



Trans Tasman Radiation Oncology
Group Limited
ACN 132 672 292

TROG POLICY AND PROCEDURES

Authorship, Publication and Spokesmanship Guidelines

TPP E11

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

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Contents

1	Authorship	2
2	Pre-Publication Procedures	3
3	TROG Publications Committee (TPC)	3
4	Sub-studies.....	6
5	Presentation	7
6	Media Spokesmanship.....	7
7	Timing of Publication and Presentation.....	8
8	Reporting of Trial Results	8
9	Ownership and Use of Data.....	8
10	Disputes	9
11	Intergroup Co-operative Studies	9
12	Meta-Analysis	9
13	References	9

1 Authorship

The ultimate responsibility of authorship rests with the Trial Management Committee (TMC) but in general the following guidelines should be followed.

Authorship credit should be based on the Vancouver statement by the International Committee of Medical Journal Editors¹, i.e. substantial contribution to all three of the following criteria:

- a) conception and design OR acquisition of data OR analysis and interpretation.
- b) drafting article OR critically revising it for intellectual content.
- c) final approval of version to be published.

In addition, a fourth criterion is included for multicentre trials:

- d) Members of the TMC and/or contributors who register / randomise a significant contribution of the evaluable cases on a trial will be listed as authors.

These four criteria will be used to decide who to EXCLUDE as well as INCLUDE as authors.

Normally, the authors of publications detailing interim and final results of the trial as well as any 'overview' of the trial will be:

- a) the Trial Chairperson as the first author;
- b) the Institutional Principal Investigators on the Trial Management Committee will follow;
- c) with the statistician and Central Data Manager following the clinicians;
- d) then the Investigators who meet the authorship guidelines above who are not already members of the Trial Management Committee;
- d) then any other participants who meet the authorship guidelines above;

Generally speaking the order of authorship will be based on the number of patients accrued. However, other considerations should be taken into account and will be decided by the Trial Management Committee.

Every publication should include an appendix or table listing all other participants.

Reference to these authorship guidelines should be included in any future TROG trial written protocol.

2 Pre-Publication Procedures

The name “TROG” should appear in the title of the publication. If this is not possible due to the journal’s publication policy, the name “TROG” should appear at the end of the author’s list. In this second option, the following statement is recommended “on behalf of the Trans Tasman Radiation Oncology Group”.

All publications will be forwarded in draft form, first to the Trial Management Committee then to all Institutional Principal Investigators and co-authors for critical review and comment. A deadline for return will be given. A reminder letter will be sent to those who have not replied within the deadline. Those investigators who do not return the draft with comment (even if this comment is just to agree with the draft in toto) will have their potential authorship reviewed.

The final draft will then be sent to the TROG Research Manager for review by the TROG Publications Committee.

3 TROG Publications Committee (TPC)

3.1 Rationale

Material that is published or presented in the name of TROG is the single most important determinant of the Group’s reputation. As such, it is essential that this material is of the highest quality, that it is presented at appropriate venues, that it is published in a timely fashion in reputable journals and that it conforms to TROG’s publication guidelines.

The responsibility for publications is delegated exclusively to the Trial Chair and TMC. While this is proper, it is desirable to have oversight of the process to provide independent scientific review of material before it is submitted and to make sure that the publication process keeps on track. A separately constituted Publications Committee will provide such oversight.

The purpose of the Publications Committee is not to delay or “censor” presentations or publications, but rather to provide constructive criticism, to improve the quality of submitted material and to ensure that TROG publication requirements are adhered to.

After working on many drafts of a paper, it is possible for the authors to get too close to the project and fail to see concerns that would inevitably be raised in the peer review process. Under these circumstances, pre-review by the TROG Publications Committee can actually accelerate

acceptance of a manuscript (by shortening the peer review process) as well as prevent potential embarrassment to the Group.

3.2 Purpose

To ensure that results of TROG trials and other TROG investigations are reported in a scientifically robust and timely fashion.

3.3 Responsibilities

- 3.3.1 To develop, with the Trial Chair, a timeline for analysing and reporting results of all TROG investigations
- 3.3.2 To review abstracts and manuscripts resulting from TROG investigations before presentation or submission to ensure that:
 - a) The material is clearly and fully presented
 - b) The conclusions drawn are justified by the data
 - c) TROG authorship and publication rules are adhered to
- 3.3.3 To consider requests for proposed presentations or publications to be based on secondary analyses of TROG data by members who were not on the TMC of the initial trial(s)

3.4 Composition of Committee

The Publications Committee will consist of four members of the Scientific Committee including the Scientific Committee Chair and the TROG statistician. The President will appoint the other two members of the Publications Committee and designate its Chair subject to Board ratification. The Chair of the Scientific Committee and the TROG statistician will serve on the Publications Committee for the duration of their respective terms of office. At large members will be appointed for 3 years with the possibility of re-appointment.

The Publications Committee Chair will co-opt alternative members from within the Scientific Committee as required if one or more regular members is unavailable, or is disqualified by being an author of the presentation or publication under review. In the case of the TROG statistician, co-authorship of a publication will not disqualify him/her from serving on the Committee to answer questions relating to the analysis. However, the Publications Committee will have the right to obtain the opinion of an outside statistician if it is deemed appropriate. If the Publications Committee Chair is disqualified by being an author, the other members of the Publications Committee will elect a temporary Chair for that specific review.

In all cases, if the necessary expertise is not available within the Scientific Committee after exclusion of author(s), outside individuals may be co-opted.

The TROG Research Manager will act as secretary to the Publications Committee, recording deliberations of the Committee and providing feedback to authors.

3.5 Frequency of Meetings

The Publications Committee will meet regularly at the time of scheduled meetings of the Scientific Committee. The committee will convene on an ad hoc basis by email or teleconference to adjudicate on manuscripts or abstracts submitted for review.

3.6 Process for Review

3.6.1 Manuscripts

Upon completion of enrolment and planned follow-up in a clinical trial or completion of data acquisition for other investigations, the Trial Chair will submit to the Research Manager a timeline for analysis of the data and generation of the manuscript. The proposed timeline will be endorsed or amended by the Publications Committee within four (4) weeks of its receipt. In the case of Phase III trials, the trigger for analysis should have been spelt out in the protocol. Milestones will be established to ensure that the proposed timeline is followed and will be monitored by the Research Manager. If it becomes clear that satisfactory progress towards generating a manuscript is not being made, the Publications Committee may recommend to the Scientific Committee a strategy for re-assigning responsibility for this task.

The final draft of the manuscript prepared by the Trial Chair and endorsed by the TMC will be submitted electronically to the TROG Central Operations Office. Along with the manuscript, the Trial Chair must submit a statement that the authorship list is consistent with the TROG authorship and publications guidelines and that all authors have signed off on the final draft submitted for review. The manuscript will be reviewed by the Publications Committee within four (4) weeks. The Committee may give approval for the manuscript to be submitted as written or may request that consideration be given to modifications or further analyses. Such recommendations will be transmitted by the Chair of the Publications Committee to the Trial Chair who should respond as to a peer reviewer. Upon receipt of the revised manuscript, the Publications Committee will authorise submission if satisfied.

In the unlikely event that agreement cannot be reached between the Trial Chair and the Publications Committee, the matter will be referred to a mutually acceptable arbiter external to TROG for an independent opinion.

3.6.2 Abstracts

Abstracts for presentations at scientific meetings must be approved by the Publications Committee before submission for content, timing and appropriateness of venue for presentation. For example, the first report of a major TROG trial must be at a high profile international conference. Abstracts will be reviewed with a one (1) week turn-around time. Abstracts are approved only for a particular meeting. If rejected or withdrawn, any new submission must be reconsidered by the Publications Committee as a new abstract.

3.7 Reporting Responsibilities and Grievance Resolution

At each Annual Meeting of TROG, the Chair of the Publications Committee will present a report on the Committee's activities. This will include a tabulation of the number of reviews undertaken, their turn-around times and specific identification of any matters referred to an external arbiter. Any TROG member with a grievance relating to the review process will have the opportunity to have the matter discussed by the full membership at the Annual Meeting. This may result in a recommendation for procedural change being made to the Board whose decision is binding.

4 Sub-studies

Various offshoot publications are likely to result from any major trial. These may involve either a distinct subset of patients, or look at specific features (eg mucosal toxicity, laboratory parameters).

These sub-studies should:

- a) be approved by the Trial Management Committee.
- b) have their own co-ordinator and, if necessary, other Investigators appointed.
- c) have draft publications approved by the Trial Management Committee and the Publication Committee.
- d) acknowledge the role of the TROG trial.
- e) list the TROG participants in the trial as an addendum.
- f) the Trial Chairperson or one of the members of the Management Committee should be one of the Authors.

Authorship of these 'sub-studies' will again follow the general guidelines but need not have the same authorship order or number as the 'main results' publications.

5 Presentation

Presentation of results of the trial (interim or final or result of various sub-studies) will be decided by the Trial Management Committee. These include results on survival, toxicity, accrual, prognostic factors and laboratory studies.

The Trial Management Committee must be forwarded the abstract of any presentation (after approval and consensus of the authors) before such presentation of any main or sub-study results and this abstract must be approved by the Trial Management Committee prior to the presentation, primarily to avoid embarrassment if retraction or correction is required.

In addition, the abstract should be forwarded to the TROG Publications Committee as detailed above.

Presentations of any substantive nature should ideally be given first to TROG, either at the Trials Review Meeting or the Annual Meeting, but it is recognised that this will not always be practicable.

6 Media Spokesmanship

The Media Spokesperson for all trial results will be decided by the Trial Management Committee.

Media releases of sub-study results will also be decided by the Trial Management Committee. This is because media involvement is likely to involve the trial in a wider sense than the coordinator of the sub-study may be competent to answer.

'Spontaneous' and 'off the cuff' media statements are to be avoided and speculation about future directions in particular are to be avoided without input from the Management Committee. Therefore, all media releases should be considered in advance and vetted by the Trial Management Committee, whenever possible.

The TROG Business Development Manager should be notified in advance of any planned media releases with a copy of the media release.

Variations between what was said and what was published in the press should be reported to the Trial Management Committee for advising appropriate action (if any) and the Trial Management Committee must report to the TROG Board who will be responsible for implementing or modifying any advised action.

7 Timing of Publication and Presentation

Phase III randomised clinical trial protocols must declare when interim and final analyses are to be performed. Any variations from this must be approved by the Trial Management Committee and the TROG Scientific Committee. It is mandatory that NO publications or presentations of the endpoints of the trial occur before these analyses.

It is also mandatory that the results of such analyses are presented to the TROG Annual Meeting and submitted for publication if analyses are final. If a trial is NOT completed for any reason, such as poor accrual, unexpected toxicity and/or unexpected differences between trial arms, a closing presentation and formal written report must be made to the TROG Annual Meeting and must include reasons for closure.

8 Reporting of Trial Results

It is recommended that the Revised CONSORT (Consolidated Standards of Reporting Trials) Statement² be used as a guideline for the reporting of clinical trials. This statement consists of a checklist of 22 items that pertain mainly to the methods, results and discussion of a report and a flow diagram detailing progress through the various stages of a trial.

9 Ownership and Use of Data

The data are owned ultimately by TROG and, in a more direct fashion, by the Trial Management Committee of the trial. However, any participant in the trial owns his / her own data and can use them as he / she likes except to reveal major trial endpoints until these are published for the trial as a whole. Publication and/or presentation of these should still comply with the TROG guidelines for sub-studies.

In addition, no analysis, presentation or publication of results can proceed using data on other participants' patients without consent of the Trial Management Committee. The statistician and Data Manager will not be allowed to release data unless the Trial Management Committee gives consent.

Proposed use of data after the final publication must be outlined to the TROG Publications Committee and approval given before data from the trial are released to that investigator. TROG Authorship and publication / presentation guidelines for sub-studies are to be complied with.

10 Disputes

Any disputes concerning authorship, contents and timing of any publication and presentation will first be dealt with by the specific Trial Management Committee. If no resolution is achieved, or if disciplinary action is deemed warranted, the matter will be referred on to the TROG Publications Committee for final decisions and action. It is to be hoped that most if not all disputes are settled at the Trial Management Committee level.

11 Intergroup Co-operative Studies

Any other group who joins in a combined venture to run a trial should agree to abide by all of the above guidelines. In any case, agreement in writing must be reached prior to trial activation on representation of the respective groups on a joint Trial Management Committee.

12 Meta-Analysis

Meta-analysis is the formal evaluation of the quantitative evidence from two or more trials bearing on the same question. This most commonly involves the statistical combination of summary statistics from the various trials, but the term is sometimes also used to refer to the combination of the raw data. A common definition of the primary and secondary endpoints is essential.

Data should not be released without the consent of the Trial Management Committee. Summary or raw data for meta-analysis should not be released until confirmation has been received that the final report of the TROG trial has been accepted for publication. The Trial Chairperson should ensure that he/she has the right to make reasonable amendments to the meta-analysis manuscript or to withdraw reference to the data altogether prior to submission if necessary. The Trial Chairperson should determine if a TROG author will be included in the authorship list. The nomination of TROG co-authors rests with the Trial Management Committee.

13 References

1. Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication. *Updated February 2006*. International Committee of Medical Journal Editors. Available at <http://www.icmje.org/>
2. The CONSORT Statement: Revised Recommendations for Improving the Quality of Reports of Parallel-Group Randomized Trials. *Ann of Int. Med.* 2001; 134(8): 663-694 Available at <http://www.consort-statement.org>