

## Authorship, Publication and Spokesperson Guideline for TROG Clinical Trials

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**Summary:** This guideline outlines procedures to maintain high standards of publications and accurate, thorough and credible research reporting for TROG trials

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## 1 Authorship

The responsibility for publications is delegated exclusively to the Trial Chair and Trial Management Committee (TMC). These TROG guidelines have been implemented to complement the Revised CONSORT (Consolidated Standards of Reporting Trials) Statement<sup>2,3</sup> and adopts the guides supporting the directives found in the Australian Code for the Responsible Conduct of Research.<sup>4,5</sup> This is to help maintain high standards of publications and encourage accurate, thorough and credible research reporting of TROG trials.

For all category A trials and applicable category D trials/projects, the name “TROG” must appear in the title of the publication. If this is not possible due to the journal’s publication policy, the name “TROG” must 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”.

### 1.1 Authorship requirements

For an individual to be named as an author, the individual must have made a significant intellectual or scholarly contribution to the work and be able to take responsibility for at least that part of the work they contributed. The individual must agree to be listed as an author.<sup>4,5</sup>

In all cases authorship credit should be based on substantial contribution to some or all of the following criteria:

- a) Conception and design of the trial or project
- b) Acquisition of research data where it has required significant intellectual judgement, planning, design, or input
- c) Contribution of knowledge
- d) Analysis and interpretation of data
- e) Drafting significant parts of the article OR critically revising it for intellectual content
- f) Significant contribution to trial accrual

It is not enough to have provided materials or routine technical support or to have made the measurements on which the publication is based to be named an author.

If an individual does not agree to be an author because they are unwilling to be accountable for their contribution, their contribution should generally not be included in the research output.

Authorship should be an ongoing discussion throughout the research project, especially when new individuals become involved. Best practice is to have an authorship agreement in place; This can be in the form of emails, meeting minutes etc and doesn’t need to be a legal document.

### 1.2 Consent for Authorship

According to the Australian Code for the Responsible Conduct of Research (the Code):

- A person who qualifies as an author must not be included or excluded as an author without their permission. This should be in writing and include a brief description of their contribution to the work.
- Authorship must be offered to all people, including research trainees, who meet the criteria for authorship listed above.
- If an author is deceased or cannot be contacted, the publication can proceed provided that there are no grounds to believe that this person would have objected to being included as an author.
  - The deceased author should be noted in the publication.

### 1.3 Order of Authorship

Providing the criteria in 1.1 are met, the suggested order for authors of a TROG publication is as follows:

- Trial Chairperson as the first author;
- followed by the trial statistician and Institutional Principal Investigators on the TMC
- then the Institutional Principal Investigators who are not members of the TMC;
- then any other participants who meet the criteria;

The order of authorship for Institutional Principal Investigators is generally based on the number of patients accrued. However, other considerations should be taken into account and decided on by the TMC.

For sub studies and secondary analyses, the order of authorship will depend upon author involvement.

#### **1.4 Acknowledgements**

Individuals who do not meet the criteria for authorship but have contributed to the research, facilities or materials, such as research assistants and technical writers shall be listed in an acknowledgments section. Where individuals are to be named, their written consent must be obtained.<sup>4</sup>

### **2 Timing of Publications and Presentations**

Collaborating researchers should agree on the authorship of a publication and a timeline for analysing and reporting interim and final results (the Publication Plan) at an early stage in the research project and should review their decisions periodically. The Publication Plan should be reviewed by the TMC periodically.

Where a publication will have several authors, one should be appointed Executive Author to record authorship and to manage communication about the work with the TPC and the publisher.<sup>4</sup> The Executive Author shall be named in the acknowledgements section of the protocol.

The results of all analyses shall be presented at the TROG Annual Scientific Meeting (ASM) and submitted for publication if analyses are final. No publications or presentations of the endpoints of the trial should occur before these analyses are finalised by the TMC.

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 must be made to the ASM and must include reasons for closure. In addition, a formal written report must be provided to the TSC. These results must also be published.

### **3 Manuscript Review**

In collaboration with the TMC, the Executive Author shall:

- Set timelines for the review and submission of publications.
- Coordinate the critical reviews of the draft publication by all confirmed authors.
- Contact authors that do not return the draft with comment by the due date (even if this comment is just to agree with the draft in total) to determine their willingness to be involved. If they no longer wish to be included as an author they shall be invited, in writing, to step down.
- Submit the finalised manuscript from the main analysis to the TROG Publications Committee (TPC) no later than 12 months following analysis

Contact will be made by the TPC with the Trial Chair and TSC when;

- The main analysis (primary endpoint) takes longer than 12 months from data maturity to complete.
- The finalised manuscript is not submitted to TPC within 12 months of the main analysis

Should the Trial Chair (and TMC) be unable to finalise and submit the manuscript detailing the main analysis of the primary endpoint to the TPC within 7 years of data maturity, the TPC will escalate the trial to the TROG Scientific Committee (TSC) for further action. The TSC will review each trial on a case by case basis, which may include taking such action as seeking a new executive author to complete the manuscript and submit to a journal for publication.

### **4 Peer Review by the TROG Publications Committee**

The term 'peer review' is described by the Code as impartial and independent assessment of research by others working in the same or a related field.

Although the TPC does not necessarily conduct an independent scientific review of material, it may provide input that contributes to maintaining high standards and encouraging accurate, thorough and credible research reporting.

### **5 Reporting Requirements**

The Revised CONSORT (Consolidated Standards of Reporting Trials) Statement<sup>2,3</sup> must be used as a guideline for the reporting of clinical trials to ensure meaningful information in order for the reliability or relevance of the findings to be judged.

## **6 Presentations**

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

The presenting of research findings should not occur until the findings have been tested through peer review. The Executive Author shall, therefore, forward the presentation of any main or substudy results to the TMC for review and approval before the presentation is given.

## **7 Media Representative**

The Media representative for all trial results must be an adequately qualified individual with sound knowledge of the trial invited by the TMC to undertake this role.

As with presentations, discussions of research findings in the public arena should not occur until the findings have been tested through peer review. All media releases (including any substudy media releases) must, therefore, be considered in advance and vetted by the TMC.

The TROG Central Operations Office should be notified in advance of any planned media releases via [TROG@trog.com.au](mailto:TROG@trog.com.au). Where required, TROG can offer advice particularly with regards to any restrictions on communications that may have been agreed to with TROG.

If a variation between what was said and what was published occurs in the press, this should be reported to the TMC. The TMC shall advise appropriate action (if any) and report to the TROG Scientific Committee (TSC) who will be responsible for implementing or modifying any advised action.

## **8 Publication of Related Data**

### **8.1 Sub studies**

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.

TROG Policy Statement TPS E3 'Guidelines for the progression of TROG trials' describes the submission process for TROG sub studies.

### **8.2 Secondary analyses**

Secondary analysis of the data can be used to address questions which were not posed in the original protocol or which have arisen as a result of new evidence becoming available.

TROG Policy Statement TPS E12 Undertaking Secondary Analysis on Data from TROG Trials describes processes for approval, access, review and publication of secondary analyses from TROG trials.

Publication of secondary analyses data must adhere to the authorship, publication and spokesperson requirements of this document.

### **8.3 Meta-analyses**

Meta-analysis is the formal evaluation of the quantitative evidence from two or more trials bearing on the same question. A common definition of the primary and secondary endpoints is essential

Data should not be released for meta-analyses until the consent of the all relevant TMCs has been obtained and confirmation received that the final report of for all TROG trials involved in the meta-analyses have been accepted for publication.

The Trial Chairpersons should ensure that he/she has the right to make reasonable amendments to the meta-analysis manuscript or to withdraw the reference to the data altogether prior to submission if necessary.

The Trial Chairpersons should also determine if a TROG author will be included in the authorship list. The nomination of TROG co-authors rests with the TMCs of the involved trials.

## **9 Intellectual Property**

The National Principles of Intellectual Property Management for Publicly Funded Research defines Intellectual Property (IP) as intangible property that attracts rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields. Property protected includes scientific works and discoveries<sup>6</sup>.

IP for the purpose of this document is all data collected and generated as part of a TROG trial.

TROG Cancer Research and in a more direct fashion, the Trial Chairperson, is the custodian of the trial data. The associated rights of the data will be included in the Clinical Trial Agreement between TROG and the Trial Chairperson. An original signed agreement will be held by both parties.

The custodianship of data generated as a result of collaborative initiatives between research groups will be vested in the Collaborative Research Group Agreement between TROG and the collaborating group. An original signed agreement will be held by both parties.

TROG trial data will be managed in accordance with the Note for Guidance on Good Clinical Practice (GCP).<sup>7</sup>

## **10 Data Sharing**

In order to comply with the recommendations of the International Committee of Medical Journal Editors (ICMJE), a data-sharing statement should be included in publications arising from TROG trials.

Data sharing statements must indicate the following<sup>8</sup>:

- Whether individual de-identified participant data (including data dictionaries) will be shared
- What data, in particular, will be shared
- Whether additional, related documents will be available (e.g., study protocol, statistical analysis plan, etc.)
- When the data will become available and for how long
- By what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism).

Please refer to Appendix 2, for examples of data sharing statements that fulfil these requirements

## **11 Disputes**

Should an allegation of a deviation from this guideline or misconduct in research be made, a prompt and effective response is required from the TMC.

Any disputes shall first be dealt with by the TMC. If no resolution is achieved, or if disciplinary action is deemed warranted, the matter will be referred on to the TPC for final decisions and action. If necessary, the TSC will be informed.

In resolving the allegation all committees shall refer to both the Code *Part B 'Breaches of the Code, research misconduct, and the framework for resolving allegations* and "*Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research, 2018*"

## 12 References

1. Uniform Requirements for Manuscripts Submitted to Biomedical Journals. International Committee of Medical Journal Editors. Available at <http://www.icmje.org/>
2. Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. [BMJ 2010;340:c332](#). Available at <http://www.consort-statement.org>
3. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, Elbourne D, Egger M, Altman DG, for the CONSORT Group. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trial. [BMJ 2010;340:c869](#). Available at <http://www.consort-statement.org>
4. Australian Code for the Responsible Conduct of Research (2018). Available at: <https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018>
5. Authorship: A guide supporting the Australian Code for the Responsible Conduct of Research (2019). National Health and Medical Research Council, Australian Research Council and Universities Australia. Commonwealth of Australia, Canberra. Available at: <https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018>
6. National Principles of Intellectual Property Management for Publicly Funded Research, available from ([www.arc.gov.au](http://www.arc.gov.au)).
7. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) - Annotated with TGA comments. National Health and Medical Research Council. 9 November 2016. Available at <https://www.tga.gov.au/publication/note-guidance-good-clinical-practice>
8. Taichman DB, Sahni P, Pinborg A, Peiperl L, Laine C, James A, et al. Data Sharing Statements for Clinical Trials — A Requirement of the International Committee of Medical Journal Editors. *New Engl J Med*. 2017 Jun; 376(23):2277-9.

## Appendix 1: Reporting Responsibilities to the TROG Publication Committee

### TPC Reporting expectations for each TROG trial category;

<b>Category A</b>	<ul style="list-style-type: none"><li>• Each manuscript/abstract should be submitted to the TPC for review prior to submission</li><li>• The name “TROG” must appear in the title (as per section 1 Authorship)</li><li>• The TPC is to be informed when the publication has been accepted</li><li>• The TPC is to be sent a copy of the published manuscript</li><li>• Inform the TPC of any presentation/poster (and the meeting details)</li></ul>
<b>Category B</b>	<ul style="list-style-type: none"><li>• The TROG trial chair is to inform the TPC of any publications in a timely manner*</li><li>• TROG to be acknowledged in accordance with the intergroup agreement and/or international trial centre’s policy</li><li>• The TPC is to be sent a copy of the published manuscript</li><li>• Inform the TPC of any presentation/poster (and the meeting details)</li></ul>
<b>Category C</b>	<ul style="list-style-type: none"><li>• The TROG trial chair is to inform the TPC of any publications in a timely manner*</li><li>• TROG to be acknowledged as per the lead groups publication policy</li><li>• The TPC is to be sent a copy of the published manuscript</li><li>• Inform the TPC of any presentation/poster (and the meeting details)</li></ul>
<b>Category D</b>	<ul style="list-style-type: none"><li>• Each publication should be submitted to the TPC for review prior to submission</li><li>• The name “TROG” must appear in the title (as per section 1 Authorship)</li><li>• The TPC is to be informed when the publication has been accepted</li><li>• The TPC is to be sent a copy of the published manuscript</li><li>• Inform the TPC of any presentation/poster (and the meeting details)</li></ul>

\* Reporting publications via the TROG biannual progress report is acceptable.



## Appendix 2: Example Data Sharing statements that fulfil the ICMJE Requirements<sup>8,\*</sup>

	Example 1	Example 2	Example 3	Example 4
<b>Will individual participant data be available (including data dictionaries)?</b>	Yes	Yes	Yes	No
<b>What data in particular will be shared?</b>	All of the individual participant data collected during the trial, after de-identification.	Individual participant data that underlie the results reported in this article, after de-identification (text, tables, figures, and appendices).	Individual participant data that underlie the results reported in this article, after de-identification (text, tables, figures, and appendices).	Not available
<b>What other documents will be available?</b>	Study Protocol, Statistical Analysis Plan, Informed Consent Form, Clinical Study Report, Analytic Code	Study Protocol, Statistical Analysis Plan, Analytic Code	Study Protocol	Not available
<b>When will data be available (start and end dates)?</b>	Immediately following publication. No end date.	Beginning 3 months and ending 5 years, following article publication.	Beginning 9 months and ending 36 months following article publication.	Not applicable
<b>With whom?</b>	Anyone who wishes to access the data.	Researchers who provide a methodologically sound proposal.	Investigators whose proposed use of the data has been approved by an independent review committee (“learned intermediary”) identified for this purpose.	Not applicable
<b>For what types of analyses?</b>	Any purpose.	To achieve aims in the approved proposal.	For individual participant data meta-analysis.	Not applicable
<b>By what mechanism will data be made available?</b>	Data are available indefinitely at ( <i>link to be included</i> ).	Proposals should be directed to xxx@yyy. To gain access, data requestors will need to sign a data access agreement. Data are available for 5 years at a third party website ( <i>link to be included</i> ).	Proposals may be submitted up to 36 months following article publication. After 36 months the data will be available in our University’s data warehouse but without investigator support other than deposited metadata. Information regarding submitting proposals and accessing data may be found at ( <i>link to be included</i> ).	Not applicable

\* These examples are meant to illustrate a range of, but not all, data sharing options