The 'Platform of Randomized Adaptive Clinical Trials in Critical Illness (PRACTICAL) Randomized Controlled Trial' Publication Policy

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Protocol Number: OZUHN-004

Platform Lead Investigators:
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Domain Lead Inveatigators:
Listed in each domain protocol

Platform Lead Investigator Signature: _____ **Date:** _____

Platform Lead Investigator Signature: _____ **Date:** _____

SECTION I: AUTHORSHIP POLICY

1. PRINCIPLES OF AUTHORSHIP

The following principles of authorship have been derived from editorial publications from leading journals[1,2] and are in accordance with the rules of the International Committee of Medical Journal Editors (ICMJE) (http://www.icmje.org/ethical_1author.html). These principles apply to any *Platform of Randomized Adaptive Clinical Trials in Critical Illness (PRACTICAL) Randomized Controlled Trial* (OZUHN-004) outputs including papers and presentations related to the general platform or individual domain protocols within the platform. The Platform Lead Investigators reserve the right to modify this document with the approval of a majority of the platform steering committee.

a. Primary paper for each domain/intervention

The paper will have individual named authorship (see Section II for further procedural details). In order to qualify for authorship an individual must fulfil the following criteria[1]:

i. Each author should have participated sufficiently in the work represented by the article to take public responsibility for the content.
ii. Participation must include three steps:
- Conception or design of the work represented by the article, and/or acquisition of data, and/or analysis and interpretation of the data; AND
- Drafting the article or revising it critically for important intellectual content; AND
- Final approval of the version to be published.

Participation solely in the collection of data or membership of an OZUHN-004 organisational committee is insufficient by itself to warrant authorship. Persons who have contributed intellectually to the article, but whose contributions do not justify authorship, will be acknowledged and their contribution described.[1]

For domain/intervention-level publications, the domain lead investigators will be responsible for ensuring that each author meets the above criteria.

The same principles will apply for platform-level publications. For platform-level publications, the Platform Lead Investigators will be responsible for ensuring that each author meets the above criteria. Where publications involve reporting of domain-domain interactions, authorship selection and permission to publish will be established by consensus of the Platform Lead Inveatigators and Domain Lead Investigators of the respective domains. Domain-domain interactions will not be reported until the domain data employed in the relevant analysis has already been reported.

b. Determining authorship

In principle, decisions on authorship will be made for the OZUHN-004 study and have been agreed by the OZUHN-004 Executive Committee through the process outlined in Section II.

These principles include:

i. The Domain Lead Investigator(s) will have final authority on authorship invitations and determine the order of authorship. In secondary analysis publications for a given dataset, the authorship will be determined as per the proposal submitted to the Domain Lead Investigators for reporting.
ii. In general, the lead author(s) will be the individual(s) who oversaw the development, evaluation, and implementation of the intervention/domain under study leading to the generation of the dataset for reporting. This will be determined at the discretion of the Domain Lead Investigators.
iii. In publications that do not report study data (e.g., protocols, simulation results), the lead author(s) will be the individual(s) who led the reported analysis (if appropriate) and brought paper to publication point (e.g., developed the initial draft and lead the redrafting). These lead authors will be responsible for other author invitations and determining the order of authorship. If these authors are not the same, the lead author(s) will be determined at the discretion of the Platform Lead Investigators or Domain Lead Investigators as applicable.
iv. Where appropriate, there may be multiple first and senior authors. In this case, there will be a footnote regarding shared/equal contributions as appropriate.
v. In secondary publications, authorship selection and order will be determined at the time the proposal is submitted by consensus between Domain Lead Investigators
vi. Other authors will include members of the Domain Protocol Committee (DPC) and additional collaborators at the Domain Lead Investigators' discretion.
vii. Generally, each recruiting centre will have the opportunity to have 1 author for the paper if they have contributed at least 10 patients to the dataset that is being reported and fulfil the criteria for authorship which they will be given the opportunity to achieve. Additional recruiting center authors can be invited at the domain lead investigators discretion.
viii. Other investigators (and some other major contributors) will have the opportunity to lead a OZUHN-004 substudy as named first or senior authors as appropriate for contribution to these papers.

ix. Unless deemed inappropriate by the Domain Lead Investigators with agreement from the Platform Principal Investigators, publications in the platform based on data from patients recruited to the platform will mention group authorship on behalf of the "PRACTICAL Platform Investigators."
x. Where possible, all investigators and sites involved in PRACTICAL will be listed as collaborators.
xi. Where authorship limits exist, authorship will be designated based on contribution level, as determined by the lead author, and group authorship will be used (if available) for all other contributors. In general, group authorship for participating networks and funders will be recognized.
xii. If conflicts arise, they will be resolved by the Domain Lead Investigators.

All these specifications are being identified *a priori* but will depend on actual contributions to the design, conduct, analysis and write up of the study.

c. *Quality assurance*

Quality assurance is essential to the good name of the OZUHN-004 study collaboration. Prior to the submission of any domain-specific publications (including abstracts, reports, manuscripts, first presentations of trial results, etc.), an internal peer review among members of the Domain Protocol Committee (DPC), Platform Steering Committee (PSC) and Statistical Analysis Committee (SAC), is mandated. Where appropriate, review may be extended to participating networks and funders. This mandatory review may delay or reject the decision to publish in cases of serious concerns regarding the scientific quality of the submission. If this results in dissatisfaction among study investigators, the PSC may be consulted for arbitration.

REFERENCES

1. Huth EJ (1986). Guidelines on authorship of medical papers. *Annals of Internal Medicine*, **104**, 269-274.
2. Glass RM (1992). New information for authors and readers. Group authorship, acknowledgements and rejected manuscripts. *Journal of the American Medical Association*, **268**, 99.

SECTION II: PUBLICATION PROCEDURES

The OZUHN-004 study collaboration has explicit procedures for undertaking individual authorship publications. Below outlines all relevant steps that should be undertaken in order to author a paper stemming from data collected as part of the OZUHN-004 study collaboration.

- Every author who is planning to write a paper for publication in a peer reviewed journal should complete a "paper/presentation proposal form" (Appendix A) providing all the necessary detail.

- The proposal form should be circulated to all the potentially relevant co-authors (see Section 1.1.a for details on how to qualify for authorship).

- Electronic copies of completed forms should be sent to the domain-lead investigator(s) via email (see Appendix A for details). The domain-lead investigator(s) will be responsible for the assessment and response to the outlined proposal.

- Given a positive decision in favour of writing a paper, the lead author on the proposal is responsible for coordinating (a) the writing of the paper (b) the circulation of drafts for comment allowing co-authors reasonable time (at minimum, 48 hours) to respond (c) ensuring quality assurance (see Section I, 2.b) and for informing the lead investigator(s) when (d) the paper has been submitted and (e) when the paper has been accepted.

- Resubmission of the same paper to a different journal following rejection should be checked with the group of authors as well as the lead investigator(s).

The INSERT NAME OF STUDY Collaboration

PAPER PROPOSAL

Date: .....

LEAD AUTHOR: .....

Working title of paper

.....

Target journal

[with key author guidance such as word limit]

Named authors, contributions to date and expected contributions

Timeline for drafts and author comments

[including target date for submission]

Background

[brief section, to include aims and research questions]

Research Aims

Required Data, Proposed Analysis Approach

Likely key messages

Key references