



Trans Tasman Radiation Oncology  
Group Limited  
ACN 132 672 292

# TROG POLICY AND PROCEDURES

## Responsibilities of Trial Management Committees

**TPP E8**

**Version 2: 5<sup>th</sup> September 2008**

(Always refer to the TROG website to check for the current version of this policy)

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## **1. Trial Management Committee Composition**

The Trial Management Committee (TMC) will normally be composed of the Trial Chairperson and representatives from Trial Sites where patient accrual is significant, or who have had a central role in protocol writing and development.

The TMC must also include the Trial Statistician, the Trial Co-ordinator, members of other disciplines and/or members of other collaborating trial groups who are involved in the conduct of the trial. Wide geographical representation is encouraged.

If the trial is of a technical nature, the TMC should also include a radiation therapist and a medical physicist.

A representative from the TROG Central Operation Office (TCOO) will be in attendance at TMC meetings when required.

It is envisaged that the TMC composition may change during the conduct of the trial, e.g. if new Trial Sites become involved. Please notify the TCOO of any changes.

### **1.1 Trial Executive Committee**

Occasionally a sub committee of the TMC is formed (usually in larger trials with the involvement of many Trial Sites), this sub committee is referred to as the Trial Executive Committee (TEC) and consists of a select few Principal Investigators (PIs) who expedite discussion on the day to day management of the trial.

### **1.2 Trial Chairperson**

The Trial Chairperson must be a Full member of TROG

The Trial Chairperson will usually act as spokesperson for the trial. However, it is not anticipated that the Trial Chairperson will make decisions or statements without prior discussion with the committee.

### **1.3 Meetings of the Trial Management Committee**

It is envisaged that the TMC will meet twice yearly, at the Annual Scientific Meeting (ASM) and Trials Review Meeting (TRM), and at such other times as it deems necessary. These other meetings could be held via teleconference (refer to Appendix 1 for teleconference organisation instructions). It is also envisaged that minutes of these meetings will be kept and that copies will be sent to the TCOO for information.

## 2. Trial Management Committee Responsibilities

The TMC must advise and obtain approval from the TROG Scientific Committee (TSC) before acting on important decisions such as discontinuation of the trial. In other instances, it is anticipated that the committee will act autonomously; they must however keep the TSC up to date with decisions made.

The TMC has responsibilities in four main areas:

- Monitoring of the progress of the trial
- Decision making
- Education / Information services
- Reporting

It is envisaged that the committee composition ultimately selected will provide the TMC with an adequately wide range of resources to tackle protocol design issues, effectively monitor the trial's progress, manage unforeseen problems and compile all the reports that may eventuate from the data.

A sharing of responsibilities within the TMC is also envisaged. It is recommended:

- a) That the Trial Chairperson would also take on the duties of main spokesperson for the TMC. Refer to Appendix 2 for a checklist of documentation required.
- b) That the Trial Coordinator and statistician would take on the responsibility for overseeing and supervising the data management and analysis aspects.
- c) That one committee member from each medical discipline involved (eg radiation, medical or surgical oncology) would monitor clinical practices, protocol deviations, adverse events and QA audits for their respective discipline and undertake to offer a counselling service when needed.

## 2.1 Monitoring

The TMC is responsible for monitoring the following areas during the conduct of the trial:

### 2.1.1 Regulatory Compliance

- all relevant Clinical Trial Agreements (CTAs) must be signed by all parties (i.e. institution, collaborating group) prior to the commencement of the trial. Refer to TROGs Trial Development Resources available at [www.trog.com.au](http://www.trog.com.au) for further information regarding CTAs.
- the Data Monitoring Committee (DMC) must be formed for all randomised Phase II and Phase III TROG clinical trials no later than the time of activation. Refer to TROG Policy and Procedures '*Data Monitoring Committee Guidelines*' available at [www.trog.com.au](http://www.trog.com.au) for responsibilities of DMCs.
- the Principal Investigator (PI) at a Trial Site must be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial.
- the PI must comply with TROG Policy and Procedures, ICH GCP Guidelines and the applicable regulatory requirements  
the PI must be a Full member of TROG
- one or two Subinvestigators should be nominated for a trial in order to undertake the PI's responsibilities in the absence of the PI
- Subinvestigators should be encouraged to become members of TROG, and
- With respect to the situation of individual international sites being considered as collaborators, it is vital that the Trial Chairperson provides evidence to the TROG Scientific Committee (TSC) of individual Trial Site's track record for good quality research, data management capabilities, the establishment of a properly constituted ethics committee and expected accrual.

### 2.1.2 Data quality

All relevant data - as indicated by the protocol – must be recorded and reported in a highly accurate and timely manner.

### 2.1.3 Protocol compliance

Adequate information and education must be provided to Trial Sites and their staff as to the contents and expectations of the protocol and trial compliance. The number, size and reasons for violations of the protocol must be reported.

#### 2.1.4 Treatment quality

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

#### 2.1.5 Follow up quality

The frequency and adequacy of patient follow up reviews and the data collected must be consistent with protocol requirements, and any missing data/follow-up information must be recorded as missing with reasons given.

#### 2.1.6 Morbidity

All acute and late treatment effects including Adverse Events, Serious Adverse Events and Serious Adverse Drug Reactions must be recorded and reported in accordance with the Protocol and ICH GCP Guidelines.

#### 2.1.7 Trial finances

Expenditure on data management, quality assurance, statistical advice, day to day running costs must be calculated and administered correctly.

#### 2.1.8 Accrual

Accrual must be reported on a periodic basis, especially if accrual rates are less than expected.

#### 2.1.9 Supervision

The TMC must provide adequate supervision and review of statistical and data management work (this may have to be sourced elsewhere)

#### 2.1.10 Regulatory

The TMC must sign all regulatory documents (such as Clinical Trial Notifications) where required

## **2.2 Decision making**

The TMC is responsible for making decisions with regards to the following areas during the conduct of the trial:

### **2.2.1 Protocol Amendments**

Modifying trial treatment, eligibility criteria, stratification and/or stopping rule details when new information is made available that will result in a risk/increased risk to the patient if an amendment isn't made.

### **2.2.2 Funding**

Completion of grant funding applications and progress reports to secure the continual financial stability of the Trial, etc.

### **2.2.3 Adverse reactions**

Action(s) that may need to be taken in the event of a Serious Adverse Events and/or Serious Adverse Drug Reactions eg protocol amendment, cessation of treatment.

### **2.2.4 Litigation**

Action(s) that need to be taken in the event of litigation. This must be done in consultation with the TSC.

### **2.2.5 Trial discontinuation**

Deciding on the application of the pre-determined stopping rules after receipt of statistical advice (refer to TROG Policy and Procedures '*Statistical Guidelines*') and/or DMC advice (if relevant), or after information has been received from another trial indicating an inferior outcome.

## **2.3 Education / Information services**

### **2.3.1 Start-up meetings**

The Trial Chairperson and the Trial Coordinator should prepare presentations of relevant trial information, eg:

- Aim of trial;
- Eligibility criteria;
- Trial design (randomisation procedure if applicable);
- Treatment plan, include dose modifications;
- Trial assessments (pre-treatment, during treatment and follow-up);
- Expected adverse reactions;
- Serious Adverse Event procedure.

This summary presentation information should be supplied to all Trial Sites planning to participate in the trial. The Principal Investigator at each Trial Site should hold a meeting with all involved in the trial (radiation oncologists, medical oncologists, pharmacy, data manager, clinic nurses etc) to discuss the practicalities of running the trial in their institution and to allocate responsibilities.

#### 2.3.2 Protocol enquiries

The TMC is responsible for responding to enquiries about all aspects of the protocol and provide support to Trial Sites in regards to interpretation and implementation of the protocol.

#### 2.3.3 Protocol deviations

The TMC is responsible for providing assistance to all participating Investigators at Trial Sites to avoid protocol deviations and adverse events.

### 2.4 **Reporting**

#### 2.4.1 'Newsflash'

If there is insufficient information for a newsletter but important news has been reported, this should be disseminated eg. Grant approval, overseas results or monthly accrual updates. This could be emailed or faxed. A copy should be sent to the TCOO and to the TSC.

#### 2.4.2 Periodic newsletters

Newsletters should be produced at least bi-annually and can include (but not be limited to) updates on accrual, problem solving and reporting, as well as contact details of the Trial Chair, Trial Coordinators, Principle Investigators and all Trial Sites involved in recruitment of trial participants. A copy should be sent to the TCOO and to the TSC.

#### 2.4.3 Formal reports

A copy of presentation abstracts and final draft manuscripts should be sent to the TCOO for review by the TROG Publications Committee prior to submission. Notifications of publications to the TCOO should include publication strategy, authorship, report type, contents and accuracy and spokesperson responsibility.

## Appendix 1

### Organising TMC Teleconferences

The TROG Central Operations Office will organise the teleconference after the following information is provided:

1. Two to three options for dates and time (keep in mind the time differences of the TMC member centres);
2. Email addresses of TMC members (if not TROG members) and **direct** phone numbers (if known);
3. If taping is required (for minute taking).

Please note that at least two weeks notice should be given to allow sufficient time for replies, decision on best date/time, booking of teleconference and notification to TMC members.

The cost of the teleconference is paid by TROG.

Once a teleconference has been organised for a particular trial, item 2 above (email addresses and phone numbers) will not be required to be re-supplied.

#### Contact Details – TROG Administrative Assistant

Phone: +61 (0)2 4921 1684  
Fax: +61 (0)2 4921 1465  
Email: [Alyson.Segrott@trog.com.au](mailto:Alyson.Segrott@trog.com.au)

## Appendix 2

### Trial Chairperson Responsibilities - Documentation

The Trial Chairperson is responsible for organising for the following documents to be forwarded to the TCOO in a timely manner. The Trial Chairperson may delegate the sending of the actual documents to the Trial Coordinator but still has overall responsibility. The following lists all documents in the trial process from new proposal to final publication.

Document	Time Required	Forwarded to TROG Central Operations Office <i>(initial when sent)</i>
New Proposal Synopsis	Requests for New Proposals will be sent out approx 3-4 months prior to the Annual Scientific Meeting which is held in the period of late March-May of each Calendar year.	
Draft Protocol Draft Participant Information Sheet and Consent Form (PIC) Draft Case Report Forms (CRF)	Approx. 2 months before Trials Review Meeting as requested (held in Sept-Nov)	
Clinical Trial Agreements (all relevant)	At the Trials Review Meeting or prior to trial activation	
Final protocol Final PIC Final CRFs (to be emailed to add to website)	After Scientific Committee approval & allocation of TROG Trial no.	
Start-up meeting presentations (to be emailed or sent on disk to add to website)	As soon as completed	
TMC Members fax numbers / email addresses (if not TROG members) for teleconference organisation	When teleconference required	
Teleconference minutes	As soon as completed	
Trial progress reports	Every 6 months as requested. These will commonly be requested 2 months prior to the ASM and TRM each year.	
Trial Newsletters (copy emailed for website)	When mailed to other investigators and to TROG Scientific Committee members (every 3 – 6 months recommended)	
Protocol amendments for approval (if applicable)	As occur but prior to distribution to sites	
Audit results (to QA Coordinator)	As occur	
Any changes to TMC members or Trial Coordinator	As occur	
Press releases	As occur – for website	
Draft publication emailed & also final publication once accepted	As occur – draft for Publications Committee review	