

# Policy Statement



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## Charter of the TROG Scientific Committee

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**Summary:** This policy statement defines the function(s) of the TROG Scientific Committee and describes the rules for its conduct in accordance with the constitution of TROG

**Author:** TROG Board of Directors

**Applies to:** TROG Scientific Committee members, TROG staff

**Approved by:** TROG Board of Directors

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<b>Revision Chronology:</b>	Vs 1: 01 Aug 2008	Original document
	Vs 2: 09 Aug 2013	Updated to reflect changes in TROG policies and procedures
	Vs 3: 17 Feb 2015	Update to TROG Board appointment of TSC Chair
	Vs 4: 04 August 2016	Updated composition of TSC and meeting agenda

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## **1.0 TROG SCIENTIFIC COMMITTEE**

The TROG Scientific Committee is a committee of the Board of TROG, appointed by the TROG Board in accordance with the TROG constitution.

## **2.0 ROLE OF THE SCIENTIFIC COMMITTEE**

The role of the Scientific Committee is to:

- (a) ratify TROGs participation in all clinical trials;
- (b) assist in the development of new clinical trial proposals which have been approved by the members of TROG;
- (c) oversee ongoing clinical trials to ensure they are being properly supervised by their Trial Management Committee;
- (d) advise the Board on scientific matters that may arise from time to time and which the Board may ask the Scientific Committee to address;
- (e) where the Scientific Committee deems it necessary, initiate an independent audit on any ongoing clinical trial and, if necessary, act on that audit, and;
- (f) perform any additional duties set out in the Scientific Committee charter or which the Board may ask it to perform from time to time.

## **3.0 COMPOSITION OF THE SCIENTIFIC COMMITTEE**

The Scientific Committee comprises:

- Scientific Committee Chair – Radiation Oncologist
- Publications Portfolio Leader – Radiation Oncologist
- Additional Advisor - Radiation Oncologist
- Additional Advisor - Radiation Oncologist
- Discipline Representative - Statistics
- Discipline Representative – Radiation Therapist
- Discipline Representative - Medical Oncology
- Discipline Representative - Physics
- Discipline Representative - Health Economics
- Special Advisor – (discipline as appointed by the committee)
- Independent Consumer Representative
- TROG Chief Executive Officer/ Research Manager
- TROG Quality Assurance and Grants Manager

All members (except Independent Consumer Representative and TROG staff representation) are to be TROG full members.

## **4.0 APPOINTMENT AND TERM**

The Scientific Committee Chair becomes a member of the TROG Board on their appointment to this position and cease to be on the Board when they no longer hold the position of Scientific Committee Chair.

The other members of the Scientific Committee will be appointed by the Board for a two year term and are eligible for re-appointment by the Board at the conclusion of each term.

## **5.0 REGULATORY AND ETHICAL CONSIDERATIONS**

The Scientific Committee will comply with the regulations and guidelines included in TROG Policy Statement TPS E2 'Ethical Principles for the Conduct of TROG Clinical Trials'.

## **6.0 PROCEEDINGS OF THE SCIENTIFIC COMMITTEE**

### **6.1 Frequency of meetings**

The Scientific Committee will meet at a minimum of three times a year including at the Annual Scientific Meeting.

### **6.2 Length of meetings**

It is anticipated that each meeting will run for approximately two hours.

### **6.3 Notice of meetings**

TSC meetings will be scheduled in advance and all meeting documentation shall be submitted to the TSC members by the TROG Central Operations Office Assistant Research Manager or Research Manager 21 days prior to the date of the meeting.

### **6.4 Quorum**

- (a) no business will be transacted unless a quorum is present;
- (b) any five members of the Scientific Committee constitute a quorum for the transaction of the business of a meeting of the Scientific Committee;
- (c) if a quorum is not present at the meeting within half an hour of the time appointed for the meeting, the meeting will be adjourned to a time and place to be determined by the Scientific Committee Chair.

### **6.5 Chair**

At meetings of the Scientific Committee:

- (a) the Scientific Committee Chair will chair the meeting, or;
- (b) if the Scientific Committee Chair is absent, the members present will choose another member to chair the meeting.

## 6.6 Agenda at meetings

At its meetings, the Scientific Committee will:

### 6.6.1 Trials approved for development

- (1) review results from the Expression of Interest surveys and, from this, determine whether the accrual target is reasonable and achievable at participating centres and if it is feasible for the trial to undergo further development.
- (2) monitor the progression of the trial in development against the TROG trial development milestones listed below:
  - Protocol
  - Statistical Requirements
  - Trial Budget and Funding
  - Trial Management Committee
  - Trial Coordinating Centre
  - Quality Assurance
  - Case Report Forms (CRFs)
  - Database
  - Indemnity, contractual and regulatory documentation
- (3) approve the trial for activation and allocation of a TROG number when the above milestones have been achieved to the satisfaction of all members of the Scientific Committee. Milestones dependant on the outcome of funding such as Electronic Case Report Form (eCRF) development, and contractual and regulatory documentation may continue to be developed after the allocation of a TROG number.
- (4) approve the trial as 'open' when all milestones have been achieved and the first participating centre is activated and ready to commence accrual.

### 6.6.2 Open trials

- (1) determine whether accrual is proceeding at a satisfactory rate;
- (2) determine whether toxicity is acceptable;
- (3) consider whether data collection and quality assurance procedures are satisfactory;
- (4) review any feedback from the independent data safety monitoring committee (IDSMC);
- (5) review any protocol amendments, and;
- (6) acknowledge when a trial closes to accrual.

### 6.6.3 Trials closed to accrual

- (1) if applicable, monitor long-term toxicity during the follow-up phase;

- (2) consider whether data collection and quality assurance procedures continue to be satisfactory;
- (3) review any feedback from the independent data safety monitoring committee (IDSMC);
- (4) consider all planned analyses;
- (5) consider any delays in publication of results and disputes in the interpretation of results or names on publications with reference to the Authorship, Publication and Spokesmanship Guidelines;
- (6) monitor trial close out procedures, and;
- (7) acknowledge when a trial is completed.

#### 6.6.4 Completed trials

- (1) acknowledge publication of results and consider disputes in the interpretation of results or names on publications with reference to the Authorship, Publication and Spokesmanship Guidelines.

#### 6.6.5 Other Business

- (1) acknowledge updates and recommendations from the New Technologies and Treatments Committee
- (2) acknowledge updates and recommendations from the Publications Committee
- (3) acknowledge updates and recommendations from the TROG Subspecialty Groups
- (4) acknowledge updates and recommendations from the New Proposal Committee

### 6.7 Reporting

As soon as practicable after each meeting the Scientific Committee will provide minutes of the meetings to the Board, which are to include

- (a) recommendations for trials approved for development and activation
- (b) recommendations for open trials, and
- (c) recommendations about delays in publication or results and any disputes in the interpretation of results or names on publications with reference to the Authorship, Publication and Spokesmanship Guidelines for closed and completed trials.

### 6.8 Voting

- (a) Questions arising at a meeting of the Scientific Committee will be determined on a show of hands or, if requested by a member, by a poll taken in the manner directed by the person presiding at the meeting.
- (b) Each member present at a meeting of the Scientific Committee (including the person presiding at the meeting) is entitled to one vote and, in the event of a parity of votes on any question the person presiding may exercise a second or casting vote.