



Exhibit B - Project PREVENT II Publication, Presentation, and Authorship Policy

The goal of this document is to define Project PREVENT II publication, presentation, and authorship guidelines. Project PREVENT II is a part of a public health surveillance project funded and led by the Centers for Disease Control and Prevention (CDC) evaluating effectiveness of COVID-19 vaccines against laboratory-confirmed COVID-19 among U.S. healthcare workers.

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/>). PREVENT II papers will also follow the recommendations from JAMA.ⁱ The Publication & Presentations Committee (P&P) will review all papers and presentations that use PREVENT II data or project information to evaluate whether it should fall under this publication policy. A PREVENT II paper consists of any publication that uses original PREVENT II data or CDC overall study, de-identified data from PREVENT II, or the PREVENT II proposal 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.

CDC should be made aware of publication plans to ensure plans are fair to all sites and that messaging

and timing align. The publication plan (list and timing of all publications and presentations) will be refined over the course of the project with input encouraged 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 project and its findings, while promoting exposure for as many co-investigators as possible.

The P&P committee reserves the right to review authors on PREVENT II publications and adjudicate if they do not meet the minimal requirements for that publication.

2. Authorship for the main CDC-led project papers:

The main CDC -led project paper to evaluate SARS-CoV-2 vaccine effectiveness in preventing laboratory-confirmed symptomatic COVID-19 among HCP and addressing primary and select secondary objectives as outlined in the project proposal, will be based on the multi-site data collected at all networks, including Project PREVENT II.

- a) Line authorship for CDC primary investigators, core primary investigators from the participating networks, and primary project statisticians, and
- b) If journal allows corporate authorship, we will include Corporate Authorship Group as "the COVID-19 HCP Vaccine Effectiveness Study Network" - comprised of site PI(s) plus 1 designee (who should be justified by a significant leadership role at the site) for each site

3. Authorship for all main project papers using Project PREVENT II data only:

- a) Line authorship for core primary investigators, primary study statisticians, and CDC primary investigators (unless they decline);
- b) *plus* 2 additional authors chosen by the P&P to comprise (with the core group) the primary writing group;
- c) *plus* Corporate Authorship Group as "the Project PREVENT Network" - comprised of site PI(s) plus 1 designee (who should be justified by a significant leadership role at the site) for each site. Additional contributions or authorship requests will be reviewed by the writing group leader and presented to the P&P;
- d) Writing group leaders will be determined by all the participants of the writing group. Any conflicts in selection will be brought to the P&P for resolution;
 - 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;
 - The writing group leader will be the person proposing the paper and approved as lead by the P&P. Cases of a dispute of authorship will be resolved by the P&P; and
- e) As a general principle, when appropriate based on the contribution to the work, PREVENT leadership will encourage, support, and prioritize more junior investigators to have prominent authorship positions.
- f) Abstracts and manuscripts with a CDC author require CDC clearance prior to submission.
- g) Publications should list CDC as the project funder and language for funding can be obtained from the CDC Vaccine Effectiveness Team.
- h) Publications that are funded by CDC and/or include a CDC author shall include the following disclaimer: *The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.*

4. Site Investigator-initiated sub projects/papers:

- a) Any site member may draft an idea and brief outline for consideration and submit to the P&P and the CDC Vaccine Effectiveness Team. This will help ensure the coordination of project manuscripts and avoid potential redundancy. At this time, decisions should be made between the site and CDC on whether there should be at least one CDC co-author and whether other sites should be offered to be included. CDC and the P&P will keep the list of proposed papers reasonably current and available so that investigators can check on potential duplication issues prior to submission;
- b) primary investigator(s) decides on additional authors (can be outside of PREVENT project) to be part of primary writing group and on the author line;
- c) Authorship order – decided by primary investigator(s) of sub project;
- d) *plus* Corporate Authorship Group as "the Project PREVENT Network."
- e) Abstracts and manuscripts with a CDC author require CDC clearance prior to submission.
- f) Publications should list CDC as the project funder and language for funding can be obtained from the CDC Vaccine Effectiveness Team.
- g) Publications that are funded by CDC and/or include a CDC author shall include the following disclaimer:
The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

5. Authorship order, general guidance when not publishable as the “the Project PREVENT Network”:

- 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 P&P 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 JAMAⁱ;
- 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.

6. 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.

7. Publications & Presentations (P&P) Committee:

- a) The P&P Committee consists of 4 primary investigators, two site principal investigators and one CDC primary investigator; 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 PREVENT Executive Committee.

8. Presentations:

- a) Abstracts with a CDC author require CDC clearance prior to submission to conferences.
- b) All presentations using PREVENT data or information should be:
 - i. On PREVENT 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
 - iii. Presentation title, content, date, and audience should be shared with all co-authors (when applicable, such as when based on an abstract) before presentation.
 - iv. Prior to presenting, CDC Vaccine Effectiveness Team will be notified of the presentation title and date for tracking impact of this vaccine effectiveness evaluation.
- c) Copies will be saved for future use.

9. Other general issues:

- a) For each PREVENT 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 P&P 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 may suggest replacing the lead author;
- b) 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 to resolve the issue;
- c) Publications and presentations are encouraged to use all-site data to best address the project question of interest. This would be a preferred strategy to using single site data; and
- d) The P& P reserves the right to modify these guidelines.

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