

## **Trial specific procedure**

### **Authorship and publication**

Version 2.1

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#### **1. Purpose**

This document outlines the policy and procedures for publications arising from the PRISM trial, including any secondary studies.

#### **2. Authorship policy**

##### 2.1 Principles of authorship

This document is based on recommendations of the International Committee of Medical Editors (<http://www.icmje.org/icmje-recommendations.pdf>).

##### 2.2 Individual authorship

A contributor claiming authorship should meet the following criteria<sup>1</sup>:

- Substantial contribution to the work: conception or design *or* data collection or analysis *or* data interpretation AND
- Contributed to drafting *or* revising the manuscript AND
- Approved the final version of the manuscript AND
- Agreement to be accountable for all aspects of the work and agree that all questions regarding accuracy and integrity of the data are investigated and resolved.

##### 2.3 Group authorship

This will apply when the intellectual work underpinning a publication 'has been carried out by a group, and no one person can be identified as having substantially greater responsibility for its contents than others'.<sup>1</sup> In such cases the authorship will

be presented by the collective title – “The PRISM Trial Group” - and a footnote will carry the individual contributors and affiliations. Where an author takes responsibility for preparing a manuscript on behalf of the trial group, but all group members qualify as authors, this would be listed as ‘John Smith *and* the PRISM Trial Group.’ Where an author takes responsibility for preparing the manuscript and for the content of the paper, the trial group would be acknowledged and the author listed as ‘John Smith *for* the PRISM Trial Group.’

#### 2.4 Authorship of the main paper

Authorship of the principal trial report will be listed as the individual members of the writing committee, who will take responsibility for the content of the paper, on behalf of the PRISM Trial Group, i.e. ‘John Smith *for* the PRISM Trial Group.’ The writing committee will include members of the trial steering committee, as well as other members of the PRISM Trial Group co-opted at the discretion of the trial steering committee. It is anticipated that the chief investigators will be the first and last authors. Members of the PRISM Trial Group, including grant-holders and local research staff, will be listed in an appendix or footnote to the manuscript or a supplementary file. There are good examples of this publication format in the published literature.<sup>2,3</sup> Only the local investigators who have registered on the study database will be included in the PRISM Trial Group.

#### 2.5 Authorship of secondary studies

It is likely that the majority of secondary studies will qualify for individual authorship (see section 2.2). For secondary studies where contributors do not meet the authorship criteria, then authorship should be attributed to ‘John Smith *for* the PRISM Trial Group.’ A list of anticipated authors should be included on any secondary study analysis plan submitted for review by the trial steering committee. Authorship opportunities will be prioritised based on contribution to the trial.

#### 2.6 Arbitration

In the event of a dispute, the trial steering committee will make a ruling. In the event of disagreement within the trial steering committee, the independent chair will be asked to make a recommendation.

### **3. Procedure for publication**

Any investigator wishing to publish any data derived from the PRISM Trial, including local data should follow the following procedure.

#### **3.1 Secondary study proposal**

PRISM investigators will be given priority to lead secondary analyses and are encouraged to do so. Participation and authorship opportunities will be based on contribution to the primary trial. The trial steering committee will consider the scientific validity and the possible effect on the anonymity of participating centres prior to granting any such requests. Where necessary, a prior written agreement may be requested to set out the terms of such collaborations. Investigators should submit a secondary study proposal for review by the steering committee. 'Cleaned' data from the international dataset will only be released after a secondary study proposal has been approved. An analysis involving any data derived from the PRISM trial will be considered a secondary analysis and subject to these rules.

#### **3.2 Confidentiality and anonymity**

The identity of study participants must be protected. Before data is released, patient-identifying information will be removed. However, it remains the responsibility of the authors to ensure that individual patients cannot be identified as a result of publication.

#### **3.3 Responsibilities of the lead author**

- Writing the analysis plan and submitting this to the trial steering committee for peer-review
- Co-ordinating the data analysis
- Co-ordinating the writing of the paper
- Circulating drafts
- Ensuring that all authors listed meet the authorship criteria
- Ensuring quality assurance of the data and analysis
- Submitting the final manuscript for internal peer review by the PRISM trial steering committee before sending the manuscript to a journal

- Informing the PRISM trial steering committee when the paper has been submitted to a journal and when it has been approved for publication.

### 3.4 Internal peer-review

Publications using data derived from the PRISM trial have the potential to impact the reputation of the trial. Before any manuscript is submitted to a journal it must be reviewed and approved by the trial steering committee or nominated deputies. This process will occur in a timely manner. If a manuscript is rejected, constructive feedback will be given to help the authors improve the paper.

### 3.5 Publications without approval

The PRISM trial steering committee is supportive of access to PRISM data by local contributors. The steering committee is responsible for protecting the reputation of the PRISM Trial Group and ensuring that publications derived from PRISM are fair and accurate. If data derived from PRISM is published without internal peer review and approval as outlined above, the PRISM trial steering committee reserves the right to contact the publisher to report a breach of the publication charter.

### 3.6 Submission of a secondary study proposal

Secondary study proposals or draft manuscripts should be submitted to the trial management group via [admin@prismtrial.org](mailto:admin@prismtrial.org). A secondary study template is available upon request

#### 4. References

1. Defining the role of authors and contributors. *International Committee of Medical Journal Editors*. <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html> Accessed 24/9/14.
2. Acute Respiratory Distress Syndrome: the Berlin Definition. *ARDS Definition Task Force, Ranieri VM, Rubenfeld et al.* 2012. *JAMA*; 307(23); 2526-33.
3. Effect of a Perioperative, Cardiac Output-Guided Hemodynamic Therapy Algorithm on Outcomes Following Major Gastrointestinal Surgery: A randomised controlled trial and systematic review. *Pearse RM, Harrison DA...for the OPTIMISE Study Group.* 2014. *JAMA*: 311(21): 2181-90.