

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

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## OVERVIEW AND DEFINITION OF TERMS

The P&P Committee is responsible for oversight of all publications and presentations that are developed using WHI data.

### Committee Structure

P&P is led by co-committee leaders (2) who are responsible for oversight of committee activities and serve on the WHI Steering Committee. The P&P committee is composed of the *Core Committee Members* and *Adjunct Reviewers*.

Members of the Core Committee consistently attend their respectively assigned committee calls (2nd or 4th Thursday) to discuss policy issues and priority paper decisions. Responsibilities for the Core members include:

1. Delivering timely, comprehensive reviews of submitted manuscript proposals and manuscripts prior to the P&P Committee call date;
2. Attending assigned calls, providing input on policy/procedures and/or manuscript proposals or full manuscripts;
3. Preparing thorough reviews for off-call assignments (abstracts, revised proposals and papers, and posters), and returning feedback to the P&P Coordinator in a reasonable timeframe (7-10 days);
4. Contributing to P&P policy, procedures and training of new investigators in the P&P process.

Adjunct Reviewers review 1-3 assignments per quarter, and will only be asked to attend Committee calls if/when their assigned paper is identified for full committee discussion.

A Women's Health Initiative (WHI) publication or presentation is one that is authored by WHI investigators, applies WHI data, and is 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 is authored by a WHI investigator must be reviewed and approved by the P&P Committee.

The terms referencing WHI members in regards to publications and presentation policies and can be found on the WHI website <https://www.whi.org/doc/WHI-Investigator-Categories.pdf>:

- *Sponsoring Principal Investigator (PI)* – must be an active WHI member as defined by the above link. The Sponsoring PI ensures 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 manuscript development (uses standard WHI manuscript proposal template).
- *Manuscripts* – final drafts of articles or book chapters that are not yet submitted to the journal
- *Abstracts* – summaries of intended presentations or posters for scientific meetings.
- *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 BAA<sup>1</sup> study.
- *Collaborative (Consortium) 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.
- *Review articles, methodological papers 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 GUIDELINE

**Submission Timeframe:** Once a proposal is submitted and approved by the P&P Committee and statistical analyses have begun, the authors are expected to submit the corresponding manuscript for Committee review within twelve (12) months.

Following Committee approval of the manuscript, authors must submit the paper for publication to a journal within 3 months. Should the paper fail to be accepted upon submission, the authors will have 3 additional months to make the necessary changes and resubmit.

Should an approved proposal fail to move to publication within three (3) years of its initial approved proposal notification from the P&P Committee, the P&P Committee will require re-assignment of lead authorship in an effort to move the manuscript to publication.

Re-assigned lead authors of manuscript proposals are expected to submit a manuscript for P&P review within 6 months and re-assigned lead authors of an approved manuscript are expected to submit a manuscript to a journal within 3 months. The P&P Committee will work with the paper’s sponsor when determining the new lead author.

Except in extenuating circumstances, manuscripts are expected to be published or accepted for publication within 3 years of proposal approval, and/or within 12 months of manuscript

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

approval. In the case of lagging papers the writing group and sponsor will be consulted to determine whether the manuscript should be cancelled, or another lead chosen.

## **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 WHI website ([www.whi.org](http://www.whi.org)) or from the WHI Clinical Coordinating Center (CCC) P&P Coordinator. A list of all WHI publications, approved proposals and approved manuscripts to date is available on the website. Prospective authors should review this list before developing a proposal to avoid overlap. *Authors are advised to contact the Chairs of relevant [Scientific Interest Groups](#) in WHI to engage necessary expertise in specific areas of research and to avoid the risk of duplication with previously published manuscripts or ongoing research as they develop their proposal. Authors are also strongly encouraged to contact Ancillary Study (AS) PIs to engage them in any new proposals that will use data generated from a specific AS.*

If overlap is identified the prospective author may either drop the idea, contact the lead author of the proposal to determine if overlap can be avoided through selective data analysis and reporting, or discuss the possibility of joining the writing group should the lead author be in agreement. A summary of these discussions should be forwarded to the P&P Chairs for final approval. This will ensure appropriate documentation is completed for WHI P&P records. Even if overlap should be identified following a proposal's approval from the P&P Committee, the authors may be asked to cease their writing.

Nearly every proposal must have a sponsoring PI who will work with the lead author as needed.

Note: The exception to this is when a paper stems from a BAA – these papers do not require a sponsoring PI from WHI.

In an effort to ensure timely completion of manuscripts, investigators are discouraged from leading more than 3 papers at one time. Exceptions to this general rule may include proposals stemming from ancillary studies, BAAs, grant-funded projects or where evidence of timely progress on existing manuscripts can be demonstrated. Petitions for exceptions to this rule may be sent to the P&P Coordinator and will be reviewed by the P&P Chairs.

All proposals must contain information specified in the Manuscript Proposal Template<sup>2</sup> (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. Statistical power estimates should also be included whenever possible or an estimated likelihood of adequate sample size based on available WHI “cases” relative to published studies with similar associations.

Prospective authors are encouraged to contact a biostatistician familiar with the WHI data (CCC or RC (W, SE, MW, NE) personnel) during the proposal development process in order to enhance the quality of the analytical plan, assure sample size for statistical power, and to begin to formulate a thoughtful approach to data analysis.

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<sup>2</sup> The template is available at [http://www.whi.org/publications/proposal\\_template.pdf](http://www.whi.org/publications/proposal_template.pdf).

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Detailed information on what data have been collected at baseline and during follow-up is available in the “Frequency of data collection” section on our [website](#).

Proposal submissions may include up to 5 authors, including the lead author, a junior or early-career author, and a biostatistical author; certain exceptions apply (i.e., BAA and SHARE papers). 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 Zoom meetings.<sup>3</sup> Submissions of proposals to P&P for review must follow the posted deadlines, generally 10 days in advance of the meeting: <https://www.whi.org/page/propose-a-paper>

Upon receipt of a manuscript proposal, the proposal is added to the next available agenda. 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., using a standard review form. Assignments for reviewers are made based on manuscript focus, matched to reviewer expertise. At that time, the committee will decide on the recommended course of action. This includes: approved, approved with recommended changes, approved with required changes, revise and resubmit to primary reviewers, revise and resubmit (to full committee), and disapproved. *Committee recommendations and reviews are provided to prospective authors within one week after the call on which the proposal was reviewed.* If additional committee review is recommended, prospective authors should submit their revised proposals to the committee for a second review ideally within 3 months. If a proposal is designated for review to primary reviewers, those reviewers will be given 2 weeks to complete reviews.

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 (and Consortium 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.<sup>4</sup>

Investigators must agree that any use of CMS data in the creation of any document (manuscript, table, chart, study, report, etc.) concerning the WHI and/or utilizing its data must adhere to CMS’ current cell size suppression policy. This policy stipulates that no cell (eg. Admittances, discharges, patients) less than 11 may be displayed. Also, no use of percentages or other mathematical formulas may be used if they result in the display of a cell less than 11. By signing this Agreement you hereby agree to abide by these rules and, therefore, will not be required to submit any written documents for CMS review. CMS agrees to make a determination about

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

<sup>4</sup> 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](https://biolincc.nhlbi.nih.gov/new_data_set_policy).

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approval and to notify the user within 4 to 6 weeks after receipt of findings. CMS may withhold approval for publication only if it determines that the format in which data are presented may result in identification of individual beneficiaries.

The P&P Committee generally does not approve broad proposals to analyze multiple outcomes/endpoints. It is recommended that authors focus on one particular endpoint per manuscript. Exposures and outcomes should have been sufficiently measured (rigor and reproducibility) to scientifically warrant use in a peer-reviewed manuscript (i.e., some variables in WHI are not rigorous enough to meet standards for quality peer-review publication).

## **Final Manuscripts**

All WHI manuscripts must be reviewed and approved by the P&P Committee prior to their submission to a journal for publication. Submissions of manuscripts to P&P for review must follow the posted deadlines: <https://www.whi.org/page/propose-a-paper>. 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 (email with letter attached) that their manuscript has been approved by the P&P Committee, within 12 months, they may 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.

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, and a new proposal will be requested, but will generally not be required to undergo a full committee review.

## **Abstracts and Presentations**

All abstracts must be approved by the P&P Committee before they are submitted to any local, national and/or international organizations. They must be submitted at least 2 weeks prior to the abstract deadline. All abstracts must be derived from P&P-approved proposals, or submitted for review concurrently with the related proposal. Abstracts submitted concurrently with the related proposal must include no more than the 5 authors listed on the manuscript proposal. Exceptions will be made for abstracts from prior-approved data consortia led by non-WHI investigators, since P&P does not require paper proposals for data consortia led by non-WHI investigators to be submitted for review. Abstracts will be circulated by email to 2 P&P Committee members with relevant expertise, with a request to complete their review within 2 weeks. Expedited reviews to be completed in < 1 week may be requested, but will only be completed if reviewers with appropriate expertise can be identified and are willing to meet a shorter timeline.

On occasion, the P&P has allowed abstracts to be submitted without prior P&P review with the understanding that authors they will withdraw the abstract or make required changes if the reviewers and the P&P Chairs deem this necessary.

Abstracts using BioLINCC or Consortium 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 below).

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 the case of a press release 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 the WHI P&P. To achieve this, the investigators should submit specific manuscript proposals (to correspond to the specific aims of the grant) to the P&P Committee. Each proposal will undergo review at a P&P Committee meeting and will need approval before the grant proposal can be submitted. In cases where the grant proposal is based on data from numerous sources beyond WHI (e.g., pooled cohort studies), 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.

Generally, review of manuscripts for grant applications will be completed by the same two reviewers to provide consistency and comprehensiveness to the review process. If the proposals are approved, the investigators may submit a draft letter of support for the P&P Chairs to edit and sign or the P&P Committee Chairs will draft and provide a signed letter of support as appropriate for submission with the grant.

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 within 18 months 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.

### **Collaborative/Consortium Papers**

Collaborative/consortium papers are defined as proposals and manuscripts developed to include WHI data in combination with other datasets including pooled analyses and meta-analyses.

Consortia are formed by application to P&P or Ancillary Studies Committee:

<https://www.whi.org/page/plan-a-study>. Once approved, a consortium is assigned a WHI liaison who is responsible for ensuring that WHI rules are followed.

**Proposals** for approved collaborative projects are not required to undergo review by the P&P Committee unless the lead or senior author is a WHI PI, Co-investigator, Associate Member, or ancillary study investigator; however, the Committee prefers that draft proposals be sent to the P&P Committee for their records.

**Collaborative/consortium manuscripts** for which a WHI investigator (or investigators) are an author (lead or otherwise) will undergo full review by the P&P Committee, per standard procedures. It is the responsibility of the WHI liaison to the consortium to ensure that P&P Committee policies are enforced. The WHI liaison will work with the consortium lead to assure appropriate representation of WHI authorship. Manuscripts that include WHI data must identify WHI in the acknowledgements using standardized language on the WHI website. Consortium papers are not authorized to present WHI-specific data independent of the pooled data analyses. WHI-specific data are reserved for investigator-lead authorship under the WHI P&P policies and procedures for manuscript development.

### **dbGaP/ Other Public Dataset Papers**

**Proposals** stemming from dbGaP/other public datasets are not required to undergo review by the P&P Committee unless the lead author is a WHI PI, co-investigator, or associate member; however, the Committee prefers that draft proposals be sent to the P&P Committee for their records.

**Manuscripts** stemming from dbGaP/other public datasets led or co-authored by a WHI PI, co-investigator, or associate member must undergo full review by the P&P Committee.

### **Ancillary Study Papers**

Ancillary Study papers are those using data primarily from one or more WHI ancillary studies. Most publications stemming from ancillary studies, including those from clinical trials, are required to adhere to the full P&P review process. This requires that manuscript proposals, abstracts, and draft manuscripts are submitted to the P&P Committee for review and manuscript proposals go through the formal WHI writing group selection process. There are a few notable exceptions:

- ***Single-Center ancillary studies***—data generated from only one Field Center



- ***Clinical Trials with outside recruitment***\*—data generated using both WHI participants and participants recruited from outside of WHI.

Proposals and abstracts stemming from ***Single-Center ancillary studies*** and ***Clinical Trials with outside recruitment*** are not required to undergo review by the P&P Committee.

WHI authorship – Proposals stemming from most ancillary studies, including those from ***Clinical Trials with outside recruitment***, are required to undergo the formal WHI writing group selection process. Since ***Clinical Trials with outside recruitment*** are not required to submit proposals for P&P review, these study PIs and lead authors are responsible for submitting proposals to the P&P Committee ([p&p@whi.org](mailto:p&p@whi.org)) to initiate the WHI writing group selection process. Proposals will be advertised for open writing group slots. Nominations are open to WHI investigators who actively participated in the study or who can demonstrate valuable subject matter expertise. Study PIs and lead authors will have the authority to approve or deny nominees but must ensure appropriate representation of WHI. Certain kinds of ancillary study papers (e.g. design and baseline findings, priority papers) may be exempt from this requirement with prior approval from the P&P Committee Chairs.

Draft manuscripts stemming from ***Single-Center ancillary studies*** and ***Clinical Trials with outside recruitment*** must undergo full review by the P&P Committee prior to journal submission.

\*These rules also apply to ancillary studies of ***Clinical Trials with outside recruitment***.

## **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 review by the P&P Committee. BioLINCC manuscripts authored by non-WHI investigators may also be submitted for review, but this is not required.

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.

## **Review Articles, Book chapters, and Editorials**

Review articles, book chapters, 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 and listed for co-author nominations. Exceptions include primary papers, ISPs, BAA papers, collaborative papers, papers focused on methodology, papers using dbGaP data, and papers based on local data (see below). Proposals are generally circulated to WHI investigators within a month following the P&P Committee's approval of a proposal, with a 2-week nomination period. Within the 2-week period, PIs and WHI Investigators may nominate themselves or a qualified colleague to participate in a writing group. Nominations must be submitted online via the WHI SharePoint site. 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:

- The P&P Committee does not restrict the number of authors per paper; however, investigators are encouraged to keep in mind the limitations established by their target journal.
- Criteria for selection of writing group members will include level of expertise (related to the manuscript topic), support of authorship by early career scientists, balanced representation across WHI RCs, 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 as well as expertise in the content area. WHI nominees are expected to be included in the authorship of the manuscript unless a reason not to do so is provided to the P&P Chairs in writing (email) and meets with their approval. If the number of nominees causes the total writing group membership to exceed a reasonable limit (typically 12-13 authors) the lead author may request to exclude a select number of nominees and may provide rationale for specific nominees to be excluded. Ultimately, the P&P Chairs will make a final impartial selection to limit a writing group.
- 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.

- Lead authors are expected to select and include a person with statistical expertise and knowledge of the WHI data base for authorship on manuscripts.
- Advanced graduate students who have a major involvement with development of a proposal as a part of their thesis work are eligible to participate in writing groups, but must be sponsored by an experienced WHI investigator who is willing to oversee this process.
- The investigator submitting the proposal for approval (the lead author) will be appointed chair of the writing group.
- The P&P Committee must approve all writing groups.

At the end of the writing group nomination period, the P&P Program Assistant will inform the lead author of the WHI nominees (email list with names and contact information); lead authors must confirm the list of nominees as co-authors on their manuscript via email to the P&P Program Assistant. 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 Program Assistant facilitates the approval of the writing group by the P&P Committee as necessary. The Program Assistant then confirms the manuscript's authorship via a memo to all authors which informs the lead author (the "writing group chair") of their responsibilities. Each writing group is allotted use of a WHI-supported conference call line for up to two calls, which shall be coordinated with the help of the P&P Program Assistant; should additional calls be required, please contact the P&P Program Assistant.

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

- **Primary papers**—Authorship is generally determined prior to the submission of a manuscript proposal. After a primary paper is identified by the SC or a SIG, the topic is circulated to the PIs so they can nominate themselves. Typically each RC is allowed a specific number of author slots on a primary paper in order to ensure fair representation of investigators on all major WHI papers. Only WHI Investigators and PO scientists are eligible to be authors.<sup>5</sup>
- **BAA papers**—Proposals are circulated to WHI investigators 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.
- **Collaborative/consortium papers**—Authorship is determined by the P&P Committee Chairs. The investigator 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 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 for additional authorship. However, manuscripts that apply a method to an outcome where new or reanalyzed data is presented must be circulated. If authors want their methodology

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<sup>5</sup> 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.

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 for broader WHI authorship. It is expected that the lead authors will include WHI investigators from that FC in their writing group if they have the relevant expertise to contribute to the manuscript. A manuscript proposal does not need to be submitted for papers based on data from a single FC.

## Conduct

The writing group chair has the following responsibilities:

- Communicate with other writing group members to identify data needed from the CCC or RC statisticians.
- Establish a plan for writing the manuscript.
- Contact writing group members and delegate tasks.
- Maintain contact with the assigned statistician (if the CCC or RC analysts are doing the analyses).
- Convene a meeting or conference call of the writing group at a time when the preliminary data analyses is completed (or before, if necessary) to finalize the analysis plan.
- Keep the P&P Committee informed of the paper's progress (notify the P&P Chairs of any delays or departures from the established production schedule, providing explanations for any delays that do occur, etc.)<sup>6</sup>.
- Inform the P&P Committee of any substantial minority opinions or reports within the writing group<sup>7</sup>. Assure that the Sponsor and all authors have reviewed the manuscript prior to submission to P&P.
- Submit the final paper to the P&P Committee for proposal and/or draft manuscript review.
- Submit the paper to a journal for publication within 3 years of the proposal's approval from the P&P Committee.

Members of each WHI writing group should participate actively in preparation of the publication assigned to that group. The writing group chair must obtain input<sup>8</sup> 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 prospective author to inform them they have been removed from the writing group. The P&P Committee must be informed of the removal of a writing group member. The individual has the right to receive written notice of the decision and to appeal the decision.

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

<sup>7</sup> 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.

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

## Appeals

If one or more writing group member disagrees with the data analyses, interpretation of the data, or authorship, the members should discuss the disagreement with the lead author, who will make a decision on how to resolve the dispute. If either of the P&P 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 Chairs, 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 first approach the Sponsor of the manuscript, if appropriate, then 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 notify the Steering Committee of the issues under discussion, and the SC will make the 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 should reference the global paper and/or any other relevant papers from WHI or the individual trials. (Global paper: Manson et. al. JAMA. 2013 Oct 2;310(13):1353-1368.)
- 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; authors should apply the most recent adjudicated dataset for analysis
- 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. Adherence measures for dietary intervention

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may vary depending on the objective of the analyses; authors should consult the manuscript by Prentice et al. for a general measure of adherence to the intervention.

- 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 or report out observational findings related to longer-term follow-up after trial completion. This policy is intended to prevent confusing the public about previously published CT findings.

## Writing Clarity

P&P Reviewers will consider the following when examining draft papers and proposals:

- Does the author identify a senior PI from WHI to sponsor the paper?
- Does the paper's topic overlap with existing literature? If so, do the authors reference those findings and discuss how they impact their current work?
- Are power calculations provided if appropriate? Or, if not is the rationale (e.g. descriptive paper etc) provided?
- Confirm that tables and graphs are relevant and well-labeled.
- Is the writing clear and readable?

## Reporting Diversity and Ancestry Data

*created by:* The WHI Race and Ethnicity Task Force ([see 9.1.2021 Guide](#))

### A. Overarching principles:

**Race** and **Ethnicity** are distinct socio-political constructs that are **not** rooted in **biology**. **Ancestry** and **genetic admixture** are **not** interchangeable with “race” or “ethnicity”. **Ethnicity** is distinct from **Race**. Both should appear in WHI characteristics tables.

### B. WHI Race and Ethnicity Variables: Baseline WHI Form 2 [\[link\]](#) and Form 41 [\[link\]](#)

The **F41-mapped\*** dataset (labeled ‘f41\_imputed\_ctos\_inv.dat’ on the WHI website) should be used in all WHI analyses and papers. “**Other**” should only be used when a participant selected “other” as her identity. It should not be used to combine racial groups (or subgroups) for any purpose.

### C. Race and Ethnicity Definitions and Terminology (Language)

A few basic language and writing guidelines are presented in the Guide, including terms which should and should not be used. Individuals should be referred to by their self-identified race and ethnicity. Terms used to group race and ethnicities should be well conceptualized in the manuscript.

### D. WHI Cohort Representativeness of U.S. Women by Age and Race and Ethnicity



Authors should address the representativeness of the U.S. (older) female population, per Census data, of the WHI cohort when interpreting analytic results (Appendices B1 & B2 provide information to support this).

#### **E. Geographic Origin and U.S. Regionalization Considerations**

**U.S. geographic diversity** is particularly rich in WHI and may be relevant when focusing on race and ethnicity. Recruitment strategies varied across WHI Clinical Centers (see Appendices C1-C4).

#### **F. Specific Considerations for Including Race and Ethnicity in WHI Analyses:**

- Develop Questions & Methodological Strategies Informed by Conceptual Frameworks, e.g. Public Health Critical Race Methodology; National Institute of Minority Health and Health Disparities Research.
- Reporting of demographic data on race and ethnicity. WHI manuscripts should:
  - state that WHI participants self-identified their race and ethnicity (F41-mapped dataset);
  - provide rationale for use of race as a key variable; if race is the **primary exposure** of interest or where analyses are **stratified by race** and/or **ethnicity**;
- Analyses by Race and/or Ethnicity
  - Comparisons between race or ethnic groups should be informed by research questions.
  - Comparisons of race or ethnic groups to Non-Hispanic White participants is not required in WHI; this should only be done when supported by a research question; “all other race categories” should not be grouped (to increase sample size, for example) to be compared with White.
  - Within group analyses should acknowledge the heterogeneity within racial and ethnic groups.
- Data Interpretation & Reporting
  - **Statistical power for race and ethnicity subgroup analyses**, should be sufficient to detect differences by that group. **Authors** should acknowledge that sample selection limits interpretation of findings to the overall U.S. population or racial or ethnic subpopulations identified in the manuscript.
  - Over time, the **WHI sample composition has been influenced by selective drop-out** that can be investigated through the use of inverse probability weighting and other methods.
  - **Limitation:** Race and ethnicity are defined and interpreted within a socio-political framework as a proxy for both historical and ongoing differences in advantages arising from racism in social determinants of health, such as education, income, resilience and stressful life events (see WHI psychosocial constructs [\[link\]](#)). Other structural factors may be important for the data interpretation of racially disparate outcomes, but are not available in WHI.

## Statistical Guidelines

The following guidelines concern statistical issues:

- Two sided p-values should be used.
- Avoid interpreting results based upon statistical significance alone. Consider scientific context, plausibility, magnitude of effects, and clinical importance of observed differences.
- In situations where results were consistent with 'no difference', describe whether results were indeterminate (in need of further study), or were negative (clinically meaningful differences were ruled out).
- Subgroup analyses should report number of subgroups and address the possibility of excessive Type I error, by stating the number of comparisons that could be significant by chance alone.
- The statistical significance of subgroups should be assessed by tests of the interaction terms between exposure x subgroups. There may be limited power for testing interactions, and this should be addressed in the discussion.
- Forest plots of hazard or odds ratios should be scaled such that HR estimates of  $\frac{1}{2}$  and 2 should be visually equidistant from unity.
- When applicable, Kaplan-Meier curves should be presented as cumulative incidence rather than disease-free survival, and should include a suitable amount of follow-up time.
- For observational studies, plots of cumulative HRs over time may be more suitable than overall HRs because Cox regression models readily allow for time-dependency in HR models.
- Issues of sequential monitoring and multiple testing should be considered and noted in the study plan and addressed in the discussion. An acknowledgment of the potential for over-interpretation of results will suffice.
- For reports that consider many outcomes, nominal CIs and nominal p-values alone may be presented, but the text should address the possibility of excessive Type I error, by stating the number of comparisons that could be significant by chance alone.
- The completeness of adjudicated outcomes depends on study component (e.g., OS vs HT), study period (i.e., study, extension 1, extension 2) and cohort (i.e., MRC vs SRC); see <https://www.whi.org/doc/WHI-Data-Preparation-and-Use.pdf> for details. Consequently, care must be taken to ensure that contrasts between exposure groups account for potential differences. For example, hip fractures were only adjudicated for the MRC during extension 2, so analyses that examine the full WHI cohort should statistically account for that (e.g., censor follow-up at the end of extension 1; IPW the MRC to reflect extension 2 participation).
- Consider presenting estimates of the exposure's effect in both absolute and relative terms so results are more comprehensive and interpretable. For example, when reporting hazard ratios, also report the number of events and annualized rates. Difference in estimated absolute risks (e.g., exposure minus control group) per 10,000 person years may provide additional context.

- Longitudinal analyses should be considered if response data were collected at more than 1 time point. Common longitudinal methods include likelihood models (e.g., linear mixed effect [LME] models) and generalized estimating equations (GEEs) that account for

within participant correlations over time, preferably so that temporally closer observations are more strongly correlated; random intercept models and compound-symmetric variance-covariance matrices are typically not sufficient.

- Missing data and length of follow-up should also be considered when selecting a longitudinal method. GEE models assume that data is missing completely at random; a potentially problematic assumption when analyzing response-data from the medications inventory for Extension 2 (i.e., only MRC surveyed), or follow-up after year-6 (e.g., due to recruitment, there is differential follow-up by baseline age-groups). LME models make weaker assumptions regarding missing data. Inverse non-missingness probability weighting may be considered for incorporation into any of these methods for a more substantial missing data provision.
- Avoid making comparisons at every time point. Instead, a single omnibus statistical test or contrast that compare exposure groups (e.g., constant treatment effect; weighted average of effects at each time point) may provide better inferences and better provision for multiple comparisons.

### References:

Prentice, R.L., Pettinger, M. and Anderson, G.L., 2005. Statistical issues arising in the Women's Health Initiative. *Biometrics*, 61(4), pp.899-911.

Hernán, M.A., 2010. The hazards of hazard ratios. *Epidemiology* (Cambridge, Mass.), 21(1), p.13.

Fitzmaurice, G.M., Laird, N.M. and Ware, J.H., 2012. *Applied longitudinal analysis* (Vol. 998). John Wiley & Sons.

Wei, L.J. and Johnson, W.E., 1985. Combining dependent tests with incomplete repeated measurements. *Biometrika*, 72(2), pp.359-364.

### 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 75N92021D00001, 75N92021D00002, 75N92021D00003, 75N92021D00004, 75N92021D00005.*”

In addition, papers must include the “short list”<sup>9</sup> of WHI investigators; primary papers must include the “long list”<sup>10</sup> of WHI investigators instead of the “short list.” Both lists can be

obtained from the P&P and are available online at <https://www.whi.org/page/propose-a-paper> . 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 <https://www.whi.org/doc/WHI-Investigator-Long-List.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 P&P Committee and the NHLBI PO when the manuscript is submitted to a journal and accepted for publication.<sup>11</sup> It is expected that authors will inform the P&P Committee of publication dates and 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 OTHER PURPOSES**

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

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<sup>11</sup> Instructions for notifying the CCC and the NHLBI Project Office are provided in the memo approving the manuscript.

## **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 P&P Committee Chairs. 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.