

Revised 1/19/2022

MESA Publications and Presentations Policies

The success of the MESA Study will be judged largely on the number and quality of its scientific publications and presentations. The purpose of the policies established herein is to encourage and facilitate important analyses while providing guidelines that ensure appropriate use of the MESA data, timely completion of projects, and adherence to the principles of authorship.

I. Administrative Structure

The MESA Steering Committee will appoint a Publications and Presentations (P&P) Committee and select a chairperson. A separate Genetics P&P Committee was established in 2007 to review MESA papers with genetics data.

The P&P Committee will report to the MESA Steering Committee on all matters relating to the publications or presentations of MESA material.

The Genetics P&P Committee will report to the MESA Steering Committee on all matters relating to the publications or presentations of MESA genetics material.

As of late July 2020, the main P&P members strongly recommend that all authors use their university or institutional affiliation email. (Using personal email accounts may cause confusion as to who people are.)

All communications to the P&P Committee (for Main and Ancillary study papers) should be sent to:

Karen Hansen, hansenk3@u.washington.edu

All communications to the Genetics P&P Committee (for Genetics papers) should be sent to:

genpp@uw.edu

II. Objectives

- To stimulate scientific presentations and papers from MESA investigators;
- To ensure and expedite orderly and timely reports to the scientific community of all pertinent information resulting from MESA;

- To ensure that abstracts, presentations, and publications based on MESA material are accurate and objective, and do not compromise the scientific integrity of this collective study;
- To ensure that all investigators, particularly those of junior rank, have the opportunity to participate and be recognized in the study-wide MESA papers;
- To establish procedures that allow the MESA Steering Committee to exercise review responsibility in a timely fashion for MESA publications and presentations;
- To encourage manuscripts based on the information collected at all MESA study sites;
- To prevent overlap of published material and duplication of analyses.

III. Procedures

A. Papers

1. Potential Overlap

It is the first author's responsibility to avoid overlap with manuscripts already in progress or published. Review previously-approved proposals and MESA published manuscripts for potential overlap with your proposal. Manuscript proposals will be available on the MESA website to help investigators determine available topics in advance. See the "Search (Paper Proposals)" subheading on the internal P&P webpage. The titles and abstracts are available online. Indicate directly on the online form which (if any) proposals could potentially overlap with your proposal. Describe how your proposal is different from those with potential overlap (if any) in the space provided in the online form.

2. Submission of a Proposal for a Paper

Analysis Only Grants

- Grants which do not propose to collect new data are called analysis-only grants. These grants do not go through Ancillary Studies committee for approval, but rather obtain approval via P&P approval for the proposed paper(s).
- Please note that MESA **requires a paper proposal for each paper that is published**. We recognize that sometimes the papers that ultimately result from the grant may differ from the original proposal(s), in which case you should submit a modification (change-in-focus) to your original proposal(s) to accurately reflect the final set of papers. These policies allow MESA to accurately track our many papers and provide overlap search capabilities for future researchers.

This will consist of a formal proposal to the P&P Committee submitted via the online proposal submission form available on the Publications page of the internal MESA website. See: MESA Manuscript Proposal Submission Form.

Enter the following administrative summary information directly on the online form:

1. Proposal Title
P&P Committee members adopted a P&P policy that requires authors to include the study name (: The Multi-Ethnic Study of Atherosclerosis) at the end of their paper title. The only exceptions to this policy are when the Journal restricts the number of words allowed in the title or the paper combines data from multiple studies.
2. Abbreviated Title (up to 50 letters and spaces)
3. Authors (including sponsor if first author is not a MESA researcher)
4. Abstract/Brief Description
5. Type of Study (Main or Ancillary study, Title & PI for Ancillary)
6. Type of Manuscript (Events, Longitudinal, Cross-Sectional or Methods)
7. Data Analysis location (Coordinating Center or local: Will data analysis be conducted locally or via a Coordinating Center statistician/epidemiologist collaborator?); sample size/power (a full description of the participants, including total sample size and any subsets of interest)
8. Genetic Information -- used? to address MESA aims?
9. PI approval -- if the first author is affiliated with a MESA Field Center (FC) or Reading Center (RC) this would be the FC/RC PI. If the first author is not affiliated with a MESA Field Center/Reading Center/Core Lab/Coordinating Center, the most senior coauthor who is so associated should obtain approval from the PI at his or her Field Center/Reading Center/Core Lab/Coordinating Center, in order to have the manuscript linked to the MESA structure. In situations where none of the authors is so affiliated, the approval of the Coordinating Center (CC) PI should be obtained.
10. Keywords
11. Additional Comments

Summarize the scientific "Proposal Details" in a separate Word document and attach it to the online proposal using the button at the bottom of the form. Please attach only a Word document - not a PDF.

Proposal details include the following:

1. Introduction: Rationale and background, brief.
2. Research Hypothesis: Clearly state scientific questions to be addressed.
3. Data: List variables to be used, sample inclusions/exclusions. **Please provide a full description of the participants, including the total sample size and any subsets of interest.**
4. Analysis plan and methods: Give detailed description of proposed statistical analysis.
5. References

Note: Given the importance of socio-economic status to cardiovascular epidemiology, it is strongly suggested that you consider one of its markers (or more than one) when modeling your data.

Important: New proposals should be no more than 2-4 pages in length, excluding the references. Proposals exceeding 4 pages will not be accepted. (Proposal examples can be found on the Publications page under Example Proposals.)

Suggested number of authors from the same site:

- Main study proposals with more than 3 authors at one site requires justification from the first author.
- Ancillary study proposals with more than 4 authors at one site requires justification from the first author.
- First authors are asked to explain how each coauthor will contribute to the paper. (Examples include data collection, analysis or help writing the paper.) Both main and ancillary study proposals should ideally only have an additional author from the same site (maximum 4 authors for main study proposals and 5 for ancillary study proposals). These maximums include the analyst.
- The online proposal form provides space below the list of coauthors for any justification information.

For each paper proposal, MESA P&P requires a Senior MESA author who will act as the responsible, sponsoring author (ideally from the same site). P&P expects that the Senior MESA author will be an experienced MESA investigator and familiar with P&P policies and procedures. The Senior MESA author is responsible for advising the first author concerning these procedures and MESA P&P deadlines for submission of abstracts, proposals and manuscripts. (This role is only for the MESA review process. Once a pen draft receives MESA approval, any member of the writing group can assume the corresponding author role for submission to a journal.)

Important reminders:

- **Make sure that the Word proposal attachment is correct before sending the submission.**
- **Check the online information for accuracy as you complete each online page.**
- **Once “finish” is selected to submit your proposal, the submitting author can’t revise the submission.**

When corrections are needed after an online submission is sent:

- **Please don’t resubmit the same proposal online if the first online submission has a mistake! Instead e-mail the P&P Coordinator right away with any changes and attach a corrected Word document if needed.**

The P&P Coordinator will review the proposal to verify that the P&P policies have been followed.

All proposals from investigators are to be submitted with the knowledge of their PI. All coauthors must have seen and **approved** the manuscript proposal prior to submission.

In general, P&P encourages proposals for analysis that can be done within a reasonable amount of time from submission.

Paper proposals will not be considered by the committee unless it is feasible to begin data analysis within 12 months of proposal approval, based on the availability of sufficient endpoint data. This does not include unavailability of data due to technical problems (e.g., re-readings of scans or correction of quality control problems), delays in data cleaning, or delays in data release.

Upon approval by the P&P Committee, the proposal will be assigned a manuscript number in the MESA database and will be visible online in the List of MESA Manuscripts with Status and Authorship option under the “Paper Status Information” subheading on the internal P&P webpage. The approved proposal will then be submitted to the MESA Steering Committee for their approval, which may include additional writing group nominations by Steering Committee members.

The P&P Committee, in consultation with the Coordinating Center, will determine priorities for data analyses of manuscripts and abstracts to be performed by the Coordinating Center. A local paper (one in which the data analyses are not performed by the Coordinating Center) may start as soon as it is approved.

3. Types of Studies and Location of Analyses

There are two study types: Main and Ancillary, which are defined below. Analyses may be done either centrally (at the Coordinating center) or locally (at a field or reading center).

Main Study Manuscripts

A Main study manuscript analyzes data collected as part of the contracted MESA data set and may be analyzed centrally or locally. A Main study manuscript may be proposed with local analysis by an investigator or group of investigators at a particular MESA site or reading center. Data for these papers are analyzed by the proposing investigator rather than by a statistician at the Coordinating Center.

All Main study paper proposals are circulated to the Steering Committee where additional coauthors may be nominated, regardless of whether analysis is done centrally or locally.

Ancillary Study Manuscripts

An Ancillary study derives funding from other than MESA contract funds. Examples include studies funded by investigator-initiated NIH research awards (R01s), grants from academic institutions, private sources (e.g., drug companies), or those performed at no cost (generally because of the special interest of a researcher).

Definition of an ancillary study:

1) A project that collects new data in MESA, whether directly from participants or from previously collected samples, images, or other sources (e.g., medical records).

2) A project that analyzes existing MESA data as part of a new external funding application, for which additional MESA Coordinating Center (CC) services will be requested beyond downloading of data already available on the MESA website (e.g., analysis by a CC Statistician or preparation of a unique dataset). Note: As of November 2010, analysis-only grants involving no such additional CC services require the submission of a Manuscript Proposal form, but not an Ancillary Study Proposal Form. Submit the Manuscript Proposal form online and see MESA Publications submission details at: <http://www.mesa-nhlbi.org/Publications.aspx>. To check the availability of online data, please contact your MESA Sponsor.

- When a paper proposal is based on an ancillary study (regardless of when the “protected” period has finished), the main author should be strongly encouraged to invite the PI of the ancillary study to join the writing group.
- Papers based on ancillary studies should always be classified as “ancillary”, even after data transferred to the main database.
- In addition to the main study contracts, please reference alternate sources of funding that made the Ancillary Study possible, especially if these were based on federal funding mechanisms: NIH and the EPA. That information can be obtained by the ancillary study PI if there is ambiguity.

Analyses are usually done by the proposal group, but may be done at the Coordinating Center if funds have been allocated for an analyst. Ancillary study papers are not tracked centrally for progress, and will only undergo a verification of analyses prior to submission to a journal if analysis is done at the Coordinating Center and funds have been allocated to do so.

Ancillary Study proposals are circulated to the Steering Committee for approval and coauthor nominations usually include investigators with special expertise and/or interest in the proposal topic.

4. Formation of Writing Groups

In order to ensure that all investigators have the opportunity to participate and be recognized in the main study papers, writing groups usually include investigators from several centers. Writing Group members for both Main and Ancillary study papers may be nominated by the first author and by the Steering Committee.

Usually the manuscript proposer will be designated as the Writing Group Chairperson and first author of the paper. The author will receive written notification of all Writing Group members and the responsibilities as chair (see below). In general, an investigator should only have two Main study (active) proposals which haven't yet progressed to the pen draft stage in which the author is the Writing Group Chairperson (first author). The

P&P Committee no longer limits the number of active proposals for Ancillary study papers.

5. Writing Group Responsibilities

The Writing Group Chairperson is responsible for all phases of manuscript preparation, from conception through publication. These responsibilities include:

- ◆ Preparation of outlines, the identification of data analyses needed, and submission of interim status reports to the P&P Committee;
- ◆ Assignment of tasks to Writing Group members with clear deadlines for completion of these tasks and determination that the tasks are completed on schedule;
- ◆ Preparation and circulation of drafts for approval by each member of the Writing Group before submission of a Penultimate Draft to the P&P Committee and before submission to a journal;
- ◆ Determination of the order of authorship on the manuscript. A major criterion will be the effort and contribution made by each member of the Writing Group in the preparation of the manuscript;
- ◆ Choice of a journal to which the manuscript will be submitted;
- ◆ Correspondence with coauthors, communication with the Coordinating Center and the P&P Committee, responses to the Steering Committee review and to journal editors.

The Writing Group Chairperson should contact each member of the Writing Group to discuss the outline of the paper, data analysis plan, and the responsibilities and assignments for each member. Members of the Writing Group are responsible for performance of tasks assigned by the Chairperson within the allotted time period. Each member is expected to actively participate in the preparation of the manuscript.

All coauthors should let the Writing Group Chairperson know of a change in contact information. Failure to respond within a reasonable amount of time to a Chairperson's request for coauthor feedback, could result in removal from the Writing Group.

If a Writing Group member does not accomplish the assigned tasks and has not contributed to the manuscript, the member may be removed from the Writing Group. The chairperson must send an email to the P&P Program Coordinator requesting the removal of non-contributing members.

If the initial results lead to a split of the original paper into more than one manuscript, a new proposal should be submitted to the P&P Committee. The new proposal should be submitted via the online proposal submission form available on the Publications page of

the internal MESA website. See: MESA Manuscript Proposal Submission Form under the “Proposal Submissions and New Authors” subheading.

6. Schedule for Manuscript Preparation

The expected schedule for the development of a manuscript is described below. Deviation from this schedule must be approved by the P&P Committee. Failure to adhere to this schedule will prompt a review of circumstances. If it is determined that a manuscript is delinquent, this could be the basis for replacing member(s) of the Writing Group responsible for the delay, or for disbanding the Writing Group.

Draft. After notification by the P&P Committee of manuscript approval and the availability of an analyst for central papers, the Writing Group will have four (4) months to prepare a first draft. A first draft will consist, at a minimum, of an Introduction, Methods and Results Sections. This draft should be sent to the members of the Writing Group. It is recommended that a response deadline of 4 (four) weeks be given to Writing Group members to prevent unnecessary delays.

Penultimate Draft. The penultimate draft becomes due three (3) to six (6) months after the first draft is distributed to the Writing Group. A penultimate draft should be sufficiently developed for subsequent submission to a journal. After review and approval of the penultimate draft by Writing Group members, the penultimate draft should be sent to the P&P Program Coordinator as an email attachment.

Include the following required information with each new pen draft:

1. MESA manuscript number (examples: MC 001, AC 025)
2. **In January 2015 the committee set a limit of only 2 separate documents (excluding the lay summary) for pen draft submissions.**
3. Confirmation that all coauthors have seen and **approved** the manuscript prior to submission
4. Specify one target journal that the author is thinking of submitting the manuscript to
5. Lay summary (see below for details)

As of October 2007, authors are also required to attach a separate lay summary (Word) document when submitting a new pen draft. The lay summary should meet the following criteria:

- In 2-4 sentences (100-200 words), please describe the relevance of this research to clinical practice and/or public health. Use plain language that can be understood by a general, lay audience.
- If an author believes that a manuscript is too technical for a lay summary, a brief explanation should be included in the submission e-mail.

P&P Committee members adopted a P&P policy that requires authors to include the study name (: The Multi-Ethnic Study of Atherosclerosis) at the end of their paper title.

The only exceptions to this policy are when the Journal restricts the number of words allowed in the title or the paper combines data from multiple studies.

Review/Deadlines. The P&P Program Coordinator will make every effort to include manuscript submissions in the next available P&P Committee teleconference. To allow sufficient time for processing and review, please submit all manuscripts by noon Pacific Time on Monday of the week before the next P&P teleconference. Refer to P&P Meetings and Paper Submission Deadlines located at the very top of the Publications page (on the internal website) for teleconference dates and deadlines.

The P&P Committee will review each manuscript followed by a discussion during a P&P Committee conference call. Afterward, the author will be sent a summary of any pertinent reviewers' comments.

If a manuscript is not approved by the P&P Committee, the draft will be returned to the Writing Group Chairperson with comments regarding the necessary revisions before resubmission.

If it is approved, it will be forwarded to the MESA Steering Committee for review within two and a half (2 ½) weeks. The Steering Committee members will vote to approve, approve with revisions or disapprove.

Preprint server policy as of January 2021:

Authors can post to a preprint server after full MESA approval is given for a pen draft. (No notification to the committee is needed.)

Journal. Within thirty (30) days of receiving Steering Committee and P&P Committee comments and verification confirmation, the revised manuscript will be circulated by the writing group chair to the Writing Group for final sign-off.

The manuscript will immediately be submitted to a journal. A copy of the journal cover letter and final draft of the manuscript must be sent to the P&P Committee in addition to all coauthors.

The Writing Group Chairperson must keep the P&P Committee and the coauthors informed as to the manuscript's progress through journal review. Upon publication of the manuscript, the Writing Group Chairperson must provide either a reprint or copies of the final publication to the P&P Committee. If there are substantive changes made in the manuscript during journal review (major findings or conclusions, alterations of the sample, exclusion/inclusion of major covariates), the revised manuscript should be submitted to the P&P Committee for re-review.

In order to stay informed of findings from large studies and to prepare for press queries, the NHLBI Project Office would like a courtesy copy of manuscripts at the time of journal acceptance or before, particularly for "high-profile" papers. These generally include the following:

- Main results papers or key secondary results papers from clinical trials
- Papers with direct clinical implications, particularly if they impact NHLBI policies
- Papers on potentially sensitive topics
- Papers published in prestige high impact journals, such as Nature, Nature Genetics, Science, NEJM, JAMA, and Lancet.

Letters to the Editor. If an author chooses to write a letter to the editor instead of a pen draft, please contact the P&P Coordinator to get instructions. This is rare and will be handled on a case-by-case basis.

When the author already has an approved manuscript (pen draft), the following policy for additional letters to the editor and/or response letters is as follows:

As a general rule, P&P will not review letters to the editor, including response letters. New data should not be presented or published unless it is part of an approved paper that went through the standard MESA review/approval process. Also, all coauthors (on the approved manuscript) need to review/approve a letter to the editor.

7. Guidelines for Investigators Using CC for Data Analysis

Guidelines for investigators to use in dealing with the Coordinating Center are:

- ◆ Plan systematically for the analysis of your data.
- ◆ Communicate with the assigned Coordinating Center representative on the Writing Group for all requests and questions on analyses.
- ◆ Be sure that data requests are made in a timely fashion; interactive analyses will be allowed within the time window before and after the first draft.
- ◆ If the Coordinating Center falls behind on the analyses, the Chairperson of the Writing Group should inform the P&P Committee; if there is a problem, deadlines can be changed.

B. Abstracts

1. Preparation and Submission of Abstracts for Submission to Conferences

New abstracts must be based **exclusively** on an approved MESA proposal or submitted or published manuscript.

An abstract based on an approved paper should be submitted (online) to the P&P Committee for review no less than 2 weeks before the conference (abstract) submission deadline. It is strongly advised that authors submit abstracts well before this

deadline, in order to allow sufficient time for revisions. **There is no guarantee that abstracts submitted after the P&P deadline will be approved prior to the conference deadline.** (For more deadline information and details regarding MESA abstracts refer to the “How to Submit an Abstract” document on the Publications page of the internal MESA website.)

New abstracts must be submitted online using the MESA website. Please use the online MESA Abstract and Presentation Submission Form to submit a new abstract to the P&P Committee. This form is available on the Publications page of the internal MESA website. Non-MESA researchers must obtain the password to the internal site from a MESA sponsor prior to submitting an abstract.

The P&P Coordinator will notify the first author (via email) when P&P Committee approval is received.

If an abstract is not accepted upon its original submission, please let the P&P Coordinator know via email before resubmitting to another conference.

If the abstract is accepted, a copy of presentation materials (including tables and graphs) and text are to be submitted to the P&P Program Coordinator as an email attachment.

C. Data Requests

Special data requests to the MESA Coordinating Center by an investigator for the purpose of development of a grant proposal, hypothesis generation and power calculations should be submitted to the Executive Committee for review and approval.

Data analysis requests for theses or dissertations should go through the P&P Committee provided there is a corresponding manuscript proposal.

D. Access to the Internal MESA Website

Non-MESA researchers or new MESA authors must obtain the password to the internal site from a MESA sponsor prior to submitting a manuscript. MESA sponsors have the responsibility for introducing the website to those they sponsor.