

Authorship, Publication and Spokesperson Guideline

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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). The guidelines below have been implemented to complement the Revised CONSORT (Consolidated Standards of Reporting Trials) Statement^{2,3} and 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

To be named as an author, a researcher must have made a substantial scholarly contribution to the work and be able to take responsibility for at least that part of the work they contributed.⁴

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
- b) analysis and interpretation of data
- c) drafting significant parts of the article OR critically revising it for intellectual content
- d) 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. Substantial intellectual involvement is required.⁴

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.

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, 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.⁴

2 TIMING OF PUBLICATIONS AND PRESENTATIONS

Collaborating researchers should agree on 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 work 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.⁴ 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.

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 analysis takes longer than 12 months to complete
- The finalised manuscript is not submitted to TPC within 12 months of main analysis

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.

The TPC contributes to the peer review process by providing independent scientific review of material and timelines, helping to maintain high standards and encouraging accurate, thorough and credible research reporting.

5. REPORTING REQUIREMENTS

The Revised CONSORT (Consolidated Standards of Reporting Trials) Statement^{2,3} 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 sub-studies) 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 sub-study 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 sub-study 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 and the TROG Communications Officer contacted for advice where required, 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 substudy 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 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) is intangible property that attracts rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields. Property protected includes scientific works and discoveries.

IP for the purpose of this document is all data collected and generated for the purpose 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).⁶

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 following⁷:

- 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 the Code *Part B 'Breaches of the Code, research misconduct, and the frame work for resolving allegations'*.

11 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 (2007) . Available at: <http://www.nhmrc.gov.au/publications/synopses/r39syn.htm>
5. National Principles of Intellectual Property Management for Publicly Funded Research, available from (www.arc.gov.au).
6. ICH GCP Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Annotated with TGA Comments. Commonwealth Department of Health and Aged Care. DSEB July 2000.
7. 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;

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

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

APPENDIX 2: EXAMPLE DATA SHARING STATEMENTS THAT FULFIL THE ICMJE REQUIREMENTS^{7,*}

	Example 1	Example 2	Example 3	Example 4
Will individual participant data be available (including data dictionaries)?	Yes	Yes	Yes	No
What data in particular will be shared?	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
What other documents will be available?	Study Protocol, Statistical Analysis Plan, Informed Consent Form, Clinical Study Report, Analytic Code	Study Protocol, Statistical Analysis Plan, Analytic Code	Study Protocol	Not available
When will data be available (start and end dates)?	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
With whom?	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
For what types of analyses?	Any purpose.	To achieve aims in the approved proposal.	For individual participant data meta-analysis.	Not applicable
By what mechanism will data be made available?	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