

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

v.2.0 10-Nov-2025

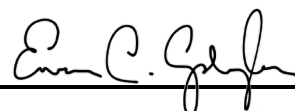
Protocol Number: OZUHN-004

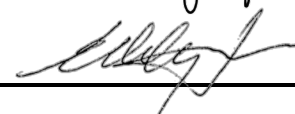
Platform Lead Investigators:

Dr Ewan Goligher, University Health Network
 Dr Eddy Fan, University Health Network

Domain Lead Investigators:

Listed in each domain protocol

Platform Lead Investigator Signature:  **Date:** January 8, 2026

Platform Lead Investigator Signature:  **Date:** January 9, 2026

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 criteria¹:

- 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 organizational 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 Investigators 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 or the PRACTICAL Executive Committee for reporting. Refer to Section II of this document for details.
- 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 or the PRACTICAL Executive Committee. Refer to Section II of this document for details.
- 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 PRACTICAL platform 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

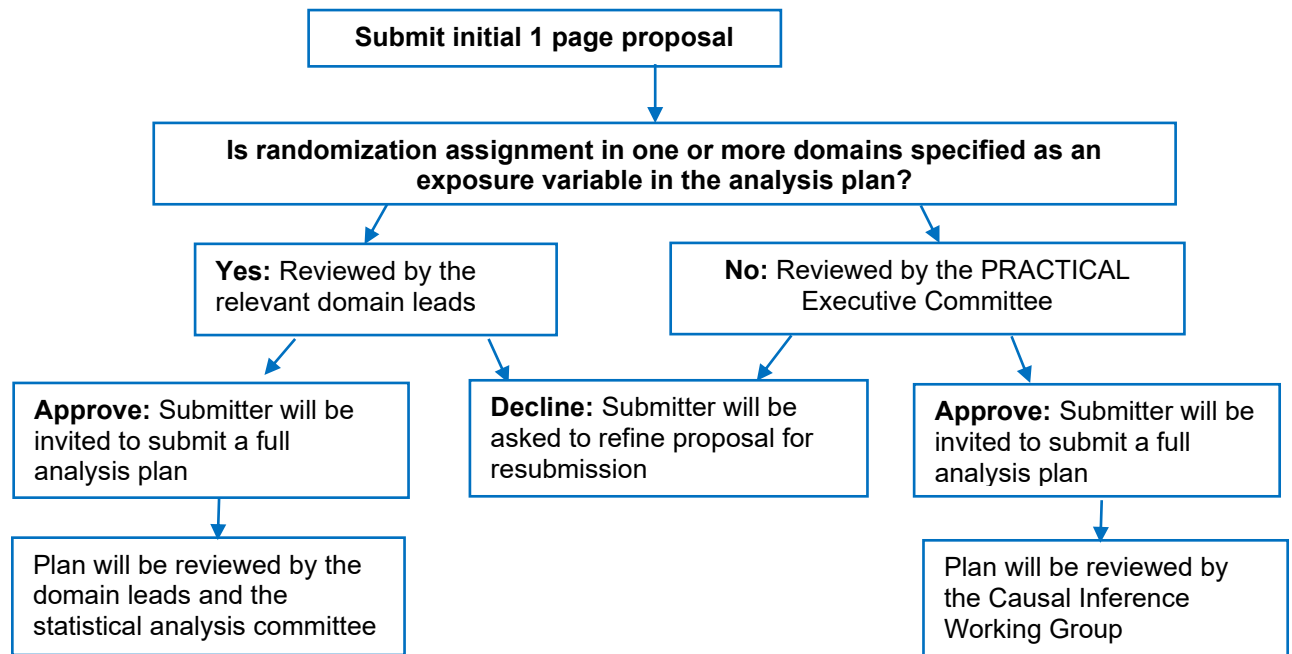
1. Huth EJ (1986). Guidelines on authorship of medical papers. *Annals of Internal Medicine*, **104**, 269-274.
2. Glass RM (1992). New information for authors and readers. Group authorship, acknowledgements and rejected manuscripts. *Journal of the American Medical Association*, **268**, 99.

SECTION II: ACCESS TO DATA

- Access to data for the primary publication is determined by the relevant intervention lead investigators and domain lead investigators
- For the first year after the primary publication, access to data for analysis and publication will be available only to PRACTICAL investigators. They can apply for access using process outlined in the ancillary analysis SOP.
- Thereafter, applications for access to data for ancillary analyses will be allowed from any investigators, following the ancillary analysis SOP process.
- In general, access to data in randomized trials conducted in PRACTICAL will not be allowed until the primary trial publication is made available. However, observational ancillary analyses may be permitted prior to publication of primary trial results where there is an appropriate rationale and randomized treatment assignment is not part of the analysis.
- In the case of ancillary analysis publications, authorship will be determined by the investigators who applied to conduct the ancillary analysis with endorsement by relevant intervention/domain lead investigators and executive committee.

SECTION III: PUBLICATION PROCEDURES

The PRACTICAL platform 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 PRACTICAL platform collaboration.



Submission Instructions:

- To propose a new scientific or observational data proposal, please complete the attached application form (Appendix) and include any relevant supplementary materials.
- Proposals need a sponsor (a domain or intervention lead in the platform); the support of this individual should be indicated on the application. The platform chairs can identify a platform sponsor for the analysis if needed. Sponsorship does not guarantee approval of the proposal.
- Submit all documents to info@practicalplatform.org.

Note re PRACTICAL platform publication policies:

Evaluation Criteria: Proposals will be assessed based on:

- Scientific rationale
- Methodological rigor
- Feasibility and data use (who will perform the analysis, where will it be performed)
- Relevance to PRACTICAL goals
- Ethical and data governance considerations
- Potential impact on clinical practice, research, and the Platform
- Proposed authorship is deemed acceptable

Appendix – Application for Ancillary Analyses

SECTION 1: GENERAL INFORMATION

Name of Applicant: Click or tap here to enter text.

Proposal Title: Click or tap here to enter text.

Prior Engagement: Has this proposal been discussed with any members of the PRACTICAL Executive Committee or domain or intervention leads? Yes No
If yes, please specify: Click or tap here to enter text.

SECTION 2: PROPOSAL DETAILS

SUMMARY INSTRUCTIONS:

Please provide a 1-2 page summary of your proposed scientific or observational data analysis, addressing the following key areas:

1. **Background & Rationale**
Briefly describe the clinical context, the knowledge gap your proposal addresses, and how it aligns with PRACTICAL's objectives (e.g., improving outcomes in acute hypoxemic respiratory failure).
2. **Methodological Approach**
Outline the study design, analytical framework, exposure variables, inclusion/exclusion criteria, and outcome measures.
3. **Implementation Plan**
Describe how the analysis will be initiated upon approval, including any planned sequential analyses and the overall timeline.
4. **Feasibility & Data Use**
Address ethical considerations, data governance, and the suitability of PRACTICAL platform data for your analysis.

Specify who will perform the analysis, and where will it be performed. Options include:

- a) In-house analysis at sponsor institution – please describe funding available to support statistician time
 - b) Virtual platform environment hosted by sponsor institution, analysis conducted by applicant's team
 - c) Data transfer to another institution for analysis by investigator, analysis conducted by applicant's team
5. **Potential Impact**
Highlight the anticipated clinical, scientific, and platform-level contributions of your proposal.