

Responsibilities of Trial Management Committees

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Summary: This policy statement defines the function(s) of TROG Trial Management Committees and describes the rules for its conduct in accordance with ethical and regulatory guidelines

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Applies to: TROG Trial Management Committee members; TROG staff

Approved by: TROG CEO and Research Manager

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Revision Chronology:	Vs 1: 30 June 1999 (revised April 2005)	New Policy
	Vs 2: 05 Sep 2008	Inclusion of RT & physicist on TMC, site agreement updated, overseas sites agreement added, reference to DMC's role added
	Vs 3: 09 May 2011	Document rewritten to ensure compliance with current TROG Policy Statements and Good Clinical Practice guidelines
	Vs 4: 17 Dec 2013	Document rewritten to ensure compliance with current TROG Policy Statements and Good Clinical Practice guidelines
	Vs 5: 05 Apr 2017	Addition of TMCs reporting responsibilities to the TSC

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1. PURPOSE OF THE TRIAL MANAGEMENT COMMITTEE

As required by TGA ICH Good Clinical Practice Guidelines, TROG, as a sponsor, must utilise qualified individuals throughout all stages of each individual trial, from the design of the protocol and Case Report Forms (CRFs) and planning the analyses to analysing and preparing the interim and final clinical reports¹. TROG complies with these guidelines by establishing a Trial Management Committee (TMC) inclusive of appropriately qualified individuals for each TROG trial.

Each TMC shall be responsible for:

1. Monitoring and supervising the progress of the trial toward its interim and overall objectives
2. Reviewing relevant information from other sources at regular intervals (e.g. other related trials)
3. Considering the recommendations of other advisory committees such as TROG Scientific Committee (TSC), Independent Data and Safety Monitoring Committee (IDSMC) and Human Research Ethics Committee (HREC)
4. In light of 1, 2 and 3, informing the TSC on the progress of the trial
5. Advising the TROG Publications Committee on publicity and presentation of all aspects of the trial, as outlined in the TROG Authorship, Publication and Spokesmanship Guidelines

2. TRIAL MANAGEMENT COMMITTEE COMPOSITION

A TMC is firstly composed of the Trial Chairperson, who shall be a full member of TROG and have overall responsibility for the management of the clinical trial.

Radiation Oncologists from Trial Sites where patient accrual is significant, or who have had a central role in protocol writing and development will be invited to participate. Wide geographical representation from Radiation Oncologists throughout Australia and New Zealand is encouraged. TMC representatives from a country or state other than the location of the Trial Chairperson's centre may provide a pivotal role in coordinating funding approaches for that region, advocating with local stakeholder groups which can influence trial recruitment, and generally facilitating the conduct of the trial in that region.

The remaining composition of the TMC should be developed with consideration for the trial-specific expertise required to provide an appropriate advisory group for development of the trial design and for ongoing monitoring of the trial's progress.

Suggested members of the Trial Management Committee are as follows:

- Medical Oncologist
- Surgical Oncologist
- Radiation Therapist
- Medical Physicist
- Translational Researcher
- Quality of Life

- Health Economist
- Pathologist
- Statistician
- Central Trial Coordinator
- Consumer Advisors

For international collaborative trials, the TROG Trial Chairperson must be included on the Trial Management Committee in order to have access to updates on trial progress and be involved in discussions regarding trial development, activation and management (as appropriate).

The Trial Chair can review the composition of the TMC and alter the composition as necessary throughout the trial. Any change to the TMC will however require an amendment to the protocol.

3. TRIAL MANAGEMENT COMMITTEE GUIDANCE NOTES

3.1 Meetings

During the active phase of all Category A studies, the TMC will meet at least twice yearly and at such other times as it deems necessary.

Conflict of Interest shall be declared at each meeting as described in TROG Policy Statement TPS C5 'Conflict of Interest Guidelines'.

The Trial Chair may delegate the responsibility for calling and organising a meeting to the Central Trial Coordinator. Attachments for the meeting should be circulated well in advance of the meeting and accurate minutes of the meeting should be approved by the Trial Chair, agreed by all members and a copy provided to the TROG Central Operations Office.

A template TMC meeting agenda is provided in Appendix 1.

3.2 Participant Safety

In all the deliberations of the TMC the rights, safety and wellbeing of the trial participants are the most important considerations and should prevail over the interests of science and society. The TMC should ensure that the protocol demands freely given informed consent from every participant. The TMC should look closely at the information provided to the patients and ensure its completeness and suitability³.

3.3 Protocol

The draft protocol should be presented as an agenda item at the first TMC meeting. The TMC must review and approve the final draft protocol before it is submitted to the TSC for final approval. Any amendments made to the protocol during the course of the trial must be approved by the TMC, TSC and the Human Research Ethics Committee (HREC) in accordance with TROG Policy Statement TPS E13 'Protocol Amendment Guidelines for TROG Trials'.

3.4 Progress of the Trial

It is the role of the Trial Chairperson, in consultation with the TMC, to identify timelines throughout all phases of the trial.

During the development phase of the trial, timelines must be set to achieve the trial development milestones and goals outlined in TROG Policy Statement TPSE3 *Guidelines for the progression of trials through TROGs trial timeline*. TROG Central Operations Office can assist with setting and monitoring these timelines however the ultimate responsibility lies with the Trial Chairperson and the TMC. The TROG Scientific Committee has the right to request the withdrawal of any trial in development that does not satisfactorily meet the agreed trial development timelines.

As a trial progresses through the open, closed and completed phases the TMC is responsible for monitoring accrual timelines, data collection and protocol compliance to maximise the chances of completing the study within the time frame specified in the protocol.

3.5 Quality Assurance

The TMC shall monitor the standard and quality of treatment delivered at each Trial Site against the Trial Protocol. The treatment technique must be appropriate for the particular disease site and stage, and the field/treatment verification and dosimetry be conducted in accordance with protocol requirements.

3.6 Independent Data and Safety Monitoring Committee (IDSMC)

An Independent Data and Safety Monitoring Committee (IDSMC) will assess safety data and, if needed, critical efficacy endpoints of a trial. Based on its review the IDSMC shall provide the TMC with recommendations regarding study modification, continuation or termination as per TROG Policy Statement TPSE9 'Guidelines for Data Monitoring Committees'. The TMC may also seek guidance from the IDSMC on queries relating to study conduct and safety that fall within the IDSMC's terms of reference.

The TMC should consider recommendations from the IDSMC, results of other studies and any other new information relevant to the trial. On consideration of this information the TMC should recommend appropriate action, such as amendments to the protocol, additional patient information or stopping of the study in accordance with Section 3.3 above. The most important considerations in these deliberations are the rights, safety and wellbeing of the trial participants.

The Trial Chair and the TMC are responsible for reporting to the TSC any IDSMC's recommended changes and the TMC's recommended actions.

7 Funding

Expenditure on data management, quality assurance, statistical advice and day-to-day running costs must be calculated and administered correctly. If a research grant or other source of funding has been obtained, the Trial Chair (or the first named Chief Investigator on the grant), in consultation

with the TMC, is responsible for ensuring that research funds are expended in accordance with the terms and conditions of the grant and that all reporting requirements are met.

3.8 Litigation

Any action(s) that need to be taken in the event of litigation must be done in consultation with the TROG Board. The Board must be notified immediately in the event of any litigation.

4. REFERENCES

1. Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) annotated with TGA comments, Therapeutic Goods Administration, Australia, July 2000. Available at <http://www.tga.gov.au/industry/clinical-trials-note-ich13595.htm>
2. Statement on Consumer and Community Participation in Health and Medical Research (Endorsed 7th December 2001). Available at: http://www.nhmrc.gov.au/files_nhmrc/publications/attachments/r22.pdf
3. Medical Research Council Guidelines for Good Clinical Practice in Clinical Trials. Available at: <http://www.nus.edu.sg/irb/Articles/MRC%20UK-GCP%20Guidelines.pdf>

APPENDIX 1

Template Trial Management Committee Meeting Agenda

Trial Name and Acronym	
TROG number	
Date of Meeting	
Face to Face meeting	Provide location and directions of where meeting will be held
Teleconference	Provide dial in numbers for each city and or country Provide PIN No.
Time of Meeting	Provide time of meeting taking into consideration different time zones for teleconferences.
Meeting Chair	
Participants	
Apologies	
Attachments	

AGENDA:

1. Declaration of Conflict of Interest
2. Minutes from Previous Meeting
3. Trial Progress
4. Quality Assurance
5. Data Quality
6. New Information
7. Funding
8. Other Business
9. Next Meeting