financial projections and financial performance reports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• provides sound financial oversight	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• takes collective responsibility for the performance of the CTN	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• understands the role and delegated authority of any sub-committees/higher committees	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• holds meetings as necessary to properly fulfil their role	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• seeks expert and professional advice when needed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• receives management reports on CTN performance that <ul style="list-style-type: none"> ○ contributes to the strategy ○ provides appropriate remedial actions ○ aligns with the budget 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
• maintains productive, supported and open relationships with key stakeholders	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

• receives full reports of any meetings with key stakeholders	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• [include any additional evaluations pertaining to the specific purposes of the Committee as required]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

In my opinion, the Chair	Yes:	No:	Needs work:
• conducts meetings in a manner that is conducive to productive debate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• allows full and open discussion before decisions are made	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• spend time on meeting items that is proportional to their significance to the CTN	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• effectively addresses arising issues that are impeding meeting progress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

[Optional]

I agree to be contacted by the Chair or Executive Officer for further information regarding my evaluation.

Signed: _____ Date: __/__/__

Name: _____