



LIBERATE Authorship, Sub-Study and Secondary Analysis Guidelines

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Drafted by:	Signature:	Date:
Dawn Opgenorth Project Manager		November 21, 2025
Revised and Approved by:		
Oleksa Rewa Principal Investigator		November 21, 2025

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1. Introduction

This document outlines the policies and procedures for authorship for the protocol manuscript, the systematic review and meta-analysis (SRMA) manuscript, the primary manuscript and subsequent sub-studies and secondary analyses and their corresponding manuscripts for the LIBERATE trial.

The LIBERATE principal investigators support and encourage the development of sub-studies and secondary analyses by co-investigators. These can be developed and proposals may be submitted while the LIBERATE trial is ongoing.

Sub-studies are defined as studies that stem from or are built leveraging the LIBERATE trial infrastructure and that capture data elements outside of the electronic case report forms used for the main trial. Secondary analyses are defined by the use of data collected during the main LIBERATE trial and are focused on an ancillary research question that was not outlined *a priori* in the LIBERATE protocol.

2. Protocol and SRMA Manuscripts

We will use named authorship for the LIBERATE trial protocol and SRMA manuscripts, respectively.

The principal investigator or designate will prepare the initial drafts of the protocol and SRMA manuscripts. The principal investigator or designate will invite co-authors to critically review the manuscripts. Co-authors will fulfill the ICMJE requirements for authorship (Table 1).

Table 1. ICMJE Authorship Requirements (available at <http://icmje.org/>)

The ICMJE recommends that authorship be based on the following 4 criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-

3. Primary Manuscript

We will use group authorship (as opposed to named authorship) for the LIBERATE trial primary manuscript that details the principal findings of the trial (i.e., primary and pre-defined secondary outcomes) (Figure 1).

Figure 1. Authorship for the primary manuscript.

Manuscript Title	
The LIBERATE Investigators and the Canadian Critical Trials Group	
Appendix:	• Writing committee • Steering Committee • Data and Safety Monitoring Board members • Data management and coordinating centre(s) personnel • Participating sites personnel

The principal investigator or designate will prepare the initial draft of the primary manuscript. The principal investigator or designate will invite members of the steering committee, co-investigators, and/or study personnel (i.e., data coordinating centre; statistician, data and safety monitoring board members) to participate on the writing committee based on their contributions to the LIBERATE trial and at their discretion. Members of the writing committee will fulfill the ICMJE requirements for authorship (Table 1). The principal investigator may request that members of the writing committee draft sections of the manuscript, provide methodological expertise and provide clinical context expertise. All members of the writing committee will critically review the manuscripts.

All contributors to the LIBERATE trial will be listed in the appendix. Journal policies for listing contributors/collaborators will be followed to ensure that all contributors are cited on PubMed.

4. Sub-Studies

The principal investigator will encourage LIBERATE co-investigators to develop and submit proposals for sub-studies of the LIBERATE trial that leverage and build upon LIBERATE infrastructure and existing data collection. LIBERATE co-investigators should submit proposals for sub-studies to the principal investigators.

Sub-study proposals should include the following information:

- Research Question
- Background/rationale
- Proposed methodology
- Statistical analysis plan
- Timeline
- Resources required (i.e., statistical analysis support)
- Budget (i.e., additional or ancillary funding if required)

The principal investigator, in consultation with the project manager and the steering committee, will review each proposal, determine feasibility, suggest revisions if applicable, obtain additional

peer review if applicable (i.e., from members of the steering committee or other investigators with content and/or methodologic expertise) and provide final approval. This will be directly communicated to the co-investigators. In general, sub-studies should not compromise or compete with successful recruitment or timelines in the main trial.

If more than one co-investigator submits similar or near identical sub-study proposals, the principal investigator, with support from the steering committee as needed, will consider priority for co-investigators who first submit a proposal. The principal investigator will also strongly encourage and facilitate as needed, collaboration between co-investigators interested in performing a sub-study. The principal investigator will recommend one co-investigator to lead the sub-study. The process of selection for lead co-investigator will consider the co-investigator contributions to LIBERATE, knowledge and expertise, available resources, opportunity to support a trainee/learners, and contributions to the LIBERATE trial to date. If the nominated lead co-investigator is unable to devote sufficient time and resources to the proposed sub-study, the principal investigator, in consultation with the steering committee and sub-study investigator team, may recommend that another co-investigator lead the sub-study.

Approved sub-studies will be listed at the end of this document.

The principal investigator (and where applicable, members of the steering committee), will work with the co-investigators and sub-study team to further enhance the protocol and incorporate into the LIBERATE trial infrastructure. The principal investigator will also provide oversight and support, as needed, to the conduct of the sub-study.

For publications arising from sub-studies, authorship credit will prioritize those co-investigators who led and participated in the sub-study with appropriate acknowledgement of the larger LIBERATE investigator team and associated trials groups (Figure 2). This will align with the criteria outlined in Table 1. All other LIBERATE contributors will be listed in the appendix, as aforementioned.

Figure 2. Authorship for the sub-study manuscripts.

Sub-Study Manuscript Title	
Co-investigator 1, Co-investigator 2, Co-investigator 3... on behalf of the LIBERATE Investigators and the Canadian Critical Care Trials Group	
Appendix:	
• Writing committee	
• International Steering Committee	
• Data and Safety Monitoring Board members	
• Data management and coordinating centre(s) personnel	
• Participating sites personnel	

5. Secondary Analyses and Manuscripts

The principal investigator will encourage LIBERATE co-investigators to develop and perform secondary analyses from the LIBERATE trial using data collected during the trial and write and publish corresponding secondary manuscripts. The principal investigator may also invite members of the steering committee to lead secondary analyses, based on their contributions to LIBERATE, and their existing fields of interest and expertise.

Similar to above, if more than one co-investigator submits similar or near identical secondary analysis proposals, the principal investigator, with support from the steering committee as needed, will consider priority for co-investigators who first submit a proposal. The principal investigator will also strongly encourage and facilitate as needed, collaboration between co-investigators interested in performing a sub-study. The principal investigator will recommend one co-investigator to lead the secondary analysis. The process of selection for lead co-investigator will consider the co-investigator contributions to LIBERATE, knowledge and expertise, available resources, opportunity to support a trainee/learners, and contributions to the LIBERATE trial to date. If the nominated lead co-investigator is unable to devote sufficient time and resources to the proposed secondary analysis, the principal investigators, in consultation with the international steering committee and secondary analysis investigator team, may recommend that another co-investigator lead the secondary analysis.

Approved secondary analyses will be listed at the end of this document.

LIBERATE co-investigators interested in the development of secondary analyses should submit a proposal outlining their planned secondary analysis to the principal investigators. The proposal should include the following information:

- Research Question
- Background/rationale
- Proposed methodology
- Statistical analysis plan
- Timeline
- Resources required (i.e., statistical analysis support)
- Budget (i.e., funding if required)

The principal investigator, in consultation with the project manager and steering committee, will review each proposal for secondary analysis, determine if suitable, suggest revisions if applicable, and provide final approval.

The LIBERATE statistician will work with the lead co-investigator and study team to develop a statistical analysis plan for the secondary analysis, along with a timeline for completion of analysis.

The lead co-investigator will submit draft manuscripts from secondary analyses to the principal investigator for review and approval prior to submission to a journal for publication. Secondary manuscript may also need to be approved by the endorsing and/or sponsoring regional critical care trials groups prior to submission for publication.

For publications arising from secondary analyses, authorship credit will prioritize those co-investigators who led and participated in the secondary analysis with appropriate acknowledgement of the larger LIBERATE investigator team and associated trials groups (Figure 3). This will align with the criteria outlined in Table 1. All other LIBERATE contributors will be listed in the appendix, as aforementioned.

Figure 3. Authorship for the secondary analysis manuscripts.

Secondary Analysis Manuscript Title Co-investigator 1, Co-investigator 2, Co-investigator 3... on behalf of the LIBERATE Investigators and the Canadian Critical Care Trials Group Appendix: • Writing committee • International Steering Committee • Data and Safety Monitoring Board members • Data management and coordinating centre(s) personnel • Participating sites personnel
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Development of the Contributor Appendix

The appendix for all LIBERATE manuscripts will acknowledge:

- The writing committee
- The international steering committee
- Data and Safety Monitoring Board (DSMB) members
- Data management and coordinating centre(s) personnel
- Participating sites personnel

Within each participating site, the following individuals will be listed:

- Site principal investigator
- Site sub- or co-investigators
- Study coordinators

The order of sites listed in the contributor appendix will be listed by geographic region. Within each geographic region, the order of sites will be alphabetical.

We will acknowledge sites that were activated; however, did not enroll patients in the contributor appendix. These sites will be listed under a sub-heading of activated but did not enroll.

The project manager at the central coordinating centre will be responsible for preparing and maintaining the contributor appendix. This will encompass contact and verification of the principal investigator, sub-investigator(s) and study coordinator(s) at each site to ensure accuracy. It is the site's responsibility to ensure that the names of all participating members at their site is up to date and that the spelling of names and credentials are correct.

Approved Sub-Study and Secondary Analyses from LIBERATE:

Date	Study Type	Lead Co-I(s)	Title