

**WOMEN’S HEALTH INITIATIVE – PUBLICATIONS
AND PRESENTATIONS (P&P) POLICY**

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OVERVIEW AND DEFINITION OF TERMS

A Women’s Health Initiative (WHI) publication or presentation is one that is authored by WHI investigators and developed in accordance with the policies of the Publications and Presentations (P&P) Committee.

Investigators are encouraged to propose and develop publications and presentations; these activities enhance the value of the WHI and promote the continued involvement of a diverse group of investigators. To protect the integrity of the WHI, any document using WHI data that is (1) intended for publication or presentation and (2) authored by a WHI investigator must be reviewed and approved by the P&P Committee.

The following terms refer to authors of WHI publications and presentations:

- *WHI investigator* – a research investigator named on a current and active contract or consulting agreement with NHLBI or its contractors to work on the WHI study.

- *Non-WHI investigator* – any researcher not covered in the previous statement.
- *Sponsoring Principal Investigator (PI)* – a PI of a WHI Field Center (FC) who takes responsibility for ensuring authors abide by the P&P Policy.

The following terms refer to types of documents reviewed by the P&P Committee:

- *Proposals* – proposed plans for analyses that will be presented in manuscripts.
- *Manuscripts* – final drafts of articles or book chapters that are not yet published.
- *Abstracts* – summaries of intended presentations.
- *Presentations* – posters or slides presented at conferences and/or meetings.
- *Talking points* – summaries of main points of a publication or presentation.
- *Media materials* – any materials intended to be sent to media (e.g., press releases).

The following terms refer to types of WHI papers (proposals, manuscripts, or publications):

- *Ancillary study papers* – papers using data primarily from one or more ancillary study.
- *BAA papers* – papers using data primarily from a BAA¹ study.
- *Collaborative papers* – papers using WHI data in conjunction with data from one or more other study cohorts, usually through participation in a consortium.
- *BioLINCC papers* – papers developed using NHLBI’s Biologic Specimen and Data Repository.
- *Primary papers* – papers that present main findings from the clinical trials (CTs) or trial follow-up periods.
- *Important Study Papers (ISPs)* – papers reporting detailed final results for individual pre-specified clinical outcomes of central interest in the CTs, written on behalf of the WHI investigator group.
- *Review articles and editorials* – papers that cite previously published WHI data or analyses, but do not present any new data or analyses.

P&P REVIEW PROCESS AND GUIDELINES

Manuscript Proposals

A proposal must be reviewed and approved by the P&P Committee prior to development of a WHI manuscript. All materials related to submission of a manuscript proposal are available on the *whiscience.org* website or from the WHI Clinical Coordinating Center (CCC) P&P Program Assistant (PA). A list of all WHI publications to date is available the website; before developing a proposal, prospective authors should review this list to avoid overlap with existing publications. To avoid overlap with approved manuscript proposals that are already in progress, prospective authors may contact the P&P PA or ask their sponsoring PI to review the list of approved proposals on the *whiops.org* website. Every proposal must have a sponsoring PI who will work with the lead author as needed.

¹ BAA refers to a study funded by the National Heart, Lung, and Blood Institute (NHLBI) through Broad Agency Announcements.

In an effort to ensure timely completion of manuscripts, investigators are discouraged from being the lead author of more than 2 papers at one time. Exceptions to this general rule include proposals stemming from ancillary studies, BAAs, grant-funded projects or where evidence of timely progress on existing manuscripts can be demonstrated.

All proposals must contain information specified in the Manuscript Proposal Template² (e.g., author information, indication of who will perform the analyses, etc.). All definitions, criteria and data to be used in the manuscript should be included in the proposal.

Proposals may list 3 authors, including the lead author; exceptions include proposals for Ancillary Study papers (allowed to list 4 authors) and BAA papers (these proposals have no author limit). Proposals submitted with more than the acceptable number of authors will not be reviewed by the P&P Committee, unless permitted to do so by the P&P Committee Chairs.

Proposals for WHI manuscripts are reviewed during P&P Committee meetings.³ Upon receipt of a manuscript proposal, a P&P Committee Chair assigns 2 committee members to review the proposal for scientific merit, analytic issues, policy issues, concerns regarding interpretation of findings, overlap with other WHI papers, etc. The P&P Chairs will monitor turn-around times for all reviews, to guard against undue delays. The proposal and reviewer comments will be discussed on the next P&P call, and the committee will decide on the next recommended course of action. These include: approved, approved with recommended changes, approved with required changes, revise and resubmit to primary reviewers, revise and resubmit (to full committee), disapproved. If additional committee review is recommended, prospective authors should submit their revised proposals to the committee for a second review. The P&P Committee requires a minimum of 2 weeks to complete reviews of proposals. If the proposal is not submitted for P&P review 2 Mondays prior to a P&P meeting, it will not be reviewed until the following meeting. If a proposal must be resubmitted to primary reviewers, those reviewers will be given 2 weeks to complete reviews. Committee recommendations and reviews are provided to prospective authors approximately one week after the call on which the proposal is reviewed.

Once a proposal has received committee approval, a writing group is formed, which includes the authors listed on the proposal and other investigators who are interested in participating and who have expertise in the proposal's subject area. The writing group nomination process is described below.

Proposers of BioLINCC papers are not required to submit proposals to the P&P Committee; however, they must abide by NHLBI's Biologic Specimen and Data Repository Guidelines.⁴

The P&P Committee generally does not approve broad proposals to analyze multiple endpoints. It is recommended that authors focus on one particular endpoint per manuscript.

² The template is available at http://www.whiscience.org/publications/proposal_template.pdf.

³ The P&P Committee usually meets by conference call on the second and fourth Thursday of every month.

⁴ The Guidelines can be found at <https://biolincc.nhlbi.nih.gov/static/guidelines/guidelines.html> and https://biolincc.nhlbi.nih.gov/new_data_set_policy.

Final Manuscripts

All WHI manuscripts must be reviewed and approved by the P&P Committee prior to their submission to a journal for publication. All publications authored by NHLBI staff must be reviewed and approved by the NHLBI Project Office (PO) in addition to the P&P Committee. Upon receipt of a draft manuscript, the committee follows a review process similar to the one described above for proposals. Once authors have received notification that their manuscript has been approved by the P&P Committee, they can submit the paper for journal publication. If their manuscript is accepted for publication, authors are expected to notify the P&P Committee and the NHLBI PO of the acceptance and inform them of expected publication dates. Authors of manuscripts that are designated as “high profile” must send an article, a lay summary, talking points, and any media materials to the P&P Committee at least one week prior to the publication date. The P&P Committee will review and distribute these materials to all PIs as appropriate; review of media materials will be expedited to accommodate deadlines.

If an investigator would like to draft more than one manuscript based on a single approved proposal, a formal request must be sent to the P&P Committee; a new manuscript number will be assigned if the request is approved.

Abstracts and Presentations

All abstracts must be approved by the P&P Committee before they are submitted to any national and/or international organizations. All abstracts must be derived from P&P-approved proposals, or submitted for review concurrently with the related proposal. Exceptions will be made for abstracts from consortia or collaborative studies not led by a WHI investigator, since P&P does not require proposals for collaborative papers to be submitted for review. Abstracts will be circulated by email to 2 P&P Committee members, with a request to complete their review within 2 weeks.

The P&P Committee requires a minimum of 10 business days to complete reviews of abstracts. If the abstract is not submitted for P&P review at least 10 business days prior to the submission deadline, approval will not be granted. Investigators may appeal this decision to the P&P Committee Chairs, who may (1) approve requests for expedited review or (2) allow the abstract to be submitted with the understanding that they will withdraw the abstract or make required changes if the reviewers and the P&P Chairs deem this necessary.

Abstracts using BioLINCC data that have a WHI investigator as a listed author are given an informational review by P&P. If the committee notes a potential problem with the topic or analyses, the investigator will be contacted directly to suggest revisions. If suggestions are not accepted, the WHI investigators cannot be listed as an author on the abstract, and the abstract must contain a disclaimer (see ‘BioLINCC papers’ section above).

The P&P Committee reserves the right to review posters and slides before presentation.

Media Materials and Talking Points

All media materials and talking points must be reviewed and approved by the P&P Committee and NHLBI PO prior to distribution. These materials are assigned to 2 reviewers from the P&P Committee; they will expedite review to comply with deadlines, but authors are expected to provide adequate time for review, i.e. 10 business days, when possible.

In cases where a press release is being issued for a presentation based on a manuscript not yet accepted for publication in a peer review journal, a sentence must be included on the front page indicating the preliminary nature of the results.

Proposals to Request Funding for Analyses of Existing WHI Data

If an investigator wishes to submit a grant proposal to obtain funding to analyze existing WHI data, they must obtain a letter of support from WHI. To achieve this, the investigators should submit three specific manuscript proposals (one for each planned objective) to the P&P Committee. Each proposal will undergo review at a P&P Committee meeting and will need to be approved before the grant proposal can be submitted. In cases where the grant proposal is based on data from numerous sources, approval of one manuscript proposal describing the proposed use of WHI data may be sufficient to obtain the P&P Committee's support.

Investigators, at their discretion, may substitute a draft of the grant proposal for the background and detailed data analysis components of the manuscript proposals. All proposals should include hypotheses or reasons for the analysis and an analytic strategy. Investigators may submit their strongest three proposals to the P&P, and then other proposals any time afterwards.

If the proposals are approved, the P&P Chairs will write the letter of support for the investigator seeking funding. This letter will be sent on behalf of ESEC; ESEC will be informed during their monthly meeting.

Once the grant proposal is submitted, the investigators must keep the P&P Committee informed of the funding decision. If funding is obtained, the approved manuscript proposals will be circulated for writing group nominations. If the funding request is not approved, the investigators will need to inform the P&P Committee of whether or not they will pursue the manuscripts. If they do not wish to proceed, other WHI investigators will be offered the opportunity to lead the manuscripts; if nobody volunteers to lead, the proposals will be dropped.

BioLINCC Papers

Proposals for BioLINCC papers are not required to undergo review by the P&P Committee. However, if a WHI investigator coauthors a BioLINCC manuscript, they must submit the final manuscript for expedited review by 2–3 members of the P&P Committee. BioLINCC manuscripts authored by non-WHI investigators may also be submitted for review, but this is not required. P&P decisions to reject a manuscript using the expedited review process may be appealed to the full P&P Committee for reconsideration.

If the P&P Committee approves the manuscript, the authors may include a statement in the publication acknowledging that the manuscript was reviewed and approved for publication by the WHI Publications and Presentation Committee. If the P&P Committee does not approve the manuscript, WHI investigators must remove themselves from authorship of the paper. If an investigator objects, they may appeal.

Collaborative Papers

Proposals for collaborative papers are not required to undergo review by the P&P Committee. However, the committee prefers that proposals be sent to the P&P PA for their records. Collaborative manuscripts will undergo full review by the P&P Committee. It is the responsibility of the WHI liaison to the consortium to ensure that P&P Committee policies are enforced.

Review Articles and Editorials

Review articles and editorials do not generally need to be reviewed by the P&P Committee. However, if these papers may be seen to be in conflict with conclusions from previously approved WHI publications, they should be submitted for review. If in doubt, authors are encouraged to submit a draft of the work (or an outline of the area of possible contention) to the P&P Chairs for an initial reading so they can decide if full review is needed.

If upon review the P&P Committee identifies concerns, and the authors wish to publish or present the work without addressing those concerns, the authors are requested to include a statement to the effect that "the opinions expressed in this publication (presentation) are those of the authors, and do not necessarily represent the opinions of other WHI investigators." The authors may not list NIH support of the work in such a case.

WRITING GROUPS

Selection and Formation

The authorship for most WHI manuscripts is determined through the formal writing group selection process after a proposal is approved; exceptions include primary papers, ISPs, BAA papers, collaborative papers, papers focused on methodology, and papers based on local data (see below). Proposals are generally circulated to WHI PIs within a month following the P&P Committee's approval of a proposal, at which time a 2 week nomination period commences. Within the 2 week period, PIs may nominate themselves or a qualified colleague to participate in a writing group. Any investigators who are not PIs may nominate themselves for a writing group only if they have a PI's approval to do so. All investigators listed as authors on a proposal will be included in the writing group; they do not need to be formally nominated.

The following guidelines apply to writing group formation:

- Writing groups are generally limited to 12 members, unless the P&P Chairs allow more authors to be included.
- Criteria for selection of writing group members will include level of expertise (related to the manuscript topic), balanced representation across WHI FCs, and consideration of individual commitments to other WHI writing group endeavors.
- WHI authors must be represented on manuscripts to reflect their scientific contribution to the project development, participant recruitment, protocol intervention, and ongoing data collection. WHI nominees with interest and expertise in the manuscript area should generally be accepted (within reasonable author number limit constraints) unless a reason not to do so is provided.
- When there are more than 5 nominees for an Ancillary Study paper, authors should be required to include at least 5 WHI investigators on their papers, in order to reflect the use of all of the data collected in the main WHI study and to obtain WHI-specific input.
- In the case of manuscripts stemming from Non-blood Ancillary Studies and Core Studies in which only certain FCs participated, only investigators from participating FCs are eligible to be on the writing group.
- Writing Groups for all papers involving analyses of WHI data must include one CCC representative, usually with statistical expertise.
- Students are, in general, not eligible to participate in writing groups. Exceptions have been granted to advanced graduate students who have a major involvement with development of a proposal as a part of their thesis work.
- The investigator submitting the proposal for approval (the lead author) will be appointed chair of the writing group.
- The P&P Committee and the CCC must approve all writing groups.

At the end of the writing group nomination period, the P&P PA will inform the lead author of the WHI nominees and ask the lead author to confirm they will include the nominees as co-authors on their manuscript. A lead author may submit the names of any additional colleagues they would like to include on the writing group at this time. The P&P PA facilitates the approval of the writing group by the CCC and the P&P Committee as necessary. The PA then confirms the manuscript's authorship via a memo to all authors which informs the lead author (AKA the 'writing group chair') of their responsibilities.

The writing group selection process differs for the following types of papers:

- **Primary papers and ISPs**—Authorship is generally determined prior to the submission of a manuscript proposal. After a primary paper or ISP is identified, the topic is circulated to the PIs so they can nominate themselves. Typically each FC is allowed a specific number of author slots on a set of ISPs, in order to ensure fair representation of PIs on all major WHI papers. Only WHI Investigators and PO scientists are eligible to be authors.⁵
- **BAA papers**—Proposals are circulated to WHI PIs through the formal writing group selection process, but lead authors are not obligated to include nominees. The P&P Committee encourages lead authors to include WHI nominees as appropriate.

⁵ Exceptions may be made if a PI allows a Non-WHI Investigator to take one of their FC's author slots; in such cases the PI is responsible for monitoring the participation of the Non-WHI Investigator on the writing group.

- **Collaborative papers**—Authorship is determined by the P&P Committee Chairs. The PI liaison to the collaborative group is responsible for negotiating an appropriate number of author slots for WHI; representation should be based on the proportion of cases WHI contributes to the overall cohort. In most cases, the PI liaison to a collaborative group will be a co-author on manuscripts resulting from this collaboration; PIs (or Co-Investigators with PI permission) will be solicited for additional author slots, and the P&P Committee Chairs will make the final decision regarding authorship.
- **Papers focused on methodology**—Manuscripts on statistical, biochemical, or molecular methods that do not report any major outcomes of WHI do not need to be circulated to PIs. However, manuscripts that apply a method to an outcome where new or reanalyzed data is presented must be circulated. If authors want their methodology paper to have restricted authorship, they need to include a request and justification for this on the proposal when it is submitted for P&P review; the decision to limit circulation for authorship will then be made in committee discussion.
- **Papers based on ‘local’ data**—Manuscripts generated by data from only one FC are generally not circulated to WHI PIs. It is expected that the lead authors will include WHI investigators from that FC in their writing group.

Conduct

The writing group chair has the following responsibilities:

- Communicating with other writing group members to identify data needed from the CCC
- Establishing a plan for writing the manuscript
- Contacting writing group members and delegating tasks
- Maintaining contact with the assigned statistician (if the CCC is doing the analyses)
- Convening a meeting or conference call of the writing group at a time when the CCC has completed the preliminary analyses (or before, if necessary) to finalize the analysis plan
- Keeping the P&P Committee Chairs informed of the paper's progress (notifying the P&P Chairs of any delays or departures from the established production schedule, providing explanations for any delays that do occur, etc.)⁶
- Informing the P&P Committee of any substantial minority opinions or reports within the writing group⁷

Members of each WHI writing group should participate actively in preparation of the publication assigned to that group. The writing group chair must obtain input⁸ from every member of the group during manuscript development. In addition, all members must review and approve the final draft manuscript before it is submitted to the P&P Committee for review. If any member of the writing group does not respond to the writing group chair's requests or does not contribute to the writing of the paper, the chair should contact the P&P Committee Chairs and request this member be removed from the writing group. Removal of a writing group member may be

⁶ If any problems emerge, the P&P Committee will confer with the involved writing group chair to resolve the situation.

⁷ This is intended to ensure that serious concerns are not arbitrarily overruled by the writing group chair without the knowledge of the P&P Committee.

⁸ *Input* may be edits or an acknowledgement that the writing group member has read and endorses the draft, analysis plan or interpretation.

confirmed by the P&P Committee. The individual has the right to receive written notice of the decision and to appeal the decision.

Appeals

If one or more writing group members disagree with the data analyses, interpretation of the data, or authorship, the members should discuss the disagreement with the lead author, who makes a decision on how to resolve the dispute. If either the members disagree with the decision, or the lead author does not respond to the request for changes, the writing group member(s) should ask for a polling or formal vote of the entire writing group relating to the issue(s) in dispute. If this does not resolve the issue(s), and the writing group member(s) believe(s) that it is in the best interests of the WHI to not allow the paper to proceed, an appeal may be made to the P&P Committee Chair, who will attempt to resolve the issues or appoint an appropriate P&P member to resolve the issue(s) in a meeting or conference call with the lead author and the member(s) who are in disagreement. If this is unsuccessful, and if the P&P Committee Chair, with the approval of the committee, cannot make a decision, then the P&P Committee Chair should solicit expert opinion from within WHI and if necessary from outside the study. If final arbitration is necessary, the P&P Committee through the chair will make the Executive Committee aware of the sequence of events and final decision.

MANUSCRIPT CONTENT

General Guidelines

The P&P Committee works to ensure consistency among WHI publications. The following guidelines apply to all papers:

- All publications for a trial should reference the global paper and any other relevant papers from that trial.
- Conclusions concerning individual outcomes should be presented in a way that considers the global outcome.
- Centrally adjudicated outcomes should be used for those outcomes that have been centrally adjudicated unless approved by P&P.
- Both hazard ratios and absolute rates should be presented when analyzing effects of the intervention.
- Effect modification by prior hormone use should combine E and E+P use, in addition to any separate analyses for E or E+P.
- Definitions of endpoints such as CVD, CHD, VTE, and fractures should be consistent with the major primary outcome paper; if defined differently, the distinction should be emphasized in the presentation.
- Effects of interventions on biomarkers should be reported in a consistent manner across papers.
- Non-adherence is defined as using less than 80% of study pills, stopping study pills, or commencing non-study prescription pills.
- The prescribed acknowledgement section should be included. [See section below.]

- WHI disallows Observational Study (OS) analyses of either CT or OS data that examine interventions tested in the CT, with the exception of studies that seek to inform or adjust CT findings with OS findings. This policy is intended to prevent confusing the public about previously published CT findings.

Reporting of Race and Ethnicity Data

WHI publications should describe the demographics of the study population included in the analysis, or refer to another publication that describes the demographics. The demographics should include a listing by race/ethnicity (numbers and/or percentages). The following guidelines apply:

- The race/ethnicity subgroups (alternative nomenclature in brackets) that should be listed in alphabetic order are those by which participants identified themselves at enrollment, with some minor modifications: American Indian/Alaskan Native (American Indian or Alaskan Native); Asian/Pacific Islander (Asian or Pacific Islander); Black (African-American); Hispanic (Latino); White not of Hispanic origin; Unknown (not one of above).⁹
- The unqualified use of the term “other” should be avoided.
- “Combining” these specific race-ethnic groups in the descriptive demographic tables is not allowed.

The following guidelines apply to analysis and interpretation of the data:

- The design of the WHI trials does not include an a priori hypothesis supporting significant differences within or between race/ethnic groups of clinical or public health importance, and therefore recruitment by race/ethnicity was not geared towards testing separate hypotheses for any particular group. When it is unknown whether there may be differences, the new NHLBI policy still requires “valid analyses” to be done by race/ethnicity in CTs. The NHLBI definition of “valid analyses” differs from analysis with the power to ascertain a “statistically significant” difference (see below). This definition applies to CTs, but for WHI purposes will also apply to the OS by substituting “exposure” or “characteristic” for the “intervention effect”.
- Valid analyses may be of a simple nature (e.g. a tabulation of the prevalence of a characteristic or outcome by race/ethnic group with or without statistical testing), or may be more complex (e.g. univariate or multivariate statistical testing for differences by race/ethnic group). All key results in the full dataset should be reviewed to determine whether the results are similar in each race/ethnic group. If the results appear to differ by race/ethnicity, then the results should be reported separately for the group(s) that appear(s) to differ, in addition to the results for the combined data. In multivariate modeling, it may be necessary to combine some subgroups (e.g. small subgroups, or subgroups that appear to have similar results), either for main effects or interactions, in order to preserve stability of the model. These may be identified as “other race/ethnic groups” in multivariate models but caution should be used in interpreting any effects associated with this subgroup.

⁹ Note that the Unknown category will therefore include those women who selected “Other” race/ethnicity as their response.

- All publications should indicate whether any race/ethnicity effects were hypothesized from previous literature and include an explanation of how the data by race/ethnicity were dealt with, whether or not there were sufficient data to do group-specific analyses, and whether or not there appeared to be differences by race/ethnicity. Investigators are encouraged to pursue hypothesis-driven analyses in this area, wherever feasible. It is not the intent of these guidelines to promote simplistic or unfocused examinations of the data. If these analyses reveal no differences, a brief statement to that effect, indicating the groups and/or subgroups analyzed, will suffice.
- In presentations regarding ethnicity and disease, the term admixture should be used if it is necessary to cite that information. Tables and figures focused on admixture should be avoided.
- WHI SHARe may not be used to investigate individual pedigree structures, individual participant genotypes, perceptions of racial/ethnic identity, or issues such as non-maternity.

If journal policy does not allow full publication of data by race/ethnicity in the main body of the article, the data by race/ethnicity should be made available to other researchers by means of an appendix to the article, or by publication on the NHLBI WHI website (contact Nancy Morris in the PO).

Statistical Guidelines

The following guidelines concern statistical issues:

- Two sided p-values should be used.
- Subgroup analyses should report number of subgroups and address the possibility of Type I error, by stating the number of comparisons that could be significant by chance alone.
- Stratified analyses should include assessments of interaction terms; if interaction terms are not significant, an interpretation of the stratified data should be agreed upon by the writing group and a justification for the interpretation presented to the P&P Committee along with the submitted manuscript. There may be limited power for testing interactions.
- Kaplan-Meier curves should be presented as cumulative incidence rather than disease-free survival, and should include the full range of follow-up as in the global paper.
- Though priority papers focus primarily on nominal Confidence Intervals (CIs), issues of sequential monitoring and multiple testing should be considered. In some cases adjusted CIs need to be presented, while in others an acknowledgment of the potential for over-interpretation of the data will suffice.
- Results for the pre-specified primary efficacy and safety outcomes (CHD and Breast Cancer) do not need to be adjusted for multiple outcomes. However, since these outcomes contributed most directly to the decision to stop the trial, the papers should also present CIs adjusted for sequential monitoring to control the (null hypothesis) error rate, given the multiple early stopping opportunities.
- Results for other major monitored outcomes (Hip Fracture, Stroke, PE, Colorectal Cancer, Endometrial Cancer, Death from Other Causes, Global Index) should be Bonferroni adjusted for 7 outcomes to control for the experimentwise error rate in regard to these monitored outcomes. These outcomes had only a limited and indirect influence

on early stopping, therefore adjustment for sequential monitoring would be too conservative (while adjustment for multiple outcomes may be viewed as being slightly liberal).

- For all other outcomes not included above (e.g., dementia, other gynecologic cancers) nominal CIs alone may be presented, but the text should state that a wide range of clinical and behavioral outcomes have been examined, increasing the probability that some nominal CIs may exclude 1 based on chance alone.
- The issue of examination of multiple subgroups within an outcome category also needs to be addressed in the text, and a Bonferroni-type adjustment considered if indicated. A statement of how many subgroups were examined, and how many interactions were examined should be included, along with a statement of how many could have been expected to be significant by chance alone if the intervention effect under study does not depend on any of the subgroups (or factors) examined.

Acknowledgements

All WHI publications must include the following statement: *“The WHI program is funded by the National Heart, Lung, and Blood Institute, National Institutes of Health, U.S. Department of Health and Human Services through contracts N01WH22110, 24152, 32100-2, 32105-6, 32108-9, 32111-13, 32115, 32118-32119, 32122, 42107-26, 42129-32, and 44221.”*

In addition, papers must include the “short list”¹⁰ of WHI investigators; ISPs and primary papers must include the “long list”¹¹ of WHI investigators instead of the “short list.” Both lists can be obtained from the CCC P&P Program Assistant and are available online at http://www.whiscience.org/publications/write_paper.php. Collaborative papers which cannot accommodate the “short list” are permitted to substitute the following acknowledgement statement instead: *“The WHI program is supported by contracts from the National Heart, Lung and Blood Institute, NIH. The authors thank the WHI investigators and staff for their dedication, and the study participants for making the program possible. A listing of WHI investigators can be found at http://www.whiscience.org/publications/WHI_investigators_shortlist.pdf.”*

PUBLICATION OF MANUSCRIPTS AND PRESENTATIONS

After a manuscript is approved by the P&P Committee, the lead author is responsible for keeping WHI updated of the manuscript’s status on an ongoing basis. The lead author must notify the CCC and the NHLBI PO when the manuscript is submitted to a journal and accepted for publication.¹² It is expected that authors will inform the P&P Committee of publication dates and

¹⁰ **“Short list”** is comprised of 1 name submitted from each FC, 5 names each from the NHLBI and CCC; plus the following numbers for the CCC Subcontractors: Bowman Gray - 2; University of California at San Francisco - 1; Medical Research Labs - 1; University of Washington - 1; University of Minnesota - 1.

¹¹ **“Long list”** is comprised of 5 names submitted from each FC and the NHLBI; 16 from the CCC; plus the following provision for the CCC Subcontractors: Bowman Gray - 4; University of California at San Francisco - 3; Medical Research Labs - 2; University of Washington - 2; University of Minnesota - 1; McKesson BioServices - 2.

¹² Instructions for notifying the CCC and the NHLBI Project Office are provided in the memo approving the manuscript.

send (1) a copy of the manuscript as accepted by the journal and (2) the published manuscript in PDF form as they become available. Any press releases, talking points, or other materials prepared for the media must be submitted to the P&P Committee and the NHLBI PO for review.

Lead authors are responsible for notifying the P&P Committee and the NHLBI when submitting a WHI manuscript to a high-profile journal. The NHLBI considers manuscripts submitted to the following journals to be “high-profile”: New England Journal of Medicine, JAMA, Circulation, Archives of Internal Medicine, Hypertension, Lancet, Nature, and Nature Genetics. NHLBI needs to be aware of such manuscripts so they can track progress and prepare for media attention.

NIH Public Access Policy applies to WHI manuscripts stemming from contracts funded in or after April 7, 2008, as well as all WHI manuscripts on which an NHLBI employee is a coauthor. WHI manuscripts arising out of contracts signed before 4/7/08 do not fall under the policy. Authors should refer to the NIH policy website at <http://publicaccess.nih.gov/index.htm> for current regulations.

Publications and presentations shall be in compliance with the rules and procedures of disclosure set forth in the Privacy Act. Confidential or proprietary information shall not be disclosed without the prior written consent of the individual or institution. Privacy Act compliance and documentation of written disclosure consents are the responsibility of each institution involved in the publication/presentation.

USING WHI DATA FOR PURPOSES OTHER THAN PUBLICATIONS AND PRESENTATIONS

The P&P Committee must approve the following uses of WHI data:

Unpublished Data in Grant Applications or Contract Proposals

Investigators who seek to use WHI data that have not been previously published but are needed for grant applications or contract proposals must have prior approval for use by the P&P Committee and the sponsoring PI. Requests submitted to the P&P Committee will be reviewed as a business item during the P&P Committee meeting.

Theses, Dissertations, and Academic Projects

All requests for use of WHI data by graduate students, medical students, residents and other trainees for theses or similar academic projects are to be reviewed by the P&P Committee. The student requesting use of WHI data must be associated with a sponsoring PI. WHI data may not be used by students if the data relate to major WHI papers in progress or if the P&P Committee deems those data to be necessary for a future major paper.

If the P&P Committee recommends approval for the use of the requested data, a writing group is established with the student as chair. The writing group is to take no action regarding the paper until the student has completed and defended the thesis, provided this occurs in a reasonable length of time, to be determined on a case-by-case basis. The student's sponsor is to report the student's progress to the P&P Committee a minimum of once annually. WHI reserves the right to proceed with preparing a paper on the thesis/dissertation topic for publication through the activation of a writing group if, in the view of the P&P Committee and the student's sponsor, the student has not made reasonable progress in completing the thesis.

The completed thesis/dissertation must include (1) a statement acknowledging WHI for use of the data and (2) a statement indicating that opinions, ideas, and interpretations included in the thesis are those of the student alone and not those of the WHI investigators. When the thesis has been completed, as determined by the sponsor, the entire writing group will develop the manuscript(s) for publication. It is the responsibility of the sponsoring PI to ensure that the thesis/dissertation accurately reflects the conduct and data from the WHI, as dissertations are technically available to the public without undergoing review by the P&P Committee. WHI P&P policy is to apply to any material published from the thesis.

Use of Data for Illustrative Purposes

Requests to use WHI data for purely illustrative purposes should be directed to the chair of the P&P Committee. The committee will act on the request with due attention to the requester's link to the WHI and to the potential impact on other WHI-related publications and presentations.