

PREMIER Manual of Procedures

2. PUBLICATIONS	3
Scope of the Guidelines _____	3
Initiation of a Writing Project _____	3
To Propose a Paper _____	3
Assigning Priorities _____	4
Forming a Writing Group _____	4
Submission of Analysis Requests _____	4
Approval of Abstracts _____	5
Approval of Manuscripts _____	6
Acceptance of Abstracts and Manuscripts _____	6
Authorship _____	8
Ancillary Studies _____	9
Paper Monitoring _____	10
Release of Data for Public Access _____	10
Appendix 1 Authorship _____	11

PREMIER Manual of Procedures

Summary of Edits

Changes between version 1.0 and 1.1:

- Updates text and figure 2.1 to show that manuscripts must only be annotated using results of data requests specific to the paper.

Changes between version 1.1 and 1.2

- Minor edits to show that publications forms are available on the website

Changes between version 1.2 and 1.3

- Change to manuscript approval process: manuscript approvals require 4 votes to approve, including one from the project office, and the trial chair resolves non-approved manuscript issues

PREMIER Manual of Procedures

Publications

Scope of the Guidelines

This policy covers papers, abstracts, posters, and oral presentations that involve data collected as a part of the PREMIER study. These policies will remain in force until the Publications Committee (PC) is formally dissolved. The PC consists of each principal investigator or his/her designee and an NHLBI Project Scientist. Other PREMIER investigators may also participate.

Initiation of a Writing Project

Initiation of a writing project can begin in one of two ways:

1. A member of the PREMIER project may complete a Proposal for a PREMIER Paper (Form #400)
2. The SC or PC may also appoint a writing group to work on a specific publication.

To Propose a Paper

A member of the PREMIER project completes Form #400 (Proposal for a PREMIER Paper), which specifies the research question(s) and the primary variables to be used in the analysis. This form is available on the PREMIER website under “Forms”.) The individual who completes this form is termed the “convener.”

The convener, after adding known interested authors from his/her own or other site(s), transmits copies of the form to the Coordinating Center and to the PC Chair. The CC will circulate the proposals to the PC members for approval via PREMIER web site. Paper ballots may still be used in certain situations. As soon as the proposals are posted on the web site, PC members will be notified that a new proposal is ready for online voting. After reviewing Form #400 via PREMIER web site, PC members can then cast their vote. If a paper ballot is used, the CC circulates the Form #400 along with Form #401 (PC Review Form for a PREMIER paper) to the PC members for approval. PC members are responsible for circulating new paper proposals to investigators at his/her site and indicating on the ballot all interested co-authors.

Writing project proposals submitted to the PC must be reviewed promptly. PC members review the proposal, and vote online or sign and return the completed Form #401 to the CC within 14 days. Nonresponse is considered to be approval. PC members who are out of town can delegate responsibility for their vote.

Once the voting deadline is reached, the CC informs the convener and the PC Chair whether or not the proposed paper has been approved. If not approved, the PC Chair discusses questions or concerns raised by reviewers on the Form #401 with the convener. The convener responds to the PC Chair with a revised request or with a written response to the concerns, and sends a copy to the CC. The PC Chair decides if the response satisfies the concerns, or may defer approval until the PC can discuss the issues in a *conference* call, *via e-mail*, or *in a face-to-face* meeting. The PC Chair notifies the CC whether or not proposed projects requiring discussion are approved.

PREMIER Manual of Procedures

The CC maintains and distributes a list of approved papers. Each approved paper is assigned a number and a short title that should be used on all correspondence related to the paper. See Figure 2.1 for an outline of the paper approval process.

Assigning Priorities

The PC, in conjunction with the SC, assigns a priority number from 1 to 3 to each paper indicating the importance of the proposed manuscript, with 1 being most important. The CC uses these priority scores to help prioritize the work it does in meeting analysis requests.

Forming a Writing Group

PIs are responsible to inform potential authors at their site of the formation of the writing group when the proposal is submitted. Interested investigators or the local PI should notify the convener. The CC also assigns a senior level statistician, who could be employed at the CC, one of the clinical sites, or the PO, to assist in the development and writing of each paper. This person will typically also be a co-author on the paper.

After approval, the convener sets up the first conference call or meeting of the writing group. At this first call/meeting, if a chair has not already been appointed, the writing group selects a chairperson from among its members. The chairperson serves as the first author on the paper, and is responsible for reporting progress on the paper to the CC at regular intervals.

The writing group chair notifies the CC that the group has convened and a chair has been selected, and also confirms the membership of the writing group. See Figure 2.1 for an outline of the writing group formation process. After formation, changes in the writing group (withdrawals or additions of members) are directed to the committee chair, who then notifies the CC. The current composition of each group is updated and posted on the PREMIER website by the CC. Membership can be changed only by the writing group chair.

Submission of Analysis Requests

All requests to the CC for statistical analysis should come directly from the writing group chair or the lead statistician on the project. The lead statistician should review all requests for appropriateness before analysis is begun. In all cases, requests should receive some level of appropriate statistical review prior to being assigned to a CC analyst. Exceptions may be made for simple requests such as descriptive tables not requiring analysis. All requests should be made using the Data Analysis Request Form (Form #403).

To facilitate manuscript preparation, the CC works with the lead author and the senior statistician to develop an analysis file for use with each approved paper. The Data Release Request Form (Form #404) is used to document the necessary information.

Copies of the analysis file are given to the lead statistician and to other members of the writing group who request a copy so that they can conduct their own preliminary analyses. The CC also

PREMIER Manual of Procedures

uses this file to fill data requests. The CC informs the investigators if the data in the analysis file have not been fully cleaned. All analyses made using preliminary data require subsequent verification before a manuscript can be approved for publication. If this verification is not conducted by the CC, a statement to this effect must be included in the METHODS section of the paper.

Once requests are submitted, the lead analyst at the CC assigns one or more staff analysts to work on various aspects of the request. The CC also sends a memo summarizing the request to the lead author to insure that it has correctly interpreted the request. The CC will not begin work on a data request until it receives confirmation from the requestor that the CC has correctly interpreted the request.

Each request is assigned a data request number that will be used on all subsequent communications related to the request. The CC often works on multiple, similar requests and uses the assigned number to avoid confusion. Some requests, due to their complexity or the nature of the programming tasks involved, may be operationally divided into several separate requests internally at the CC. When this occurs, each of these “requests” is treated according to the procedures outlined above.

The data request number should be left on all tables and figures that the CC generates until the final manuscript submission. This number should also be used to reference any numbers used in the text (i.e., in parentheses, following the text). This annotation allows the CC to efficiently return to the original output to verify the numbers in a table, figure, or text discussion as part of the manuscript verification process. Failure to use this data request number may add substantially to the verification time. If this number is missing, the CC will be unable to verify the manuscript and will return it to the author for the information to be added. Authors are advised to flag these and other data annotations as “hidden” text, so that they can be stored with subsequent iterations of the document and yet be conveniently turned on or off for purposes of viewing or printing.

See Figure 2.1 for an outline of the analysis request process.

Approval of Abstracts

Abstracts of PREMIER results intended for presentation at scientific meetings should be sent directly to members of the PC and to the Project Office along with a completed Form #405 (PREMIER Abstract Review Form), for approval prior to submission. A copy is also sent to the lead analyst at the CC for numbers verification. The sites and the CC must receive these abstracts at least five working days prior to the intended date of submission. Members of the PC and the Project Office must respond (using Form #405) within three working days of receipt of an abstract. Designated alternates may respond on behalf of PC members or Project Office representatives who are unavailable. Non-response within 3 days is considered approval. The CC must verify all numbers on the abstract prior to approving the abstract request.

PREMIER Manual of Procedures

Responses shall be sent directly to the PC Chair and the CC and shall indicate approval, disapproval, and any suggested/required edits. The PC Chair will notify the author and the CC when an abstract is approved. Abstracts may not be submitted for publication until the PC chair informs the requester that the abstract was approved.

Approval of Manuscripts

Prior to submission of manuscripts for approval, a copy of the annotated manuscript is submitted to the CC for verification of all numbers and figures, including those in the text, by the analyst staff. Once the numbers and figures have been verified and any needed corrections have been made, the manuscript can be submitted for approval. Manuscripts not verified by the CC shall explicitly state this in the METHODS section.

A copy of the manuscript and a completed Manuscript Review Form (Form #406) should be sent to the Coordinating Center, which in turn forwards two copies to the NHLBI Project Scientist and one copy to each member of the PC for review. The NHLBI Project Scientist submits the manuscript for NHLBI internal review, which can require up to six weeks. All manuscripts must be received by NHLBI. NHLBI approval is required only if there is an NHLBI author. Although PC approval and Project Office approval may be requested simultaneously, the PC chair may require a second PC review if the Project Office recommends substantive revisions.

The members of the PC must respond in writing (using Form #406, PREMIER Manuscript Review Form) within 30 days of receipt of the manuscript to the PC Chair, who will relay comments to the chairperson of the writing group and to the coordinating center. Designated alternates can respond on behalf of PC members who are out of town. Approval for a manuscript requires a minimum of 4 votes for approval, including one from the project office. The first author is encouraged to make sure that the manuscript is reviewed and votes are submitted. If the 30day deadline is reached and the CC has not received the minimum number of approval votes, the trial chair has the option to extend the deadline by two weeks or approve the manuscript based on his or her judgment.

The SC resolves conflicts over the acceptability of manuscripts. If a consensus cannot be reached, then a majority vote of the committee resolves the issue. Authors can appeal any such decision to the Steering Committee. The SC may withdraw, by majority vote, any manuscript after it has been submitted and before it is published.

See Figure 2.1 for an outline of the manuscript approval process.

Acceptance of Abstracts and Manuscripts

The main author sends a copy of the submitted abstract and submitted manuscript to the CC, and, if further revisions were made to the manuscript, a copy of the final version. It is the responsibility of the first author of any manuscript, abstract, or presentation to notify the PC Chair and the CC of the acceptance or rejection of the paper, abstract, or presentation. After publication, the main author shall send to the CC seven copies and the appropriate citation for

PREMIER Manual of Procedures

any published abstract and seven reprints and the citation for any published manuscript. The CC will store copies of all scientific manuscripts both for ancillary and for full study papers and abstracts, and will distribute a copy of the published abstract or manuscript to each PI and the Project Office. It is the responsibility of individual PIs to distribute copies of abstracts and manuscripts to other investigators at their sites. The CC distributes regular reports of publications and presentations. Investigators are encouraged to share copies of slides and handouts. Hard or electronic copies of data slides and handouts to be presented at national meetings should also be circulated to the PC Chair and the CC for distribution to other PREMIER investigators. The coordinating center maintains copies of all the slides it receives, and makes them available to other investigators upon request.

Figure 2.1: Outline of PREMIER Process for Producing a Paper

Approval

PREMIER investigator proposes paper
PC members review proposal, inform potential authors at their site, and vote
CC notifies convener and PC chair of outcome
CC assigns statistician
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Writing Group Formation / Exploratory Analyses

Convener works with assigned statistician to prepare for first call
Writing group convened, writing group identifies chair; Writing group chair informs CC of group membership/chair
Writing group chair works with assigned statistician on exploratory analyses
Writing group chair and assigned statistician generate formal analysis requests
-

Analysis Requests

Requests sent to CC Lead Analyst; Analyst is assigned to each request
Analyses completed and reviewed; Results or data release sent to writing group chair
-

First Draft

Writing group reconvened
Chair prepares outline of manuscript and distributes writing assignments
First draft completed and circulated for review
-

Subsequent Drafts

In consultation with assigned statistician, additional analyses may be specified
Requests sent to CC Lead Analyst; Analyst is assigned to each request
Analyses completed and reviewed; Results or data release sent to writing group chair
Manuscript draft recirculated to writing group.
-

Review

Annotated manuscript submitted to Lead Analyst at CC for numbers verification
Note: Annotate using data requests specific to the paper; do not use results other than from data requests specific to the manuscript to annotate
Manuscript submitted to PC for approval
Manuscript submitted to NHLBI for review (or approval if NHLBI author on paper)
Final revisions made
-

Submitted to Journal

Manuscript submitted for publication; author supplies CC with copy of submitted manuscript
Author notifies PC Chair and CC of acceptance or rejection of manuscript
-

Paper Published

Author supplies CC with 7 copies of the published manuscript;
CC distributes copy of published manuscript to PIs and Program Office

These items are paper milestones that are reported in the PREMIER Paper Milestones Report. The writing group chair is responsible for updating the CC on the progress of a paper through each its milestones.

Authorship

Authors who participate in the writing of a manuscript from the PREMIER project do so in accordance with the International Committee of Medical Journal Editors guidelines (*N Engl J Med* 1991;324:424-8)(see Appendix 2.1). First authors are expected to delete names from the final list of authors if those individuals have not participated in the writing and/or analysis of the paper in accordance with those guidelines. Unless prohibited by journal policy, all papers (excluding those resulting from ancillary studies) should include the words “PREMIER Research Group” in the authorship line, even if the analyses were not done by the CC. If analyses were done locally and not checked by the CC, a note must be added stating that analyses were done locally, e.g. “all analyses were conducted locally and have not been verified by the Coordinating Center.” The SC may allow exceptions to this policy. All papers should also include an “Acknowledgments” section that lists the PREMIER investigators and key staff at the Clinical and Coordinating Centers and Project Office unless journal policy prohibits publication of such a list. In general, at least one representative from each participating institution (i.e., Clinical Centers, Coordinating Center, and Project Office) should be included as an author on papers using study-wide PREMIER data. However, membership from each site is not required.

First authors will usually be PREMIER investigators or individuals who are substantively involved in the design or conduct of the study. Others may serve as first authors if:

- the opportunity of first authorship on a project has been offered to all PREMIER investigators and none requested to serve as first author,
- at least one other PREMIER investigator serves as a co-author and “sponsor” of the project, and
- the fellow or scientist has played a major role in the data analysis and writing for the paper.

First authorship is decided by the writing group at its initial meeting and will typically be the convener. The first author also serves as Chair of the writing group. Conflicts about first authorship should be resolved, if at all possible, by members of the writing group. In case the writing group is unable to resolve a conflict, the PC will adjudicate and may assign first authorship. This assignment may be appealed to the SC.

If progress on a given writing project is unduly slow, the PC may request an explanation from the chair of the writing group or the lead statistician, depending on the source of the delay. If timely progress is not likely to occur in the near future, the PC may, at its discretion, assign a new Chair to the writing group, or may ask the CC to increase the priority rating of the paper. Such action may be appealed to the Steering Committee.

PREMIER Manual of Procedures

The first author should determine the order of co-authorship on a paper. In general, authors will appear in order of contribution to the writing and analysis of the paper. When contributions to writing and analysis have been similar, priority should be given to:

- those who have contributed to a greater degree to the design and implementation of the trial,
- balance across centers, and
- junior investigators.

If the writing group cannot resolve conflicts regarding the order of authorship, the PC will adjudicate and may assign the order.

Ancillary Studies

All studies of participants enrolled in the PREMIER project that are not part of the main protocol, including proposals to analyze stored specimens, must be approved by the Design and Analysis Committee (D&A) prior to enrolling participants and collecting data. In order to obtain approval, the investigator wishing to do an ancillary study must complete and submit the Ancillary Study Request Form (Form #402) to the CC for circulation to the D&A Committee.

PIs are responsible for ensuring IRB approval for ancillary studies at their site. If a proposal is subsequently submitted for IRB approval, copy of the final approval letter from your IRB must be sent to the CC, which maintains a centralized file of all such approvals for archival purposes. The D&A reviews the proposal within two weeks. The primary purpose of this review is to ensure that the ancillary study will not interfere with recruitment, intervention or data collection for the main study. The D&A may make suggestions for modification in order to assure that the ancillary study meets the non-interference criterion. The D&A may refuse to approve ancillary projects that appear to interfere with conduct of the main trial.

All ancillary studies approved by D&A must then be approved by the Steering Committee. The CC maintains a listing of approved ancillary studies and periodically provides a copy to the DSMB. Once the ancillary study has been approved, oversights of publications resulting from it are the responsibility of the Publications Committee.

For papers resulting from ancillary studies, the following statement, or its equivalent, should be inserted in the Methods section of the paper:

“This was a study ancillary to the PREMIER study and, as such, was designed, conducted, and analyzed by the co-authors only.”

Papers resulting from ancillary studies should acknowledge the PREMIER research group and participants by including the following statement, or its equivalent, in the acknowledgement section. Acknowledgement of specific individuals, groups, or committees may also be appropriate. The local PI will adjudicate disagreements over authorship.

“The authors are extraordinarily appreciative of the PREMIER participants and of the entire PREMIER Research Group, which included investigators and staff from the Division of Epidemiology and Clinical Applications, National Heart, Lung, and Blood Institute, Bethesda,

PREMIER Manual of Procedures

MD; the Kaiser Permanente Center for Health Research, Portland, OR; Duke University Medical Center, Durham, NC; Pennington Biomedical Research Center, Louisiana State University, Baton Rouge, LA; and The Johns Hopkins Medical Institutions, Baltimore, MD.

No abstracts from PREMIER ancillary studies that include post-randomization data may be submitted until the main outcomes abstract has been presented. Papers for PREMIER ancillary studies may not be submitted until the main outcome paper for PREMIER has been accepted for publication.

Paper Monitoring

The CC notifies the requestor of the projected number of hours and timeline for completion of all data requests. The CC also supplies regular reports to PREMIER investigators as to the status of requests, and progress of individual papers. It is recognized that timelines may change from initial estimates due to unanticipated difficulties or competition from requests with higher priorities.

Release of Data for Public Access

At the end of the trial, the CC supplies each PI and the PO with a clean copy of the study data along with appropriate documentation in electronic form. The Project Office is responsible for making the dataset available to the general public under the terms of the Freedom of Information Act.

PREMIER Manual of Procedures

Appendix 1 Authorship

Excerpt from “Uniform Requirements for Manuscripts Submitted to Biomedical Journals,” from The New England Journal of Medicine, 324(6):424-428, 1991.

All persons designated as authors should qualify for authorship. The order of authorship should be a joint decision of the co-authors. Each author should have participated sufficiently in the work to take public responsibility for the content.

Authorship credit should be based only on substantial contributions to (a) conception and design, or analysis and interpretations of data; and to (b) drafting the article or revising it critically for important intellectual content; and on (c) final approval of the version to be published. Conditions (a), (b), and (c) must all be met. Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is also not sufficient for authorship. Any part of an article critical to its main conclusions must be the responsibility of at least one author.

A paper with corporate (collective) authorship must specify the key persons responsible for the article; others contributing to the work should be recognized separately (see Acknowledgments).

Editors may require authors to justify the assignment of authorship.