

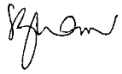


STARRT-AKI Authorship, Sub-Study and Secondary Analysis Guidelines

Version 1.0

Date: November 21, 1018

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| Drafted by: | Signature: | Date: |
|--|---|-------------------|
| Sean M Bagshaw Principal Investigator |  | November 21, 2018 |
| Revised and Approved by: | | |
| Ron Wald Principal Investigator |  | November 21, 2018 |
| Sean M Bagshaw Principal Investigator |  | November 21, 2018 |

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1. Introduction

This document outlines the policies and procedures for authorship for the protocol manuscript, the statistical analysis plan manuscript, the primary manuscript and subsequent sub-studies and secondary analyses and their corresponding manuscripts for the STARRT-AKI trial.

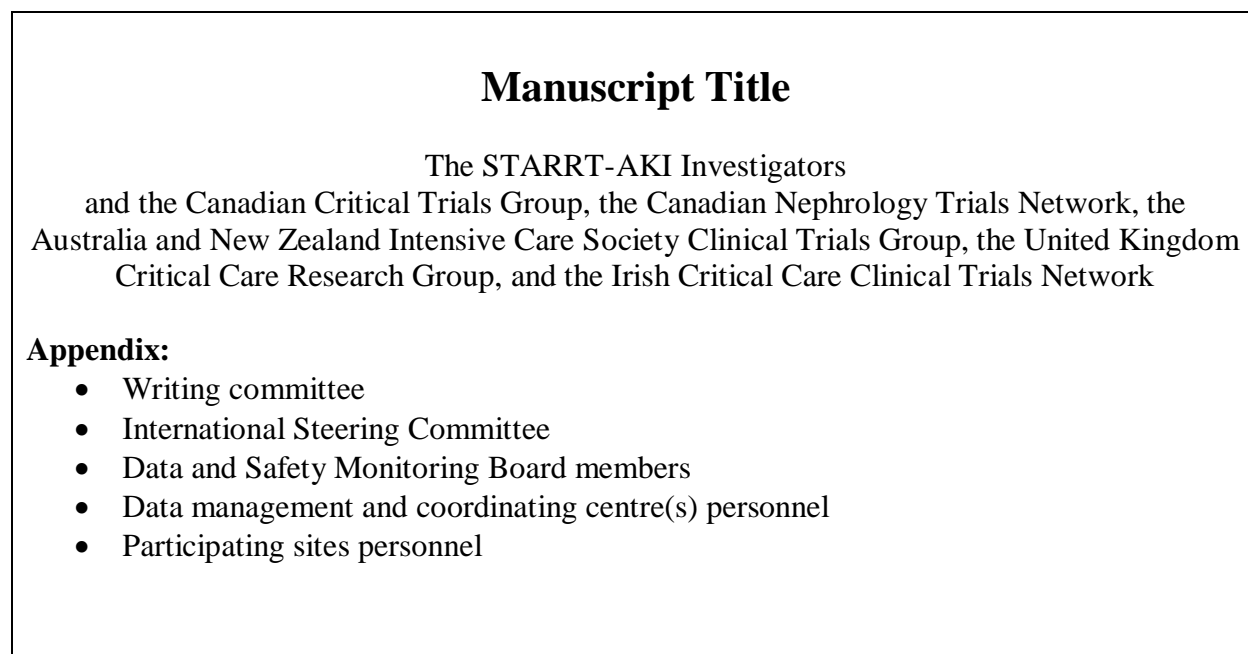
The STARRT-AKI principal investigators support and encourage the development of sub-studies and secondary analyses by co-investigators. These can be developed and proposals may be submitted while the STARRT-AKI trial is ongoing.

Sub-studies are defined as studies that stem from or are built leveraging the STARRT-AKI trial infrastructure and that capture samples or 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 STARRT-AKI trial and are focused on an ancillary research question that was not outlined *a priori* in the STARRT-AKI protocol.

2. Protocol and Statistical Analysis Plan Manuscripts

We will use group authorship (as opposed to named authorship) for the STARRT-AKI trial protocol and statistical analysis plan manuscripts, respectively (Figure 1).

Figure 1. Authorship for the protocol, statistical analysis plan and primary manuscripts.



The principal investigators will prepare the initial drafts of the protocol and statistical analysis plan manuscripts. The principal investigators will invite members of the international steering committee, and additional co-investigators (i.e., country leads, site leads with substantial trial recruitment) and/or study personnel (i.e., data coordinating centre; statistician, data and safety monitoring board members) to participate on the writing committees for the protocol and

statistical analysis plan manuscripts based on their contributions to the STARRT-AKI trial to date and at their discretion. Members of the writing committee will fulfill the ICMJE requirements for authorship (Table 1). The principal investigators may request that members of the writing committee draft sections of the manuscripts, provide methodological expertise, or provide clinical context expertise. All members of the writing committee will critically review the manuscripts.

For both the protocol and statistical analysis plan manuscripts, all contributors to the STARRT-AKI trial will be listed in the appendix. Where possible, journal policies for listing contributors/collaborators will be followed to ensure that all contributors are cited on PubMed.

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-authors.

3. Primary Manuscript

We will use group authorship (as opposed to named authorship) for the STARRT-AKI trial primary manuscript that details the principal findings of the trial (i.e., primary and pre-defined secondary outcomes) (Figure 1). The principal investigators will prepare the initial draft of the primary manuscript. The principal investigators will invite members of the international steering committee, co-investigators (i.e., country leads, site leads with substantial trial recruitment) 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 STARRT-AKI trial and at their discretion. Members of the writing committee will fulfill the ICMJE requirements for authorship (Table 1). The principal investigators 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 STARRT-AKI 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 investigators, along with members of the international steering committee, will encourage STARRT-AKI co-investigators to develop and submit proposals for sub-studies of the STARRT-AKI trial that leverage and build upon STARRT-AKI infrastructure and existing data collection. STARRT-AKI 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 investigators, in consultation with the project managers and the international 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 investigators, with support from the international steering committee as needed, will consider priority for co-investigators who first submit a proposal. The principal investigators will also strongly encourage and facilitate as needed, collaboration between co-investigators interested in performing a substudy. The principal investigators 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 STARRT-AKI, knowledge and expertise, available resources, opportunity to support a trainee/learners, and contributions to the STARRT-AKI trial to date. If the nominated lead co-investigator is unable to devote sufficient time and resources to the proposed sub-study, the principal investigators, in consultation with the international 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 investigators (and where applicable, members of the international steering committee), will work with the co-investigators and sub-study team to further enhance the protocol and incorporate into the STARRT-AKI trial infrastructure. The principal investigators 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 STARRT-AKI investigator team and associated trials groups (Figure 2). This will align with the criteria outlined in Table 1. All other STARRT-AKI contributors will be listed in the appendix, as aforementioned.

Figure 2. Authorship for the sub-study manuscripts.

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| <p style="text-align: center;">Sub-Study Manuscript Title</p> <p style="text-align: center;">Co-investigator 1, Co-investigator 2, Co-investigator 3... on behalf of the STARRT-AKI Investigators and the Canadian Critical Care Trials Group, the Canadian Nephrology Trials Network, the Australia and New Zealand Intensive Care Society Clinical Trials Group, the United Kingdom Critical Care Research Group, and the Irish Critical Care Clinical Trials Network</p> <p>Appendix:</p> <ul style="list-style-type: none">• 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 investigators will encourage STARRT-AKI co-investigators to develop and perform secondary analyses from the STARRT-AKI trial using data collected during the trial and write and publish corresponding secondary manuscripts. The principal investigators may also invite members of the international steering committee to lead secondary analyses, based on their contributions to STARRT-AKI, 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 investigators, with support from the international steering committee as needed, will consider priority for co-investigators who first submit a proposal. The principal investigators will also strongly encourage and facilitate as needed, collaboration between co-investigators interested in performing a substudy. The principal investigators 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 STARRT-AKI, knowledge and expertise, available resources, opportunity to support a trainee/learners, and contributions to the STARRT-AKI 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.

STARRT-AKI 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 investigators, in consultation with the project managers and international steering committee, will review each proposal for secondary analysis, determine if suitable, suggest revisions if applicable, and provide final approval.

The STARRT-AKI 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 investigators 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 STARRT-AKI investigator team and associated trials groups (Figure 3). This will align with the criteria outlined in Table 1. All other STARRT-AKI contributors will be listed in the appendix, as aforementioned.

Figure 3. Authorship for the secondary analysis manuscripts.

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| <p>Secondary Analysis Manuscript Title</p> <p>Co-investigator 1, Co-investigator 2, Co-investigator 3...</p> <p>on behalf of the STARRT-AKI Investigators</p> <p>and the Canadian Critical Care Trials Group, the Canadian Nephrology Trials Network, the Australia and New Zealand Intensive Care Society Clinical Trials Group, the United Kingdom Critical Care Research Group, and the Irish Critical Care Clinical Trials Network</p> <p>Appendix:</p> <ul style="list-style-type: none"> • Writing committee |
|---|

- International Steering Committee
- Data and Safety Monitoring Board members
- Data management and coordinating centre(s) personnel
- Participating sites personnel

Development of the Contributor Appendix

The appendix for all STARRT-AKI 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(s) at the central coordinating centre(s) 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 STARRT-AKI:

| Date | Study Type | Lead Co-I(s) | Title |
|------|------------|--------------|-------|
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