

http://www.covered-study.org (731) ID-COVER (432-6837) EmergencyIDNet-COVERED@uiowa.edu

PROJECT COVERED PUBLICATION/DATA SHARING REQUEST

Thank you for your interest in using and reporting the findings from Project COVERED. We are excited that you are interested in conducting analysis using Project COVERED data.

All requests for publication, presentation, and data use will be considered by the Publications and Presentations Committee and/or the Project COVERED Executive Committee. Please refer to the relevant policies attached to this request form prior to submitting your request. Additional information can be found on our web site at http://www.covered-study.org.

All requests should be submitted to EmergencyIDNet-COVERED@uiowa.edu, and you should expect a response within 2 weeks.

Proposal Main Contact (Name)	
Institution	
E-mail	
Phone	
Study Team (Names)	
Proposed Study Title	
Key Question(s)/Aim(s) Please include hypothesis with each question/aim.	(1) (2)
Data/Analysis Request [select one]	 □ Request data set for me to do my own analysis □ Request analysis by Data Coordinating Center
Publication Request	☐ I would like to draft a manuscript for publication

[select one]	☐ I would like to use this analysis for a purpose other than
	publication. Please describe:
-	
Presentation Request	☐ I plan to present our findings in a regional or national
[select one]	meeting. Please list:
	☐ I do NOT plan to present our findings publicly at a regional
	or national meeting.
Requested Date of	
Delivery (if you are	
requesting a data set)	
Background Summary	
Background Gummary	
Analysis Plan (Please	
include details of how	
this analysis will be	
completed.)	
Torget leurnel	
Target Journal	
Timeline (Please	
include planned	
manuscript submission	
date.)	

Data Elements
Required (if you are
requesting a data set) -
please list <u>each variable</u>
(by data element item
number from Project
COVERED codebook) required for you to
conduct your analysis
conduct your arranysis
O to the Data II
Contact for Data Use
Agreement (if you are
requesting a data set) – name/e-mail
Requested Date of
Delivery (if you are
requesting a data set)

Attachments:

- Project COVERED Publication and Presentation Policy
- Project COVERED Data Sharing Plan
- Project COVERED Codebook

COVERED Publication and Presentation (P & P) Policy

The goal of this document is to define COVERED publication, presentation, and authorship guidelines.

Authorship criteria are based on the *Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals* and International Committee of Medical Journal Editors recommendations (http://www.icmje.org/recommendations/). COVERED papers will also follow the recommendations from JAMA (Fontanarosa, et al., 2017) The Publication & Presentations Committee will review all papers and presentations that use COVERED data or trial information to evaluate whether it should fall under this publication policy. A COVERED paper consists of any publication that uses original COVERED data, deidentified data from COVERED, or the COVERED protocol itself.

1) Criteria for Authorship (each author must meet criteria a, b, c, and d below):

- a) Substantial contributions to conception and design, acquisition of data, or analysis, and interpretation of data;
- b) Drafting the article or providing timely critical revisions for important intellectual content;
- c) Final approval of the version to be published; and
- d) 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.

Also important additional criteria:

- a) Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship;
- b) All persons designated as authors should qualify for authorship, and all those who qualify should be listed; and
- c) Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

The publication plan (list and timing of all publications and presentations) will be refined over the course of the study with input welcome from all investigators. The P&P will set the schedule for P&P products based on an overall dissemination strategy. The goal of this plan will be to ensure maximum, high impact exposure for the study and its findings, while promoting exposure for as many co-investigators as possible. The executive committee will serve as the P&P until the volume of work grows and then a separate committee will be created.

2) COVERED-specific points for all papers:

- a) Increasingly, authorship of multicenter studies is attributed to a group ("corporate authorship") and COVERED will use this approach for all papers (e.g., the target journal accepts this format). The author byline "COVERED Collaborative" will be applied; the writing group submitted for MEDLINE listing and contributing stakeholder advisors, research faculty and staff, clinical site leads and their designees will be described and acknowledged as COVERED Collaborative Investigators. The P & P committee reserves the right to review authors on COVERED publications and adjudicate if they do not met the minimal requirements for that publication;
- b) Writing group leaders will be determine by all the participants of the writing group, any conflicts in selection will be brought to the P & P Committee for resolution;
- c) Writing groups will include up to 2 members per site (determined by site leads) along with a representative from each research core (CCC, DCC) and selected members of the executive committee (determined by the writing group leader). Additional contributions or authorship requests will be reviewed by the writing group leader and presented to the P & P Committee;
- d) All proposed members of the writing group will meet the above criteria for authorship. Those included in the final writing group will be determined by the writing group leader;
- e) The writing group leader will be the person proposing the paper and approved as lead by the P&P committee. Cases of a dispute of authorship will be resolved by the P&P Committee; and
- f) As a general principle, when appropriate based on the contribution to the work, COVERED leadership will encourage, support and prioritize more junior investigators to have prominent

authorship positions.

3) In some cases, journals do not accept corporate authorship. In that case, we will follow this policy: Authorship order, general guidance when not publishable as the "COVERED Collaborative":

- a) The person who has taken lead responsibility for the paper will be the first author;
- b) If more than one person wants to be the first author on a specific manuscript, those individuals will be encouraged to discuss this and reach a satisfactory agreement; if the involved authors cannot come to a satisfactory agreement, the COVERED Publication and Presentation Committee will decide who will be the lead, making an effort to equitably distribute lead authorships. In some cases, co-first [or co-last] authors can be used; this must be agreed upon by all authors of each paper. This approach is similar to that recommended by JAMA. (Fontarosa et al., 2017);
- c) Subsequent author order is decided by the lead (1st) author. Suggested guidelines for author order:
 - i. 2nd author: person who makes the most substantial contribution, after the first author;
 - ii. Last (senior) author: person who has general responsibility for the project; and
- iii. 3rd author: person who makes the next most substantial contribution, after the first two authors, if this is clear; if this is not clear and for remaining authors, list in random (not alphabetical) order.

4) Collaboration Standards:

- a) The lead author is responsible for gathering input from all co-authors, using a transparent and collaborative process:
- b) Best practices include co-author teleconferences to encourage sharing of different perspectives and use of Word edit mode to record and share comments and highlight areas of disagreement of co-authors:
- c) Writing groups should strive to resolve areas of conflict through compromise;
- d) If the lead author is unable to resolve authorship concerns/disputes, the P&P will address the issue. The decision of the P&P will be final; and
- e) If there are disputes among the authors about content or interpretation of data, the first attempt should be a discussion among all authors to see if consensus can be reached. In the absence of consensus, the lead author should bring the dispute to the P&P Committee for final resolution. Note that consensus is not equivalent to unanimous agreement of a position; rather, it is the position that all authors can accept even if some feel the resolution is not optimal.

5) Publications & Presentations (P&P) Committee:

- a) The P&P Committee consists of the COVERED Executive Committee until the volume of work grows such that a separate committee is warranted; and
- b) If a member of the P&P committee leaves the project, then the committee will decide as a group with whom to replace that member with approval by the COVERED Executive Committee.

6) Presentations:

- a) All presentations using COVERED data or information should be:
 - i. On COVERED branded slides: and
 - ii. Presentation title, content, date, and audience should be sent to the P & P committee at least 2 weeks before the presentation
- b) Copies will be saved for future use.

7) Other Issues:

- a) For each COVERED manuscript considered, the lead author will submit to the P&P Committee a brief outline that includes the manuscript aims/objectives and a timeline for completion and submission. If the proposed timeline is not met, the lead author must notify the Chair of the P&P Committee (currently the Executive Committee) within one month of lapsed deadline. The lead author should provide a brief explanation and modified timeline. If a manuscript is delayed beyond the originally proposed timeline without reasonable explanation, the P&P Committee may suggest replacing the lead author;
- b) Any site member may draft an idea and brief outline for consideration and submit to the P&P Committee. This will help ensure the coordination of COVERED manuscripts and avoid potential redundancy. The P&P Committee will keep the list of proposed papers reasonably current and available

- (updated in advance of the monthly Executive meetings) so that investigators can check on potential duplication issues prior to submission;
- c) The lead author must obtain approval of EACH co-author before submitting a manuscript to a journal. If an individual co-author does not provide approval in a timely manner, the lead author may ask the P&P Committee to resolve the issue;
- d) Publications and presentations are encouraged to use all-site data to best address the research question of interest. This would be a preferred strategy to using single site data; and
- e) The P & P reserves the right to modify these guidelines.

Reference:

Fontanarosa P, Bauchner H, Flanagin A.. Authorship and team science. JAMA. 2017;318(24):2433-7.