

**Optimisation of Perioperative
Cardiovascular Management to
Improve Surgical Outcome II
(OPTIMISE II) Trial**

Publication Charter

Chief Investigator: Professor Rupert Pearse

1. Authorship policy

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

1.1 Group Authorship

The principal OPTIMISE II paper will be published on behalf of all contributors. The author will be listed as 'The OPTIMISE II Study Group' and a footnote will carry the names and affiliations of contributors. Individual contributors will be included in this list if they registered as local investigators on the OPTIMISE II data entry website and have a certificate of participation, or they are a member of the core study management team. Where an author takes responsibility for preparing a manuscript on behalf of the study group, this would be listed as 'John Smith *and* the OPTIMISE II Study Group'. Where an author takes responsibility for preparing the manuscript and for the content of the paper, the study group would be acknowledged and the author listed as 'John Smith *for* the OPTIMISE II Study Group.'

1.2 Individual Authorship

Reports of sub-studies using OPTIMISE II data may qualify for individual authorship. A contributor claiming authorship should meet the following criteria¹:

- 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.

Authors should be listed on any secondary study analysis plans that are submitted for review by the steering committee.

1.3 Acknowledgements

The trial funders must be acknowledged in all publications.

1.4. Arbitration

In the event of a dispute, the steering committee will make a ruling. In the event disagreement within the steering committee, the Chief Investigator will be the final arbiter.

2. Standard Operating Procedure – publications

Any investigator wishing to publish any data derived from OPTIMISE II, including national or local data should follow the following procedure.

2.1 Secondary study proposal

The OPTIMISE II trial steering committee encourages high quality secondary analyses of the trial data and supports the wider principle of data sharing. OPTIMISE II investigators will be given priority to lead secondary analyses. Participation and authorship opportunities will be based on contribution to the primary study. No publications are allowed before the primary publication, however, if the primary manuscript has not been accepted for publication within twelve months following the completion or termination of the clinical trial at all sites, a co-ordinating investigator may publish clinical methods and data from their own site. Where necessary, a prior written agreement will set out the terms of such collaborations. Investigators should submit a secondary study proposal for review by the steering committee. The steering committee will consider the scientific validity and the possible effect on the anonymity of participating centres prior to approval of secondary study proposals. 'Cleaned' data from the international dataset will only be released after the statistical analysis plan for the secondary study has been approved. Any data sharing requests/proposals must be approved by the Data Sharing Committee at the coordinating centre and will require a Data Sharing Agreement. Any analysis incorporating OPTIMISE II data from one or more study sites will be considered a secondary analysis and subject to these rules.

2.2 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.

2.3 Responsibilities of the lead author

- Writing the statistical analysis plan and submitting this to the 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 manuscript for internal peer review by the OPTIMISE II trial steering committee
- Informing the OPTIMISE II study group when the paper has been submitted to a journal and when it has been approved for publication.

2.4 Internal peer-review

Publications using data derived from OPTIMISE II have the potential to impact the reputation of the study. 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.

2.5 Funders Peer Review

The trial funders must be afforded the opportunity to review any proposed publication in accordance with the relevant contracts.

2.6 Publications without approval

The OPTIMISE II Study Group is supportive of access to OPTIMISE II data by local contributors. The OPTIMISE II trial steering committee is responsible for protecting the reputation of the OPTIMISE II Study Group and ensuring that publications derived from OPTIMISE II are of high quality, accurate and representative of the data collected. If data derived from OPTIMISE II is published without internal peer-review and approval outlined above, the OPTIMISE II trial steering committee reserves the right to contact the publisher to report a breach of the publication charter. We expect that this would result in either the retraction of the paper or refusal to publish the work.

2.7 Submission of a secondary study proposal

Secondary study proposals and data sharing requests should be submitted to the data management team (admin@optimiseii.org).

3. References

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>