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

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OVERVIEW AND DEFINITION OF TERMS

The Publications and Presentations (P&P) Committee is responsible for oversight of all publications and presentations that are developed using Women's Health Initiative (WHI) data.

Investigators may submit a manuscript proposal at any time, using the WHI Proposal Application Form and templates found at: https://www.whi.org/propose-a-paper

The WHI Publications and Presentations Committee meets twice a month. Investigators should consult the P&P tab on the WHI website for relevant submission deadlines and P&P meeting review dates (https://www.whi.org/propose-a-paper). Manuscript proposals are typically reviewed offline by 2 P&P members. If they agree to approve or agree that it needs revision, it does not get discussed by the committee and the investigators are promptly informed. If there are substantive disagreements between the reviewers or other reasons for discussions, the committee will discuss the topic brought forth and provide a recommendation.

Once a manuscript proposal is approved, other WHI investigators and their nominees are invited to join the writing group. The lead author(s) has the ability to select co-authors from among these nominations based on qualifications, expected contributions to the paper, and equitably balancing the number of currently active co-authorships. The lead author is not required to accept nominations. The lead author(s) conduct the analyses (may choose to use WHI analysts or their own, using data download from our secure website), prepare the manuscript, get input from the entire writing committee, and finalize the manuscript.

The final manuscript must also be reviewed by the P&P committee before journal submission. The same timeframes and structure as for the initial manuscript proposal apply, usually with the same P&P reviewers.

Review of all proposals and papers should be kept confidential and not shared. Discussions that occur during P&P meetings should be kept confidential.

Some notes:

- Manuscripts proposed by someone without designation as a WHI Sponsoring Investigator, Associate Member I or Associate Member II need a WHI sponsor. It is the responsibility of the WHI sponsor to ensure that P&P Committee policies are adhered to. The WHI sponsor will work with the lead author to assure appropriate representation of WHI authorship. There are many options for WHI sponsoring investigators (see https://www.whi.org/sponsors).
- If this paper is part of a consortium that WHI has joined, the P&P reviews only the final manuscript, not an initial proposal with a few exceptions. (see Consortium/Pooling Project Guidelines and Procedures for the WHI below).
- Manuscript proposals that are submitted for P&P review are often required to revise and resubmit initial submissions, especially when they come from investigators new to using the WHI data. The WHI database is complex and understanding all of the documentation is challenging so there are often significant structural issues (e.g., a result of subsampling, or differential protocols by study components).
- There is a queue, often 9-12 months long, to get access to WHI analysts because of the high demand. Many investigators choose to do their own analyses to avoid the long wait. However, WHI analysts are probably more efficient as they all have deep knowledge and application of the data.

- Some data cannot be released outside of the clinical coordinating center (CCC) (e.g., Medicare, NDI, geospatial coordinates, dates of events). The CCC maintains a virtual data enclave that allows investigators outside of the coordinating center to access these confidential data for approved analyses.

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 (SC). The P&P committee is composed of the *Core Committee Members* and *Adjunct Reviewers*. Staff support comes from the CCC.

Members of the Core Committee consistently attend their respectively assigned committee calls (2nd or 4th Thursday) to discuss policy issues, manuscript proposals, and paper review decisions. The review documents and meeting minutes are made available to all committee members.

Responsibilities for the Core members:

1. Deliver timely, comprehensive reviews of submitted manuscript proposals and manuscripts prior to the P&P Committee call date (specific due dates are designated by P&P Chairs). Attention should be given to making sure the application page is filled out correctly.
2. Attend assigned calls, provide input on policy/procedures and/or manuscript proposals or full manuscripts.
3. Prepare thorough reviews for off-call assignments (abstracts, revised proposals and manuscripts, and posters) and return feedback to the P&P Coordinator in a reasonable timeframe (7 working days).
4. Contribute to P&P policy, procedures, and train 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.

P&P Coordinator: Communicates and facilitates manuscript proposals and questions from lead authors to P&P chairs, reviewers, and adjunct reviewers. Communicates to WHI investigators manuscript proposals for writing group nominations.

What is a WHI publication or presentation? A WHI publication or presentation is one that is authored by WHI investigators or applies WHI data and is developed in accordance with the policies and procedures of the 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 intended for publication or presentation and is authored by a WHI investigator must be reviewed and approved by the P&P Committee. See exceptions under Consortium/Pooling Project Guidelines and Procedures for the WHI for BioLINCC, dbGAP, SHARe, and publications with other public data sets. In some instances, final manuscript review is only needed if a WHI investigator, co-investigator, or associate WHI member is a first author.

WHI member categories used in this document can be found on the WHI website https://www.whi.org/doc/WHI+Investigator+Categories+revised+March.2022.pdf:

- ~~*Sponsoring Principal Investigator (PI; also referred to as Sponsoring Investigator), Associate*~~

Member I and Associate Member II – must be an active WHI member as defined by the above link. The Sponsoring PI ensures authors abide by the P&P Policy and mentor lead authors.

Terms for types of documents reviewed by the P&P Committee:

- *Abstracts* – summaries of intended presentations or posters for scientific meetings.
- *Manuscript Proposals* – proposed plans for manuscript development (uses standard WHI manuscript proposal application form).
- *Manuscripts* – final drafts of articles or book chapters that are not yet submitted to the journal
- *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).

Terms for types of WHI papers (proposals, manuscripts, or publications):

- *Ancillary study papers* – papers using data primarily from one or more ancillary studies.
- *BAA papers* – papers using data primarily from a BAA[1] study.
- *BioLINCC papers* – papers developed using NHLBI's Biologic Specimen and Data Repository.
- *Collaborative (Consortium) papers* – papers using WHI data in conjunction with data from one or more other study cohorts, usually through participation in a consortium.
- *dbGaP papers* – papers using GWAS Data on WHI Participants. GWAS has been performed through many WHI ancillary studies with different platforms and different outcomes/exposures of interest. Raw GWAS data from over 42,000 WHI participants is currently available from dbGaP. This is a list of all GWAS that include at least 1,000 WHI participant listed here: https://www.whi.org/md/gwas
- *Review articles, methodological papers, and editorials* – papers that cite previously published WHI data or analyses, but do not present any new data or analyses.
- *SHARe papers* – papers using data from the Women's Health Initiative - SNP Health Association Resource (WHI-SHARe) https://www.whi.org/md/gwas

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

P&P REVIEW PROCESS AND GUIDELINES

Submission Timeframe

Once a manuscript 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 manuscript fail to move to publication within three (3) years of its initial approved manuscript 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 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.

If a paper is retracted after publication, the P&P should be informed immediately and provided with a brief as the to the reason and documentation (e.g., email correspondence with journal).

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 at "*How to Develop and Publish a Manuscript"* 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 WHI Papers and Proposals. 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 drop the idea, contact the lead author of the manuscript 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 lead authors may be asked to cease their data analysis and writing.

Nearly every proposal must have a sponsoring PI (sponsoring investigator), Associate Investigator I or Associate Investigator II, who will work with the lead author as needed or be at an investigator level not needing a sponsoring investigator (see WHI Manuscript Proposal Application Form). 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 be accompanied by the Manuscript Proposal Application Form (e.g., author information, indication of who will perform the analyses, etc.). A sample proposal is posted on the WHI website. Examples of elements requested in the manuscript application form include but are not limited to the following:

• Introduction • Objectives • Analysis Plan • List of pertinent variables • Conclusion(s) • Planned Mock Tables or Figures Description • References	• All definitions, criteria, and data to be used in the manuscript should be included in the manuscript 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.

Helpful resources on the WHI website

- Query Builder can be used to support the development of statistical power estimates. A WHI account and password are required to access the tool. To request an account, please contact the WHI Help Desk. For first-time users, a video tutorial, FAQ, and user guidance are available to assist with getting started (https://www.whi.org/qb/).
- Frequency of data collection provides detailed information on what data have been collected at baseline and during follow-up. https://www.whi.org/datasets
- Sponsoring Investigator and WHI Scientific Interest Groups (SIGs). Prospective authors new to WHI are encouraged to work with their sponsoring investigator and WHI SIGs while developing their proposal. The WHI website query builder add ink??? has detailed information about the WHI data. Contact the WHI Help Desk for additional assistance with questions. Regional Center (W, SE, MW, NE) personnel may be available during the proposal development process to assist with questions. Either the CCC or a regional center (RC) may be available to conduct analyses (see Manuscript Proposal Application Form), though the wait time for a CCC or RC analyst may be 9-12 months.
- WHI Help Desk is available by email.

Proposal submissions may include up to 5 authors, including the lead author, a junior or early- career author, and a biostatistical author; certain exceptions may 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. Names of additional co-authors to be considered may be added to the WHI Manuscript Proposal Application Form.

Proposals for WHI manuscripts are reviewed during P&P Committee virtual meetings.[3] Submissions of proposals to P&P for review must follow the posted deadlines, generally 10 days in advance of the meeting.

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.

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

P&P Reviewers will consider the following when examining proposals:

- Does the author identify a sponsoring investigator, if applicable, from WHI to sponsor the paper?
- Is the quality/ quantity of WHI data for the exposure and/or outcome variables robust enough to support peer-reviewed publication?
- 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 mock tables and graphs are relevant and well-labeled.
- Is the writing clear and readable?
- That the authors have reported Diversity and Ancestry Data correctly (see guidelines later in document)

Late Review Guidelines for P&P Reviewers:

- All P&P committee members are expected to turn in their reviews by Tuesday midnight of their time zone prior to the Thursday P&P meeting.

- Individuals who have not completed their reviews by Tuesday morning will be sent a reminder by the P&P coordinator to complete their reviews by Tuesday evening (midnight in the time zone of the reviewer).

- If only one of two P&P reviewers reviews the proposal by the due date, only that reviewer's vote and comments will be provided to the P&P committee and to the lead author (and sponsoring investigator if applicable). Comments from the late P&P reviewer may be shared with the lead author at a later date, at the discretion of the P&P Chairs

After the document is reviewed, the committee will decide on the recommended course of action. *P&P Committee recommendations and reviews are provided to prospective authors within one week after the call on which the proposal was reviewed. Reviews are graded as follows (see below table):*

P&P Committee Recommendation Options for Manuscript Proposals	Action Item
Approve	Authors can proceed with analyses
Approve with recommended changes	Authors can proceed with analyses and should consider the recommendations of the reviewers but are not required to make them.
Approve with required changes	Authors can proceed with analyses and should make the required changes noted by the reviewers. When the manuscript is submitted for P&P review, the reviewers will be given the memo noting the required changes to ensure they were made in the full manuscript.
Revise and resubmit to primary reviewers	Make the noted changes and resubmit to P&P to send back to the 2 reviewers who reviewed the proposal initially. **Reviewers have 2 weeks to review and respond to the revisions.**
Revise and resubmit to full committee	Make the noted changes and resubmit to P&P to send back to committee for a new review. P&P will attempt to assign the proposal to the same reviewers.
Disapprove	If the proposal is disapproved by one or more of the assigned reviewers, the proposal will be sent to the next P&P review committee and assigned to 2 new reviewers. All four reviewers will discuss the proposal after all reviews are submitted and make a decision about how to proceed with the proposal. The authors should be notified of a delayed response.

If additional committee review is recommended, lead authors should submit their revised manuscript proposals to the committee for a second review ideally within 3 months.

Once a manuscript 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.

Manuscript proposal-related restrictions:

Using Centers for Medicare and Medicaid Services (CMS) data: CMS data are available through the WHI Virtual Data Enclave (VDE) for investigators with approved paper proposals and approved VDE access. See the Virtual Data Enclave webpage for information on data available in the VDE and how to apply for access.

Circumstances where manuscript proposals are not required for P&P review:
NEVER REQUIRED
Proposers of ***BioLINCC papers*** are not required to submit manuscript proposals to the P&P Committee; however, they must abide by NHLBI's Biologic Specimen and Data Repository Guidelines.[4]
Manuscript proposals stemming from ***Single-Center ancillary studies.*** This means that all participants of the ancillary study are from a single-center (previously known as Clinical Centers or Field Centers). Ancillary studies run out of a single-center but including participants from many centers are not considered single-center ancillary studies.
IN SOME CIRCUMSTANCES THE MANUSCRIPT PROPOSAL IS NOT REQUIRED
P&P does not require paper proposals submitted for review when the paper originates from a ***Clinical Trials with outside recruitment*** *and is led by a non-WHI PI, co-investigator, or associate member.*
P&P does not require paper proposals submitted for review when the paper originates from a Consortium***/Pooling Project*** *by a non-WHI PI, co-investigator, or associate member.*
Manuscript proposals stemming from ***dbGaP, SHARe or other public datasets*** are not required to undergo review by the P&P Committee *if the paper is led by a non-WHI PI, co-investigator, or associate member;* however, the Committee prefers that draft proposals be sent to the P&P Committee for their records.

[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. Submissions of manuscripts to P&P for review must follow the posted deadlines at 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.

P&P Reviewers will consider at least the following when examining final manuscripts:

- Is the writing clear and readable?
- Confirm that tables and graphs are relevant and well-labeled.
- Ensure that the authors have reported Diversity and Ancestry Data correctly (see guidelines later in document)
- WHI investigators short list and NHLBI Funding Statement.
- Clinicaltrial.gov identifier when appropriate
- Ethics statements (IRB approval, written informed consent etc.)

Late Review Guidelines for P&P Reviewers:

- All P&P committee members are expected to turn in their reviews by Tuesday evening of their time zone prior to the Thursday P&P meeting.
- Individuals who have not completed their reviews by Tuesday morning will be sent reminders to complete their reviews by the P&P coordinator.
- If only one of two P&P reviewers reviews the manuscript in time, only that reviewers vote and comments will be provided to the committee. Comments from the late reviewer may be shared at a later date, at the discretion of the P&P Chairs.

After the document is reviewed, the committee will decide on the recommended course of action. *Committee recommendations and reviews are provided to prospective authors within one week after the call on which the proposal was reviewed. Reviews are graded as follows (see table below).*

P&P Committee Recommendation Options for Manuscripts	Action Item
Approve	Authors can proceed with submission to journal
Approve with recommended changes	Authors can proceed with submission to journal and should consider the recommendations of the reviewers but are not required to make them
Approve with required changes	Authors can proceed with submission to the journal once the required changes noted by the reviewers have been made. Note that when the manuscript is submitted for P&P review, the reviewers will have been given the memo noting the required changes to ensure they were made in the full manuscript.
Revise and resubmit to primary reviewers	Make the noted changes and resubmit to P&P to send back to the 2 reviewers who reviewed the manuscript initially. **Reviewers have 2 weeks to review and respond to the revisions.**
Revise and resubmit to full committee	Make the noted changes and resubmit to P&P to send back to committee for a new review. P&P will attempt to assign the manuscript to the same reviewers.
Disapprove	If the paper is disapproved by one or more of the reviewers, the paper will be sent to the next P&P review committee and assigned to 2 new reviewers. All four reviewers will discuss the proposal after all reviews are submitted and will make a decision about how to proceed with the manuscript. The authors will be notified of a delay in response.

Once authors have received notification (email with letter attached) that the P&P Committee has approved their manuscript they are expected to submit their paper for journal publication within 12 months.

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.

Drafting more than one manuscript from a single proposal: 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

The P&P Committee must approve all abstracts 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.

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

These rules apply to the following:

- Abstracts using **BioLINCC** and have a *WHI investigator, co-investigator, or associate member as the lead* author. This applies even though they were not required to submit a manuscript proposal.
- Abstracts stemming from ***Single-Center ancillary studies*** even though they were not required to submit a manuscript proposal.
- Abstracts stemming from ***Clinical Trials with outside recruitment*** and have a *WHI investigator, co-investigator, or associate member as the lead* author.
- Abstracts stemming from **Consortium/Pooling projects** and have a *WHI investigator, co-investigator, or associate member as the lead* author.
- Abstracts stemming from ***dbGaP, SHARe or other public datasets*** and have a *WHI PI, co-investigator, or associate member,* as the lead author.

Circumstances where P&P abstract approval are not required:
Abstracts stemming from ***BioLINCC papers*** led by a *non-WHI investigator, co-investigator, or associate member*.
Abstracts stemming from ***Clinical Trials with outside recruitment*** led by a *non-WHI investigator, co-investigator, or associate member.*
Abstracts from ***prior-approved Consortium/Pooling Projects*** led by a *non-WHI investigator, co-investigator, or associate member.*
Abstracts stemming from ***dbGaP, SHARe or other public datasets*** led by *non-WHI PI, co-investigator, or associate member.*

- If the committee notes a potential problem with the topic or analyses, the investigator will be contacted directly to provide recommended or required revisions. If required revisions are not accepted, the WHI investigators cannot be listed as authors on the abstract, and the abstract must contain a disclaimer. 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.
- 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.

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 to the P&P Committee. 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.

Consortium/Pooling Project Guidelines and Procedures for the WHI

WHI defines a consortium/pooling project as a research project that is developed by an organized group of researchers with the focus of including WHI data in combination with other datasets. Examples include pooled analyses and meta-analyses**.** It often has its own independent governance structure, publications and presentations committee, or external advisory board.

A consortium/pooling project is a research project that is developed by an organized group of scientific investigators representing multiple study cohorts and usually with an independent governance structure. WHI is often asked to participate in consortium/pooling projects by contributing data and/or biospecimens. Such projects have the potential to maximize the scientific value of resources generated by WHI. They also have potential challenges, such as ensuring that independent publication of WHI data is done when possible, in advance of pooling, ensuring confidentiality of study participants, and managing investigator and staff effort, data integrity and data harmonization. Consortium/pooling projects typically require complex decision-making in the design, analysis, and interpretation of findings. WHI consortium/pooling project guidelines are found at **whi.org/md/consortia**.

There are Two Main Types of WHI Consortium/Pooling Projects.

1. **Ancillary study consortium/pooling projects generate new data** (e.g. a blood assay, an intervention, a questionnaire, follow-up study) and are subject to both the WHI Ancillary Study Policy and the WHI Publications and Presentations Policy.

2. **Paper proposal consortium/pooling projects combine existing data from WHI with data from other sources** (e.g., data pooling of existing biospecimen test results, clinical outcomes, and lifestyle assessment data with those from another cohort or cohorts), and are subject to the WHI Publications and Presentations Policy and Procedures.

Consortium/Pooling Project Resources

- **Consortium/Pooling Projects Guidelines and Procedures**
- **Consortium/Pooling Project Application**
- **Consortium Data Use Agreement**

Process for Obtaining WHI Data for a Consortium/Pooling Project

Step 1: Consortium/Pooling Project Application

WHI investigators must submit a consortium/pooling project application when initiating or leading a consortium/pooling project.

a. *WHI Consortium/Pooling Project Application form completion.* This form provides detailed information to support the initial reviews and discussions of the project (Steps 2–4). Submit the completed application to the WHI Publications and Presentations Committee at p&p@whi.org

b. *Initial Proposal review.* This review is completed by the *Publications & Presentations (P&P) Chairs* who will evaluate the application's merits and/or contributions to the WHI's scientific goals. Further, they assess whether WHI could meet the project's goals without participating in the consortium/pooling project as well as the overall feasibility of the project. This review will also determine whether the consortium/pooling project involvement by WHI constitutes an ancillary study or a paper proposal.

c. *Identification of a WHI Consortium/Pooling Project Liaison.* If the project does not yet have a WHI investigator as the consortium/pooling project liaison, the P&P Committee will assist in identifying someone whose expertise is compatible with the project. If an individual decides to withdraw from the role of liaison for a project, they should notify P&P who will assist in identifying a new liaison for the project, generally with assistance from topic-relevant WG leads.

   It is the responsibility of the WHI liaison to the consortium/pooling project 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.

d. *Determination of number of WHI authors on resulting papers.* Follow P&P Policy, which states that authorship is to be proportional to the number of cases contributed. Note that some consortia limit authorship slots to two authors per cohort, thus negotiation may be needed. The number of authorship slots would ideally be determined before the manuscript is drafted.

Step 2: Ancillary Study Application (if needed)

Consortium/Pooling Projects may need to submit an Ancillary Study Application
(NOTE: Please allow at least 3 months for this review process.)

1. *Follow the guidelines online at* Plan an Ancillary Study. The guidelines are a step-by-step guide to completing an Ancillary Study Application. The application will ensure you have filled out a Consortium/Pooling Project Application Form (as requested in Step 1 above) and provide you with a link to additional information at the WHI Ancillary Studies Application Procedures Guides.

2. *Identification of a WHI Consortium/Pooling Project Representative.* If the project does not yet have a WHI investigator as the consortium/pooling project representative, the applicable SIG assists in identifying one. It is the WHI consortium/pooling project representative who helps "shepherd" the study through the WHI review process and acts as a liaison between WHI and the consortium/pooling project leadership.

3. *ASC review.* Consortium/pooling project ancillary studies, and consortium projects judged by the ASC to be scientifically valuable endeavors for WHI, are required to complete an Ancillary Study Application form and a Consortium/Pooling Project Application form, submit the proposal, and abide by both the WHI Ancillary Study Policy (including submission of annual progress reports) and WHI Publications and Presentations Policy and Procedures.

4. Manuscripts resulting for a consortium/pooling project must follow the manuscript guidelines in Step 3 (Manuscript Proposal) directly below.

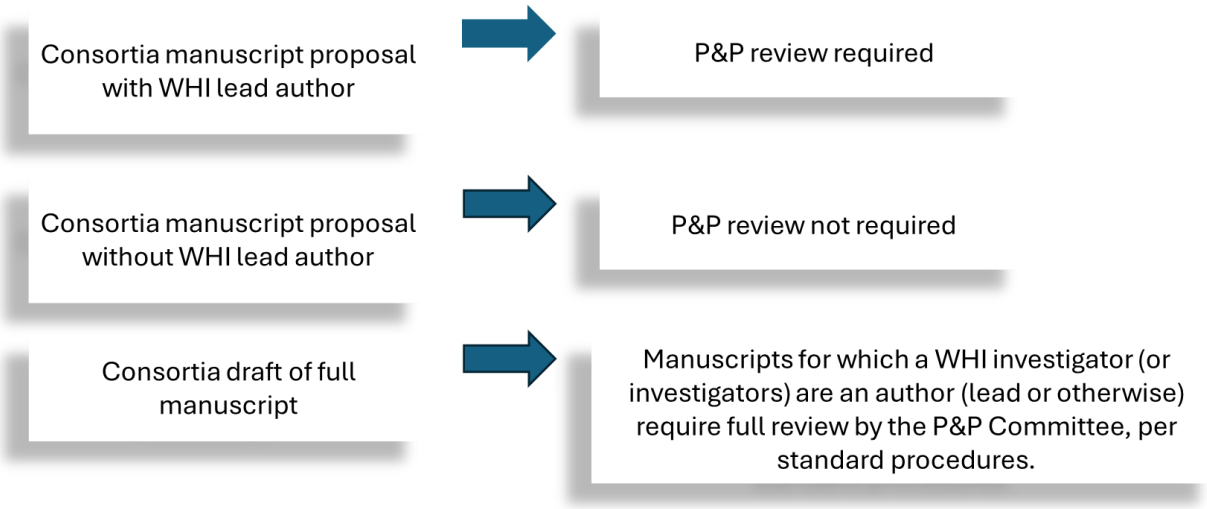
Step 3: Manuscript Proposal

If a WHI investigator is a lead on a manuscript, the manuscript proposal is required to be submitted for review by the P&P Committee, per standard procedures (see WHI Publications and Presentations Policy and Procedures).

Paper authors are responsible for identifying overlap between their proposals and previous publications in WHI. This includes WHI-specific papers on the topic of interest.

Step 4: Manuscripts

Written manuscripts, for which a WHI investigator (or investigators) are an author (lead or otherwise), *require full review by the P&P Committee,* per standard procedures (see WHI Publications and Presentations Policy and Procedures).



It is the responsibility of the WHI liaison to the consortium/pooling project 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.

Paper authors are responsible for identifying overlap between their papers and previous

publications in WHI. This includes WHI-specific papers on the top of interest.

Consortium/pooling project papers should limit their presentation of WHI-specific data independent of the pooled data analyses unless there is scientifically justified rationale for doing so. WHI-specific data are reserved for investigator-lead authorship under the WHI P&P policies and procedures for manuscript development. However, the inclusion of WHI-specific data will be evaluated in the context of P&P manuscript review. For example, Forest Plots showing WHI data are fine. Waivers to limiting WHI-specific data may be submitted to P&P by sending an email and scientific rationale for the waiver to P&P@whi.org.

All consortium/pooling project manuscripts that include WHI data must identify WHI in the acknowledgements using standardized language as noted in the P&P policy and procedures and Ancillary study policy.

BioLINCC Papers

Manuscript proposals for BioLINCC papers are not required to undergo review by the P&P Committee. BioLINCC manuscripts proposals authored by non-WHI investigators may also be submitted for review, but this is not required.

Manuscripts: However, if a *WHI investigator*, *co-investigator, or associate member* coauthored or led a BioLINCC manuscript, they must submit the final manuscript for review by the P&P Committee.

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.

dbGaP/ SHARe / Other Public Dataset Papers

Manuscript Proposals stemming from dbGaP/SHARe/ or other public datasets are not required to undergo review by the P&P Committee unless the lead author is a *WHI investigator*, *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/ SHARe/ or other public datasets led or co-authored by a *WHI investigator*, *co-investigator, or associate member*, they must submit the final manuscript for review by the P&P 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 be submitted to the P&P Committee for review and manuscript proposals go through the formal WHI writing group selection process.

Exceptions to P&P Policies for Ancillary Studies where the manuscript proposals are not required (and thus there are no WHI-wide co-author nominations).
Single-Center ancillary studies—data generated from only one center (formerly known as Clinical Centers or Field Centers). This is a legacy category from the clinical trial years when the WHI had Clinical Centers and Field Centers, which have been aggregated into RCs. Manuscript proposals stemming from Single-Center ancillary studies are not required to undergo review by the P&P Committee for manuscript proposals. This means they are not required to undergo the formal WHI writing group selection process.
Ancillary Studies that are Clinical Trials with outside recruitment **(**clinical trials with data generated using both WHI participants and participants recruited from outside of WHI) NOT led by a *WHI investigator, co-investigator, or associate member*.**

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.

Paper proposals listing AS data for which the lead authors are not the AS PIs

Check to see if the data are listed in the data dictionaries. If yes, proceed with manuscript proposal application. If no, approval from the AS PIs is required to use the data.

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.

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. All authors should meet the criteria for authorship as specified in each journal's Guidelines for Authors.
- 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 selected by the lead author are 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. This includes AS proposals.
- 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.
- For Ancillary Study papers, authors are *encouraged* 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.
- Lead authors are advised to select and include a person with statistical expertise and knowledge of the WHI database for authorship on manuscripts.
- 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 Coordinator Staff 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 Coordinator Staff. 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 Coordinator Staff facilitates the approval of the writing group by the P&P Committee, as necessary. The P&P Staff then confirm the manuscript's authorship via a memo to all authors which informs the lead author (the "writing group chair") of their responsibilities.

Conduct

The writing group chair (aka. lead/first author) 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 solicit input by email of the writing group at a time when the preliminary data analyses are 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.)[6].
- Inform the P&P Committee of any substantial minority opinions or reports within the writing group.[7] 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[8] 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 Chairs 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.*

[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.

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 SC 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 a relevant WHI design paper.
- Centrally adjudicated outcomes should be used when available 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 an intervention.
- It is recommended, that 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 cardiovascular disease, coronary heart disease, venous thromboembolism, 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.
- In trial 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 may vary depending on the objective of the analyses; authors should consult prior publications.

- The prescribed acknowledgement section should be included. This includes the WHI investigators short list and NHLBI Funding Statement. [See section below.]
  .
- Confirm that tables and graphs are relevant and well-labeled.

- Ensure that Diversity and Ancestry Data are reported correctly (see guidelines later in document)

- Include a Clinicaltrial.gov identifier when appropriate.

- Include an ethics statements (IRB approval, written informed consent etc.)

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 statistical power calculations provided if appropriate? Or, if not is the rationale (e.g., descriptive paper etc.) provided?
- Confirm that mock 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 *(Brief Overview)*

WHI Race and Ethnicity Language and Data Application and Interpretation Guide- Brief Overview

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 or 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 of 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 unless a one-sided p-value hypothesis is scientifically supported.
- 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 are 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 ½ 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 are 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 compares 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 NHLBI Funding Statement posted to the WHI website.

In addition, papers must include the "short list"[9] of WHI investigators at "short list."

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.[11] 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, any JAMA journal, Circulation, 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. Authors are expected to following the new NIH and Publisher Guidelines found here: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-048.html

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.

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

USING WHI DATA FOR OTHER PURPOSES

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 submitted as paper proposals that are reviewed by the P&P Committee. The student requesting use of WHI data must be associated with a WHI sponsoring PI (Sponsoring Investigator), Associate Member I or Associate Member II. 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 student and WHI Sponsoring Investigator are to work reciprocally with recommendations and requirements from the student's academic committee as well as WHI use and interpretation of data. 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.