

OUTLINE FOR WHI MANUSCRIPT DEVELOPMENT

Recommended Steps to Complete a WHI paper

1. **Review the procedures and policies** at http://www.whiscience.org/publications/write_paper.php.
2. **Draft a proposal** (use the Proposal Template at http://www.whiscience.org/publications/proposal_template.pdf). Also refer to the Manuscript Analysis Guidelines (<http://www.whiscience.org/publications/guidelines.pdf> for tips in developing your analysis plan.
3. **Submit the proposal to the P&P Committee** by emailing the P&P Program Assistant (PA)¹. The proposal will be sent to two committee members for review and will be presented at the next P&P meeting. The PA will contact the investigator regarding the committee's decision.²
4. After the proposal is approved, the PA will solicit nominations for the writing group from WHI investigators. After a two week nomination period, the PA will send the list of nominees with appropriate expertise to confirm they will be accepted on the writing group. **Confirm the WHI nominees and provide the PA with the names and contact information for any additional co-authors** to be included on the manuscript.
5. The PA will send a memo, designating you as the Chair, to the final approved writing group members. After you receive this memo, **circulate the proposal to co-authors for review and feedback**.
6. **Schedule a writing group conference call** to finalize analysis plan. Contact the PA to obtain a conference call number.
7. **Incorporate feedback from writing group**. The P&P wants the proposed analysis to be as strong as possible. Be as specific as possible regarding which data items off the forms should be included.³
8. *If the analyses are being done at the CCC*, a statistician will be in contact as soon as they are available to start work on the paper.⁴
 - a. Any descriptive tables requested will be sent first. The statisticians prefer to get feedback on the data in these tables before proceeding with any modeling or other multivariate methods. **Notify the statistician if you will be unable to review the data shortly after receipt**.
 - b. After any required modifications have been made, work on the remaining analyses will begin. It usually takes a few iterations before all analyses are finished. When data analyses are completed, analyses and results will be sent for review.

If the authors intend to perform their own analyses, all investigators who will work with the data must **complete and return a WHI data distribution agreement form⁵**; the sponsoring PI will assist with accessing the data.

¹ Papers may be submitted to the PA via the helpdesk@whi.org account if you are unaware of the current PA's email address.

² Possible decisions are as follows: approve; approve with recommended changes; approve with required changes (proposal does not need further review, but changes must be incorporated into manuscript); revise and resubmit to primary reviewers (further review by the full P&P Committee is not necessary, but the 2 reviewers must re-review); revise and resubmit; disapprove.

³ Forms are available at <http://www.whiscience.org/data/forms.php>.

⁴ If you are concerned about the timeframe or feel that the analyses for your paper are not progressing, please contact the Statistics Unit Manager.

⁵ This form is available at http://www.whiscience.org/data/data_distribution_agreement.pdf or by emailing helpdesk@whi.org.

Recommended Steps to Complete a WHI paper (continued)

9. **Distribute final analyses and results to all writing group members** to solicit input.
10. **Contact co-authors and begin to prepare the draft manuscript.** You may assign tasks to committee members or set up conference calls to discuss the manuscript.⁶
11. **Circulate the draft manuscript to all writing group members** to solicit input. The final draft of the manuscript must be approved by all co-authors before submission to the P&P Committee.
12. **Submit the final draft manuscript to the P&P Committee for review** by emailing the PA. The manuscript will be sent to two committee members for review and will be presented at the next P&P meeting. The PA will contact the investigator regarding the committee's decision.⁷
13. After the manuscript is approved, **submit the manuscript to a journal.** Notify the PA and the NHLBI if submitting to a high-profile journal.⁸ If the journal requests revisions or responses to comments, inform the writing group and solicit their input as appropriate. If the manuscript undergoes substantial revisions in context or interpretation, then the revised paper must be re-submitted to P&P for approval.
14. **Notify the PA and the NHLBI when the manuscript is accepted for publication.** Provide copies of the accepted manuscript and expected publication dates as they become available.
15. **Inform the PA immediately if any press releases or media materials are generated.** The P&P Committee will expedite their review, and must approve all materials before they are distributed.
16. After the manuscript is published, please **send a copy of the final paper** to the PA. PDF copies are preferred.

⁶ The P&P recommends no more than 4 conference calls per group. WHI sponsors up to two calls per group.

⁷ Manuscripts with an NHLBI co-author will need to undergo additional review by the NHLBI Project Office.

⁸ Examples include Archives of Internal Medicine, Circulation, Hypertension, JAMA, Lancet, Nature, Nature Genetics, and New England Journal of Medicine. NHLBI monitors submission to these journals to anticipate media attention.

Outline of WHI Manuscript Development

