



Trans Tasman Radiation Oncology  
Group Limited  
ACN 132 672 292

## TROG POLICY AND PROCEDURES

# Guidelines for the Development and Conduct of Clinical Trials

## TPP E3

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

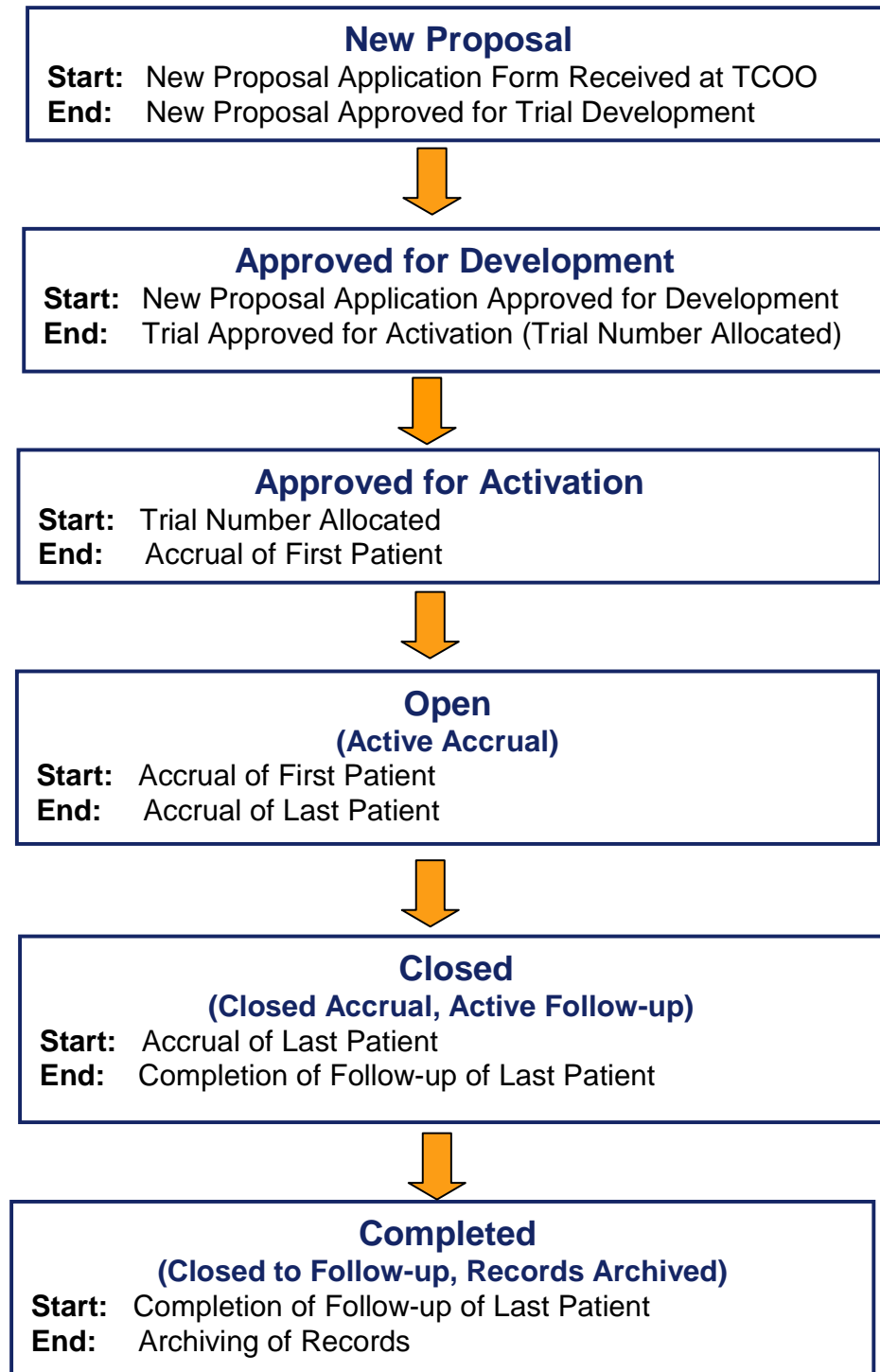
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## TROG Trial Timeline



## **1 New Proposal**

TROG aims to foster and promote the design and execution of high quality clinical trials, preferably involving radiation therapy and which require multi-centre participation. If your proposal fits these aims it is suitable. If in doubt, contact the TROG Central Operations Office (TCOO).

Two types of trial initiatives are welcomed by TROG:

- New trial proposals to be carried out under the auspices of TROG.
- Trials under consideration or activated already by another group or Institution whose desire it is to see the proposal carried out under the joint auspices of TROG and the group or institution concerned.

The Investigator who prepares and presents a new trial proposal to TROG will be referred to as the 'Trial Proponent' until the trial has been approved by TROG for further development, the Trial Proponent will then be referred to as the Trial Chairperson.

### **1.1 New Proposal Synopsis for Annual Scientific Meeting**

A new proposal synopsis (refer to Appendix 1 for form and guidelines) must be forwarded to the TCOO no later than the date stipulated on the new proposal synopsis form. Special attention must be made to the rationale for the proposed trial providing references or data in support, and to the hypothesis to be tested. All proposals will be considered by a subcommittee of the TROG Scientific Committee (TSC) (designated by the TSC for the specific purpose of reviewing new proposals), with preference given to those involving disease sites or areas where TROG is currently deficient.

The proposals will then be referred to selected experts in the areas for an independent scientific assessment, as appropriate. The assessment will be reviewed by the TSC subcommittee and a maximum of 6 proposals will be presented at the forthcoming Annual Scientific Meeting (ASM). This scientific assessment will be forwarded to the Trial Proponent for information. The Trial Proponent will be expected to attend the ASM in person and must not make more than one proposal at each meeting (excluding exceptional circumstances). No more than 2 proposals per disease site will be presented at the ASM.

Follow-on trials will be also actively solicited by the TROG Board by encouraging TROG members who have already demonstrated enthusiasm for trials in specific areas to form steering committees to develop new proposals to submit to the TSC subcommittee.

New proposal summaries to be presented will be sent to all TROG members and members of the TSC prior to the ASM for discussion within the institution so that any issues can be raised at the ASM by the members attending the meeting.

## **1.2 Annual Scientific Meeting Assessment**

One of the major roles of the ASM is to hear and assess new proposals. The Trial Proponent will be required to make a presentation of the proposal which will then be followed by any questions from the floor. The ASM Chairman will then direct the Trial Proponent to discuss this further with specific members attending. Every attempt must be made by the Trial Proponent to try and resolve/pursue issues raised in the question time during the remaining period of the ASM. More time is then allotted during the open forum and summing up session when these issues can be discussed further.

### 1.2.1 Annual Scientific Meeting assessment of trial proposals

The role of the ASM is to determine whether there is general support based on scientific merit for a trial proposal to proceed to further development.

Approval at the ASM will be based on a majority Yes/No vote. This will be by a poll taken in conjunction with a brief assessment feedback questionnaire. All full TROG members present are able to vote. Proxy voting will only be allowed if a member has been present for the initial presentation, but not for the final summing up where voting will occur. In the case of a tied vote the protocol will proceed. Protocols rejected at an ASM can be re-presented at subsequent ASMs with no limit on the number of presentations. Past experience has indicated that support for trials with similar endpoints changes from year to year and investigators are encouraged to re-present should they wish to do so. There may be more compelling data (either pilot or from elsewhere) to support a trial proposal previously rejected. Institutions may have proceeded with a trial regardless of TROG support and if successful accrual has occurred this provides a good reason for a trial to be reconsidered. However once the trial is allocated a TROG trial number patients accrued prior to this date will not be able to be included in the analysis of the TROG approved trial.

Members voting at the ASM in favour of or against further development of a protocol must base their decision on the following

- Potential for the protocol to alter clinical management practices for the better, improved treatment outcome which may either relate to improvement of the results of treatment or to the reduction of treatment morbidity. This will involve an assessment of the degree of benefit to individual patients that may be demonstrable as a result of the successful completion of the trial, together with an estimate of the total number of patients likely to benefit nationally and internationally. The assessment will also include the relevance of the protocol in question to international initiatives (i.e. will the result still be relevant to ongoing international progress when it is finally obtained). The feedback questionnaire can be utilised to provide a more detailed appraisal than the Yes/No vote
- Likelihood of successful completion in proposed time frame (this includes availability of data management support and anticipated local accrual).
- New Trial Chairperson. (i.e. all other considerations being equal, a proposal with a potential new Trial Chairperson should be given priority).
- New area/field of research for TROG.

If a member has serious doubts about a particular proposal then he/she should vote NO. If it is unlikely that the member or the institution he/she represents would be willing to enter eligible patients under his/her care in a proposed trial (ignoring all other issues such as funding, accrual, etc) the member should vote NO. There is little to be gained pursuing trials which eventually have poor accrual. This wastes the time of investigators and, more importantly, exposes patients to risks they might not otherwise have faced, without any tangible benefit for future patients.

TROG recognises the potential problem of a trial attracting only a few members who treat a large number of eligible patients but the majority of members may only see a few eligible patients. Under these circumstances members who treat only a small number of potential trial patients may abstain from voting on the proposed trial.

Not all proposals that receive support at the ASM will proceed to activation and this may be for a variety of reasons, such as:

- a) funding implications
- b) competing trials

- c) lack of support from institutions where accrual would be needed for success
- d) failure to develop the protocol further than the presentation stage at ASM
- e) decision to delay (rather than cancel) the activation of a trial
- f) lack of success elsewhere by another group.

### **1.3 Post Annual Scientific Meeting Proposal Procedures**

Those trials supported at the ASM will be contacted independently by the TSC subcommittee and asked to conduct a feasibility assessment (refer to Appendix 1). This involves surveying possible trial participants in Australia, New Zealand and internationally (with or without the support of the ASM votes) to ascertain viability. If the proposal is in any way modified by input gained at the ASM, the feasibility assessment needs to involve the modified proposal. The TCOO should be contacted for assistance with the distribution of the feasibility survey to TROG members. The result of the feasibility assessment is then reviewed by the TSC Chairperson with or without other members of the TSC subcommittee. If the proposal is deemed feasible, the proposer is asked to proceed with development of a provisional protocol.

Those members not at the ASM wishing to obtain a copy of the proposal summary may do so through the appropriate Trial Proponent. Under no circumstances should the proposals discussed at the TROG ASM be circulated to other persons without the prior approval of the appropriate Trial Proponent. Ad hoc circulation in the past has led to difficulties in activating protocols at a later date. Trial Proponents have the right to refuse to circulate widely any 'Draft' proposal at any stage in development up until a 'Final' protocol is developed. TROG members should understand that refusal to circulate a Draft may be in the best interests of successful initiation of some trials and is not intended to exclude participants. TROG members are encouraged to communicate freely with the Trial Proponent as this will help in the strategy development, review by other potential investigators and activation stages of protocol development.

## **2 Approved for Development**

The trial phase of "Approved for Development" commences when a new proposal receives the endorsement of the membership at the ASM, successfully completes a feasibility assessment and is approved by the TSC for further development.

During the development stage a trial would be expected to make significant progress towards preparation for activation. A trial will complete the “Approved for Development” phase and enter the “Approved for Activation” phase when it is considered that there are no significant issues which may result in the trial experiencing delays in opening to accrual within a reasonable timeframe.

## **2.1 Trial Development Resources**

To complete the development phase and be ratified by the TSC for the allocation of a TROG Trial Number a new trial must have advanced in several key areas. As well as the completion of the final protocol document, the following ten ‘development strategies’ have been identified as priorities for the trial development phase. Ideally the goals of each strategy should be met before the trial is presented to the TSC for approval for activation (and allocation of a TROG trial number).

### **2.1.1 TROG Trial Development Strategies**

1. Protocol
2. Financial
3. Trial Centre
4. Indemnity
5. Trial Management Committee
6. Database
7. Case Report Forms (CRFs)
8. Quality Assurance
9. Statistical
10. Contractual and Regulatory Documents

The TROG Trial Development Resources document (see appendix 1) provides detailed information and instruction to assist Investigators with meeting the end of development goals defined for each development strategy. TROG encourages all Investigators to use the Trial Development Resources which are freely available on the TROG website. [www.trog.com.au](http://www.trog.com.au)

## 2.2 Trials Review Meeting

### 2.2.1 Draft Protocol Review

Trials under development will be required to forward the most recent draft Protocol and sample PIC to the TCOO to allow circulation to all members of the TSC for preliminary review no later than 4 weeks prior to the Trials Review Meeting (TRM).

The preliminary review of the draft protocol will include assessment by the TROG Statistician, who is a member of the TSC. The PIC will be reviewed by the TSC to ensure that all possible risks are stated. Protocols not circulated for this review cannot be adequately assessed and their review by the TSC will be deferred until the next meeting.

A copy of the draft protocol will also be made available to TRM registrants by the TCOO to allow consideration prior to the meeting and to assist active discussion.

### 2.2.2 Presentation at Trials Review Meeting

A presentation will be required at the TRM with time for discussion. The presentation must address the following aspects of the proposal:

- Objectives and endpoints
- Treatment details
- Anticipated toxicity if applicable
- Projected accrual (including numbers required from outside the Trial Chairperson's institution)
- Statistical considerations including stopping rules
- Resource implications
- Possible implications of trial for other groups or institutions
- Development and activation strategy
- Funding
- Progress with contracts (if applicable i.e. pharmaceutical companies). Please refer to the TROG Policy and Procedures Manual *'Intergroup and Industry Collaborative Guidelines'*
- Quality Assurance
- Image Guidance

After considering the presentation at the TRM, the TSC has responsibility for:

- Recommending final refinements to the protocol to ensure scientific acceptability of the protocol.
- Evaluating the resource implications of conducting the protocol
- Notifying the Board whether or not the trial is ready for activation, and whether there are any conditions attached to approval

If a trial is considered not ready for activation, the protocol will be in some cases required to be resubmitted to the next TSC Meeting..

Appraisal of newly approved for development trial proposals at the TRM of TROG differs from the ASM in that the mechanics of running a trial, such as funding issues, accrual and the likelihood of successful completion, are more critically evaluated.

### 2.2.3 Ratification by the TROG Scientific Committee

In accordance with the responsibilities of the TSC, set down in the Board approved Scientific Committee charter of the constitution; the TSC must ratify all Protocols for those trials that have completed the trial development phase. Only after ratification is the trial activated, and the Protocol allocated with a TROG number.

The TSC has ultimate authority for deciding whether a trial proceeds and will notify the Board when a trial has been activated.

The Trial Chairperson will be notified in writing of trial activation and allocation of a TROG number.

The TROG membership will be notified of the outcome via the TROG newsletter (available on the TROG website [www.trog.com.au](http://www.trog.com.au)) so as to promote the activation of the trial.

## 2.3 **Progress Reporting**

Progress reports for trials in development will be requested by the TCOO twice a year. Prior to the time of the ASM and TRM the TCOO will provide Trial Chairperson with the progress report template for 'trials in development' (see appendix 1) which must be completed and returned to the TCOO by the date specified. The Trial Chairperson will be instructed to report on the progress of each of the ten trial development strategies as outlined in the Trial Development Resources.

### 3 Approval for Activation

Activation of the trial at an Institution cannot occur until the trial has been ratified by the TSC and allocated a TROG trial number. In no circumstances, should a Trial Chairperson designate a TROG trial number themselves.

A decision as to the timing and method of activation must be made by the Trial Chairperson. This could be:

- a) Human Research Ethics Committee (HREC) approval/Clinical Trial Notification (CTN - applies to Australia only) application at single institution / multiple institutions. Once approved other institutions to follow.
- b) Multiple institutions to present protocol to Ethics committees in no particular sequence.

In practice, the first option is often preferable, with circulation of the final protocol only to occur after ethics/CTN procedures have been dealt with at the originating institution.

A copy of the HREC approval letter and approved Participant Information Sheet and Consent Form (PIC) from each institution is to be forwarded to the Trial Chairperson and/or Trial Coordinator. The HREC letter must clearly state the version number and date of the approved Protocol and PIC (the PIC may not necessarily have the same version number and date as the protocol).

Prior to the trial being activated at an Institution and the Trial Site beginning patient recruitment, minor PIC changes mandated by an institution's ethics committee can be made without prior approval of the TSC, however under no circumstances can the protocol risks as stated in the original TROG version be excluded. It is the Trial Chairpersons responsibility to make certain that this does not occur by ensuring that the final PIC of each institution is checked as soon as HREC approval is granted.

Patient recruitment at individual Trial Sites may commence only after Institutional Ethics approval and CTN acknowledgment (if applicable) has been obtained.

Trials that have been approved for activation must be presented at the ASM and the TRM. The presentation must include an update on progress towards active accrual for the trial. Refer to section 2.2.2 for additional information on presentation at meetings.

### **3.1 Registration of Clinical Trials**

In 2004, the International Committee of Medical Journal Editors (ICMJE) published an editorial on clinical trial registration due to concerns of selective reporting<sup>1</sup>. “Unfortunately, selective reporting of trials does occur, and it distorts the body of evidence available for clinical decision making. Researchers (and journal editors) are generally most enthusiastic about the publication of trials that show either a large effect of a new treatment (positive trials) or equivalence of two approaches to treatment (non-inferiority trials). Researchers (and journals) typically are less excited about trials that show that a new treatment is inferior to standard treatment (negative trials) and even less interested in trials that are neither clearly positive nor clearly negative, since inconclusive trials will not in themselves change practice.”

The ICMJE proposed comprehensive trials registration as a solution to the problem of selective awareness and announced that all eleven ICMJE member journals will adopt a trials-registration policy to promote this goal. The ICMJE member journals will require, as a condition of consideration for publication, registration in a public trials registry. Trials must register before the onset of patient enrolment. The ICMJE recommended the registry at [www.clinicaltrials.gov](http://www.clinicaltrials.gov), sponsored by the United States National Library of Medicine.

The TROG Board endorses the above and requires that all TROG trials are registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) prior to the recruitment of the first trial participant. The TCOO has registered all open clinical trials and will register all newly activated TROG trials in consultation with the Trial Chairperson. The Trial Chairperson and Trial Coordinator will be notified of the Trial Registration number.

In addition, open TROG trials will also be registered with the Australian Clinical Trials Registry (ACTR) [www.actr.org.au/](http://www.actr.org.au/) in order to promote accrual.

### **3.2 Grant Applications**

The TCOO must be notified by the Trial Chairperson as soon as the TMC decides to proceed with a competitive funding grant application (eg. NHMRC, Cancer Council). The deadline for final submission with the granting body must also be provided, noting the additional time required ahead of the submission deadline for internal review, as described below. The TCOO will coordinate relevant input for the grant application process.

As part of the grant application process, identification of in-kind support is considered favourably, as is clear and appropriate budgeting. These elements of the process are assisted by the preparation of a Trial Support Agreement, detailing the range of services that TROG will provide to the trial on an in-kind and cost recovery basis. The Trial Support Agreement can then be used to provide summary information for the budgeting section of the grant applications, both in terms of the budget for services provided through TROG (where partial or full cost recovery is required, eg Quality Assurance), as well as the level of in-kind support provided by TROG.

The range of services provided by TROG specifically in relation to the grant application process may include:

- Advice from the QA Manager in relation to QA requirements and processes, the central QA and trial managements services that can be provided through TROG, and the associated budget requirements.
- Advice from the TROG Business Development Manager in relation to the availability of augmenting funding, such as Research Infrastructure Block Grant allocations from administering institutions.
- Drafting of a Trial Support Agreement, including details of in-kind support and cost recovery items, with a summary of this information to be provided to support the grant application.
- Assistance with preparation of the grant application including the electronic lodgement, subject to available resources.

All draft grant applications must be forwarded to the TCOO for review two weeks prior to submission to the Administering Institution. The Administering institution may also require submission of the application one to two weeks prior to the deadline for final submission to the granting body, so three to four weeks may be required in total. The TCOO will forward the submission to the TSC Chair and other members of the TSC for review, as appropriate.

The Trial Proponent must ensure that the TCOO is informed of the outcome of the grant and if successful, provide details of total funding, duration and payment schedule on a year by year basis.

The following general points should be considered when writing a grant submission:

- It is important that TROG is adequately and appropriately represented on the submission and also included in the application title (where possible).
- The track record of the Trial Chairperson and Associate Investigators should be carefully considered when selecting potential grant investigators.
- Include an experienced investigator.
- Pilot data is very helpful to support the feasibility and promise of the Trial eg pilot study or retrospective review to support the hypothesis.
- Evidence must be properly referenced.
- Ensure the endpoints described can prove or disprove the hypothesis.
- In the absence of preliminary data, the literature review (Background) must be very focused to support the hypothesis and feasibility.
- Model costings on those of other funded grants, where appropriate.
- Be as transparent and detailed with the budget as possible.
- Collaborations are regarded favourably.
- Institute track record can also help eg statistical support, data management, collaborative trial group – TROG has an excellent record.
- It is essential to have the statistical section water-tight.
- Collaborate with other disciplines – identify the TMC, identify affiliate members involved in the trial
- Include a statistician as an investigator.

### **3.3 Protocol Amendments**

All amendments to a protocol and PIC (regardless of how minor) need to be forwarded to the TCOO for approval by the TSC prior to distribution to any Ethics Committee (including the Trial Chairperson's centre) or to trial sites.

The Trial Coordinating Centre must forward the following to the TCOO:

- a summary list of the amendments, which must include a clear rationale for the proposed change
- a statement outlining if the proposed amendments introduce any new risks to participants (eg. changes to confidentiality provisions, physical or psychological risks, increased time commitments etc)



- increase in drug dose
- increase in total radiation dose
- changes in scheduling that could increase toxicity
- any change in planned sample size or early closure criteria

These changes cannot be made without the approval of the full TSC. The TSC will consider if the change(s) are appropriate and will convene a teleconference if there is diversity of opinion. The TSC is committed to make a rapid ruling in all cases, but especially when there are safety issues involved.

Once significant changes have been approved by the TSC, it is the responsibility of the Trial Chairperson and the Trial Management Committee to ensure that all principal investigators immediately notify local ethics committees of the changes, and obtain approval prior to implementation

### 3.3.3 Major Amendments

Major amendments include the following:

- addition of extra treatment modality, eg chemotherapy
- substantial changes in trial design, eg phase III to phase II
- clear change in intent over that which was originally approved by the Membership

These changes cannot be made without the approval of the TSC, which will carefully consider the rationale for making the changes. In some cases, particularly when the trial in question is being performed by a group of investigators who have been active in TROG trials on the particular cancer for some time, the TSC will make a decision without recourse to the Membership. In other cases, the TSC will refer the matter back to the Membership, although in this situation it is not envisaged that the trial would have to re-enter the New Trials development process at the beginning again. A simple majority vote for or against the change is all that would be required.

The TSC will consider the appropriateness of the change(s), and will convene a teleconference if there is diversity of opinion. The TSC is committed to make a rapid ruling in all cases, but especially when there are safety issues involved.

Once major amendments have been approved by the TSC, the revised protocol will require HREC approval at Trial Sites before accrual can recommence.

### **3.4 Progress Reporting**

Progress reports for trials approved for activation (i.e. TROG number received) will be requested by the TCOO twice a year. Prior to the time of the ASM and TRM the TCOO will provide Trial Chairpersons with the progress report template for 'open trials' (see appendix 1) which must be completed and returned to the TCOO by the date specified.

### **3.5 Presentations**

Trials approved for activation must be presented at the ASM and the TRM. The presentation must include an update on trial progress. It must also include any issues that have arisen since becoming an activated trial, refer to section 2.2.2 for more information on presentation at TROG annual meetings.

## **4 Open Trials**

A trial becomes an open trial when the first patient is accrued. At this point, the final protocol plus any amendments have ethics approval at the Trial Coordinating Centre and other Trial Sites.

### **4.1 Grant Applications**

Grant applications for open trials must follow the same process as trials in activation. Refer to section 3.2 Grant Applications for further information on the process.

### **4.2 Protocol Amendments**

Protocol amendments must follow the same process of approval as per trials in the activation phase. Refer to section 3.3 for further information regarding the amendment process.

### **4.3 Substudies**

A sub-study is essentially an add-on study to the main protocol designed to ask a separate research question and includes new data collection from some or all of the trial subjects from the main protocol.

A concept sheet for the proposed sub-study must be forwarded to the TCOO who will in turn forward on to the TSC for approval. The sub-study concept sheet must include:

- A description of the sub-study including its hypothesis, aim and objectives
- Any impact on the main protocol (i.e. are visit schedules different to those in the main protocol?)

- Specific efficacy, safety or other assessments
- Statistical power and summary of planned analysis.

If the TSC agrees the proposed sub-study concept is relevant and valid, it may then be developed into an appendix to the main protocol (by the proponent) and forwarded to the TCOO for final approval by the TSC.

A separate PIC may be required for enrolling trial participants into the sub-study. This will be determined by the TSC.

All sub-studies (including the PIC) must obtain HREC approval

Publications or presentations arising from the sub-study must be approved by the TROG Publications Committee prior to journal submission

#### **4.4 Progress Reporting**

Progress reports for open trials will be requested by the TCOO twice a year. Prior to the time of the ASM and TRM the TCOO will provide Trial Chairpersons with the progress report template for 'open trials' (see appendix 1) which must be completed and returned to the TCOO by the date specified.

#### **4.5 Presentations**

Open trials must be presented at the ASM and the TRM. The presentation must include an update on trial progress and accrual. It must also include any issues that have arisen since becoming an open trial, refer to section 2.2.2 for more information on presentation at TROG annual meetings.

### **5 Closed Trials**

A trial is considered closed after the last participant has been recruited and the total number of trial participants accrued meets the protocol sample size. Trial participants are in follow up.

#### **5.1 Progress Reporting**

Progress reports for closed trials will be requested by the TCOO twice a year. Prior to the time of the ASM and TRM the TCOO will provide Trial Chairpersons with the progress report template for 'trials in follow-up' (see appendix 1) which must be completed and returned to the TCOO by the date specified.

## **5.2 Presentations**

Closed trials are not required to have an update presented at the ASM or the TRM unless there is new information to report.

## **6 Completed Trials**

A completed trial is a trial which has concluded normally. Trial participants are no longer being examined or treated (i.e. no longer in follow up); the final Database Lock has occurred and records have been archived.

### **6.1 Progress Reporting**

Progress reports are not required for completed trials

### **6.2 Presentations**

Completed trials need only to have the final trial results presented when available at the ASM or the TRM.

## **7 References**

1. Clinical Trial Registration. A statement from the International Committee of Medical Journal Editors, eMJA Rapid Online Publication 9 September 2004.

## **Appendix 1**

The following documents, as varied from time to time, can be accessed through the TROG website [www.trog.com.au](http://www.trog.com.au)

1. TROG New Proposal Synopsis Form
2. TROG Feasibility Survey
3. TROG Trial Development Resources
4. TROG Protocol template (and instructions for use)
5. TROG Participant Information Sheet and Consent Form (PIC) template
6. TROG Case Report Form template (under development)
7. TROG Progress Report (Trials in development)
8. TROG Progress Report (Open trials)
9. TROG Progress Report (Trials in follow-up)