1 PURPOSE

1.1 The Publication Guidance document provides recommendations for authorship, manuscript concepts, writing teams, review and approval process, acknowledgements, and resolution of disputes. The overarching goal of this guidance document is to encourage transparency and fairness.

2 SCOPE

2.1 This guidance document is intended for PCORnet designated studies and investigators not necessarily affiliated with PCORnet designated studies but are presenting or publishing PCORnet-related research results, infrastructure, or other PCORnet perspectives.

2.2 Recommendations provided in this guidance document may be tailored to the individual study and/or project.

3 BACKGROUND

3.1 Studies that receive PCORnet study designation will use data and/or resources from one or more PCORnet networks (Patient Powered Research Networks (PPRNs) or Clinical Data Research Networks (CDRNs). These studies will be of various sample sizes and will use different study designs; nonetheless, each is expected to disseminate research findings in a timely manner.

3.2 Attribution of collaborators and networks will vary by study and contributions. Authorship and other options for attribution should be determined as early as possible during idea generation, concept development and preparation of draft documents that summarize findings such as manuscripts, abstracts and technical reports.

4 RELATED DOCUMENTS

4.1 PCORnet Branding Guidelines

4.2 PCORnet Governance Policy

5 DEFINITIONS/ACRONYMS

5.1 CDRN – Clinical Data Research Network

5.2 ICMJE – International Committee of Medical Journal Editors; http://www.icmje.org/

5.3 Network – There are two types of Networks in PCORnet: Clinical Data Research Networks (composed of health systems) and Patient-Powered Research Networks (composed of patient or participant communities).

5.4 PCORI – Patient Centered Outcomes Research Institute

5.5 PPRN – Patient Powered Research Network

6 AUTHORSHIP

6.1 There are at least 2 privileged places in authorship due to visibility – first and last (senior). PCORnet recommends these places be determined before work starts on the paper, although this may be renegotiated as the contributions come to fruition. The order of authors for large groups may include ordering alphabetically, by number of patients contributed, or some other fair and transparent process.

6.2 PCORnet recommends that the lead and senior authors guide the manuscript iterations, but includes other authors as needed during the initial writing phase.

6.3 Ultimately the first and senior authors have the final say in who meets authorship criteria and what order authors appear.

6.4 Decisions about authorship should be based on the following criteria:

6.4.1 Intellectual contribution to the conception, design, and writing of the study protocol,

6.4.2 Enrollment of subjects into the study protocol,

6.4.3 Contributions to data quality (protocol compliance, missing data, etc.), and

6.4.4 Other major contributions to the successful completion of the study (e.g., major role in statistical analysis, core lab functions, etc.).

6.5 PCORnet recommends the study include opportunities for junior investigators to meet authorship criteria.

6.6 PCORnet encourages collaboration and group authorship. The name of the study/network may be included as an author in two categories:

6.6.1 Corporate Authorship – The name of the group is listed in the byline but the member list is not included as part of the paper/appendix. Individuals are not indexed in PubMed but the group receives attribution.

6.6.2 Collaborative Group Authorship – The group name is listed and individual members are included as part of a list submitted with the paper. Individuals are indexed. PCORnet recommends collaborative group authorship to provide the broadest amount of credit.

6.6.3 Journals may have specific guidelines for corporate and collaborative authorship which should be checked prior to submission.

6.7 Individuals within the PPRN or CDRN may also be included as a named author with the obligation to fulfill roles through the ICJME guidance.

6.8 To assist in managing large writing groups in a timely manner, researchers may find it useful to refer to the manuscript timeline and/or author contract templates included as appendices in this document (e.g., Rosenberg et al., 2015, Dan Med J 62(2):A5009).

7 PLANNING STAGE

7.1 PCORnet recommends that early in the course of the study when the data elements are identified, the members of the study group generate ideas for papers based on the data being collected and the analysis plan. These ideas may go beyond the main study aims and include secondary uses of the collected data.

7.2 Collate the list and review for overlapping and redundant ideas. A committee should be established to review the scientific merit of the concepts and the potential for overlap with others previously submitted or in the planning stage.

7.3 Create collaborations among people with similar ideas or interests.

7.4 Prioritize final list of ideas and assign leads and teams for each that will develop the manuscript concept.

8 MANUSCRIPT CONCEPTS

8.1 Concepts should be developed to identify the primary authors who will develop the papers that result from the main aims as well as other secondary analyses the study group is planning.

8.2 Concepts should include an estimate of the timeframe to complete the manuscript, possible journals for submission, and any deadlines for abstract submissions.

8.3 Concepts should respect the privacy of patients and institutions in how the results will be presented.

8.4 A unique tracking number should be assigned to approved and disapproved concepts for reporting and tracking productivity and timeliness. Manuscripts resulting from the concept would have a modified but unique number that can be linked back to the concept. For example, for PCORnet study P09-2016-0002. The tracking system allows for comprehensive reporting to PCORI, as applicable, and the ability to review lists for productivity and timeliness.

8.5 A copy of a manuscript concept template is included with this guidance document.

9 WRITING TEAMS

9.1 The primary authors help to efficiently develop the first draft of the manuscript and to establish authorship early.

9.2 PCORnet encourages study teams to invite patients, participants, caregivers, clinicians, and other types of research participants to be part of the writing groups.

9.3 Team should agree on a deadline for the first draft. 1-2 people may ultimately be responsible for developing the first draft in a timely manner.

9.4 If the paper does not move forward as planned, another person may be assigned by the grant principal investigator, to the role of primary author.

9.5 The study may want to include an authorship agreement for the authors.

9.6 At the start of the study, the study should consider offering inclusion to all those individuals from the networks that are contributing data who have helped in areas highlighted in 6.4, noting that these individuals must fulfill ICJME requirements to be an author

9.7 The network representative on the writing team should be the site principal investigator; however, an appropriate representative may be selected based on topic area.

9.8 Writing team members need to be active participants on calls, reviewing data, and contributing to the writing of the manuscript.

9.9 Writing teams should look for opportunities to include junior and early-stage investigators for career development.

10 REVIEW AND APPROVAL PROCESS

10.1 Each approved PCORnet designated study is required to have a process for review of concepts and manuscripts that will lead to publically disseminated documents.

10.2 The process should include deadlines for timely review, keeping in mind other deadlines such as abstract submission dates and reports to funding agencies.

10.3 The overall principal investigator of the study and network site PI, or their designee, should review all manuscripts submitted for publication (except those using public access datasets) so they are aware of all research findings and confirm that all PCORnet PPRN and CDRN descriptions are accurate.

10.4 Approval is not required from the PCORnet Council or any of its standing Committees for publications or presentations.

11 ACKNOWLEDGEMENTS

11.1 Those that contributed to the study or the paper, but did not meet authorship criteria, e.g., interviewers or clinicians doing recruitment, should be listed in the acknowledgement section. These individuals may include stakeholders, advisory groups and patient representatives if criteria was not met. Permission from the named individual in the acknowledgements is usually required by the journal.

11.2 Acknowledgement of all funding agencies with grant/contract numbers is required.

11.3 Acknowledgement of the study's status as a PCORnet study is required in all websites, reports, presentations, and manuscripts.

11.4 Refer to the PCORnet Branding Guidelines for approved acknowledgements.

12 RESOLUTION OF DISPUTES

12.1 A process for resolving any disagreements or disputes in authorship, acknowledgements, and manuscript revisions is required for PCORnet designated studies, and is also recommended for investigators not necessarily affiliated with PCORnet designated studies but are presenting or publishing PCORnet-related research results, infrastructure, or other PCORnet perspectives.

12.1.1 Examples may include a majority vote by the review committee or the study's governance or steering committee, sole decision by the primary/first author, engagement of a 3rd party not involved with the project to adjudicate, or some other transparent method. Ample opportunity is recommended for discussion of any issue that results in conflict within the study or project team.

14 APPENDICES

Authorship Agreement for Primary Authors
Adopted from Rosenberg et al., 2015, Dan Med J 62(2):A5009)
Appendix A

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In order to avoid conflicts about authorship, it may be advisable to use a formal authorship contract that should be signed by at least one local investigator per study site as well as by all other persons in the initiating study group. Preferably, this should be done before the first patient is included in the trial. An examples of an authorship contract is included in Appendix A. The coordinator for such a contract would be the lead author (most often the first author) on the paper. It is his or her responsibility to obtain all the signatures and to ensure communication to all involved persons in the trial about the agreements on authorship. The writing team may add other content as they feel appropriate.

AUTHORSHIP CONTRACT
Project Name: _____

_____

Date: _____

The ICMJE recommends that authorship is based on the following four criteria:

- ☐ Substantial contributions to the conception or design of the work; or the acquisition, analysis or interpretation of data for the work; AND
- ☐ Drafting the work or revising it critically for important intellectual content; AND
- ☐ Final approval of the version to be published; AND
- ☐ 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.

All those designated as authors shall meet all four criteria for authorship, and all who meet the four criteria shall be identified as authors. Those who do not meet all four criteria shall be acknowledged as contributors, typically in the acknowledgements section in the manuscript.

If a group-name is used in the byline, then typically a footnote and the acknowledgement section shall clearly state who are regarded (and indexed) as authors and who shall be regarded (and indexed) as contributors. Other terminology such as protocol committee, writing committee etc. may be misleading for the indexing process and it is highly recommended only to use the terms authors and contributors stating exact names for the persons involved.

In large multi-center trials, numerous persons will typically be involved in ICMJE-authorship criterion one, e.g. acquisition of data. The present authorship contract designates the criteria for these persons to be offered participation in authorship criteria two, three and four, thus who will be included in the manuscript preparation to an extent that they will qualify to be an author instead of a contributor.

It is the responsibility of the first author, if applicable, to involve all co-authors to an extent that they fulfill all four authorship criteria.

Authorship Agreement for Primary Authors
Adopted from Rosenberg et al., 2015, Dan Med J 62(2):A5009)
Appendix A

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First Author: _____

Last Author: _____

Predefined members of the writing group, all will be co-authors as they fulfill the four authorship criteria:

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Additional persons who will be offered involvement in the manuscript process (authorship criteria two, three and four). Typically 1-2 per participating center, but more people may be involved.

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All the above-mentioned names will appear on the final manuscript in the byline as authors, and all other persons involved in the research project will be mentioned in the Acknowledgements section as contributors.

Signatures:

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Manuscript Workflow for Multi-centre Trials

☐ Before initiating the study, any authorship issues will be clarified in the authorship contract (see Appendix A).

☐ The manuscript may be prepared by a writing group typically consisting of 3-5 members or may be drafted by the first author and then undergo critical revision among the co-authors.

☐ The authors in the byline of the manuscript may include more people than those participating in the writing group and this is clearly defined in the authorship contract.

BEFORE FIRST DRAFT

☐ *2-3 weeks before* the first manuscript draft is ready, the author in charge of manuscript drafting should notify all co-authors by e-mail.

FIRST REVISION

☐ When distributing the manuscript draft to the co-authors, it should be pointed out that each co-author has e.g. a maximum of *two weeks* to revise the manuscript draft.

☐ If the co-author is not able to complete the revision within the timeframe, the author in charge of manuscript drafting should be notified as soon as possible.

☐ If a co-author does not report back in time, he/she should no longer be considered an author (cf. ICMJE authorship criterion two).

☐ After the specified timeframe, the author in charge of manuscript drafting prepares a new draft based on all co-authors' revisions.

SECOND REVISION

☐ Next, the author in charge of the manuscript distributes a new manuscript draft to the coauthors with clearly identifiable corrections, and each co-author has e.g. *one week* to revise the new manuscript draft. Again, if the co-author is unable to complete the revision in time, the author in charge of the manuscript should be notified as soon as possible.

FINAL APPROVAL

☐ When the manuscript is finished and ready for submission, it should be sent to all co-authors for final approval (ICMJE authorship criterion three). The co-authors should be given only e.g. *two days* to respond to the final approval of the manuscript. The final approval is given by e-mail as a response back to the author in charge of the manuscript and thereafter the manuscript can be submitted to a journal.

Revision of the manuscript after editorial response from a journal

☐ There are no strict rules regarding involvement of co-authors in the revision process, although it may be considered good ethical behavior to at least get critical revisions and a final approval from all co-authors before submitting the revised manuscript.

☐ Thus, most often the first and last author will collaborate on the preparation of a revised version of the manuscript taking into account all the issues raised by the editor and peer reviewers. The final revised manuscript together with a cover letter describing all the changes made will then be sent to all co-authors for final approval before re-submission to the journal. A fair amount of time for this process of final approval would be e.g. *one week*.

☐ Final approval of the revised manuscript should be given as e-mail responses from the coauthors back to the author in charge of the manuscript before submission.

Signatures:

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RESEARCH CONCEPT PROPOSAL

Complete this form to describe your proposed research and request use of existing data. The text boxes will expand as you type. Attach IRB approval, if applicable.

Once your application is final, it will take approximately 2 weeks for it to be reviewed and discussed by the [Publications Committee].

Email completed application to [email address].

1. Short Descriptive Title

2. Authors and Affiliations (including lead author and primary co-investigators)

Author	**Affiliation**

3. Background and Rationale

4. Aims and Objectives

5. Short statement in lay language of significance of proposed research

6. Characteristics of patient population to be included (i.e., eligibility criteria)

Diagnosis, age, gender, etc.

7. Type of data requested for analysis (study should list the types of data collected. [Examples are included below]

☐ [Patient Demographics] ☐

☐ [Diagnosis] ☐

☐ [Treatment] ☐

☐ [Genetic test results] ☐

☐ [Co-morbidities] ☐

7a. More details about specific data requested if not obvious from Q.7.above

8. Other inclusion or exclusion criteria

9. Describe analysis plan or type of analyses to be conducted

10. Anticipated deadlines (e.g., abstract due dates)

11. Source of funding for this proposal

12. Status of IRB approval ☐ Attached ☐ Pending ☐ Not applicable

13. Estimated date of first draft of manuscript _____

14. Other comments:

NOTE: Publications and presentations that use [study] data must cite the [study] using the acknowledgement language as described in the PCORnet Publication Guidelines.

To be completed by [study name]:

Tracking Number	
Date Received	
Date Reviewed by Publications Committee	

Status of Original ☐ Approved ☐ Needs Revisions ☐ Not Approved

Status of Revised ☐ Approved ☐ Not Approved

Date of Final Decision by PC	
Date Final Decision Sent to Requestor	

Comments
