

Authorship and publication

Authors: S. Mehta, L. Prisco, and the SANDMAN Steering Committee

1. Purpose

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

2. Authorship policy

2.1 Principles of authorship

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

2.2 Individual authorship

A contributor claiming authorship should meet the following criteria:

- 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'. In such cases the authorship will be presented by the collective title – "The SANDMAN Study Group" - and a footnote will list the individual collaborators and affiliations. Where an author takes responsibility for preparing a manuscript on behalf of the study group, but all group members qualify as authors, this would be listed as 'Jane Smith *and* the SANDMAN 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 'Jane Smith *for* the SANDMAN Study Group.'

2.4 Authorship of the main paper

Authorship of the principal study 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 SANDMAN Study Group, i.e. 'Jane Smith *for* the SANDMAN Study Group.' The writing committee will include members of the steering committee, as well as other members of the SANDMAN Study Group co-opted at the discretion of the Executive committee. It is anticipated that the 2 co-principal investigators will be the first and last authors. Members of the SANDMAN Study Group, including a maximum of 2 local research staff, will be listed in an appendix to the manuscript or in a supplementary file. All national coordinators and site investigators who recruit 20 patients with less than 20% missing data will be listed as collaborators.

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 authorship criteria, then authorship should be attributed to 'Jane Smith *for* the SANDMAN Study Group.' A list of anticipated authors should be included on any secondary study analysis proposal submitted for review by the Executive committee (see section 3.6). Executive committee members will be included as authors on all secondary studies.

2.6 Publication of data from an individual investigator's site

Each investigator is entitled to export their site data which was collected locally. After the primary SANDMAN manuscript is published, site investigators may publish their own site data.

2.6 Arbitration

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

3. Procedure for publication

Any investigator wishing to publish any data derived from the SANDMAN Study, including local data should follow the following procedure:

3.1 Secondary study proposal

SANDMAN 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 study. The study 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 Executive committee. 'Cleaned' data from the international or national datasets will only be released after a secondary study proposal has been approved. An analysis involving any data derived from the SANDMAN study 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 steering committee for peer-review
- Costs associated with data extraction and statistical analysis
- Coordinating the data analysis
- Coordinating 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 SANDMAN steering committee before sending the manuscript to a journal
- Informing the SANDMAN steering committee when the paper has been submitted to a journal and when it has been accepted for publication.

3.4 Internal peer-review

Publications using data derived from the SANDMAN study 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 SANDMAN steering committee is supportive of access to SANDMAN data by international contributors. The steering committee is responsible for protecting the reputation of the SANDMAN study Group and ensuring that publications derived from SANDMAN are fair and accurate. If data derived from SANDMAN is published without internal peer review and approval as outlined above, the SANDMAN 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 should be submitted to the Executive committee. A secondary study template can be found on the SANDMAN study website (<https://www.esicm.org/research/trials/trials-group-2/sandman/>) or from the Principle Investigators: Dr. Geeta Mehta (Geeta.mehta@utoronto.ca) and Dr. Lara Prisco (lara.prisco@ndcn.ox.ac.uk).