

MrOS Publications and Presentations Guidelines

A. GOALS

1. To encourage high quality publications and presentations produced in a timely fashion.
2. To encourage broad participation by MrOS investigators in publications and presentations.

B. SCOPE OF THE GUIDELINES

These guidelines cover papers (including methodology, validation and meta-analysis papers), abstracts, oral and poster presentations, letters to the editor, meeting proceedings and extended abstracts that use data, including genetic data, collected as part of the MrOS study. These policies remain in force after funding for the study ends.

C. PUBLICATIONS COMMITTEE

Leadership and membership in the Publications Committee may be subject to approval by a majority of the MrOS Steering Committee.

D. TYPES OF PUBLICATIONS

1. Papers reporting MrOS data collected from field centers. “Main papers” will be identified by the Steering Committee and, generally, include results about the main outcomes of the study analyzed from the study-wide database.
2. Abstracts, meeting proceedings/extended abstracts, and presentations (oral and poster) submitted to meetings.

Note that doctoral and/or master theses that are publicly available, but not peer-reviewed, may not be subject to review by the Publications Committee. Any peer-reviewed material arising from theses (e.g., abstracts for meetings, papers) should follow the regular review and approval process as described below. Please contact the Coordinating Center to determine if formal review by the Publications Committee is necessary.

E. AUTHORSHIP

1. Authors should participate in the writing of the paper in accordance with the International Committee of Medical Journal Editors guidelines (N Engl J Med. 1997 Jan 23;336(4):309-15.).

- a) Primary authors should feel justified in not including potential coauthors who do not meet the criteria outlined in the Guidelines. This will usually happen when potential co-authors do not participate in email and/or in-person discussions about project design, data analyses, interpretation of findings, or manuscript drafting/editing. Final approval is not sufficient to satisfy the guidelines for authorship.
- b) It is strongly suggested that the primary authors arrange a forum (e.g. teleconference or email) among co-authors at the beginning of the project to discuss the initial design and approach. This will allow co-authors to have early input and will encourage engagement in the process.

2. Authorship of study-wide papers and abstracts:

- a) MrOS investigators may propose study-wide papers. Students, fellows and non-MrOS investigators may serve as first authors on study-wide papers and abstracts if at least one MrOS investigator serves as a co-author and at least one MrOS investigator serves as a sponsor. The sponsor will serve as a link between the first author and the MrOS study. If the first author is affiliated with a MrOS site, the sponsor should be the PI or Co-PI at the same site. For first authors that are not affiliated with a MrOS site, the sponsor will be selected based on expertise and willingness to serve as sponsor. The responsibilities of the sponsor include:
 - i. Review of analysis plans before submission to the MrOS Publications Committee
 - ii. Assist with the analytic approach
 - iii. Assist with the interpretation of results
 - iv. Assist with abstract/presentation/manuscript preparation, particularly to ensure that the MrOS study is described accurately, and the results are interpreted appropriately in the context of the MrOS study design.
 - v. Review of abstracts/presentations/manuscripts before submission to the MrOS Publications Committee
 - vi. Serve as co-author (authorship should be discussed with the first author)
 - vii. For meta-analyses, the lead author on the analysis should be the investigator leading the meta-analysis. This will not necessarily be the participating MrOS investigator. The participating MrOS author should serve as the sponsor of the analysis.
- b) Investigators will be limited to lead roles on three active analysis proposals (“active” is defined as the manuscript not yet submitted for publication).

3. Lead authors...

- a) In general, the investigator who proposed the analysis will be the lead author, or in certain circumstances, the senior author.
- b) The lead author will assemble the group of co-authors and determine the order of authorship. Authorship should be ordered by contribution to the conceptualization,

analysis and writing of the paper. The Steering Committee may mediate disagreements that cannot be resolved by the writing group.

- i. Please note that in some cases, authorship for meta-analyses may be restricted based on consortium policies.
 - c) Lead authors are expected to organize conference calls for the writing group, submit and discuss manuscript drafts with the publications group on publication progress conference calls and be responsible for timely submission of drafts for review and publication.
 - d) Lead authors are expected to delete names from the final list of authors if those individuals have not participated in the writing and/or analysis of the paper in accordance with the International Committee of Medical Journal Editor guidelines.
4. All study-wide papers, abstracts, and presentations (oral and poster) should include "for the Osteoporotic Fractures in Men (MrOS) Study Group" in the authorship line. For meta-analyses, the study should be included in an acknowledgment.

F. OFFICIAL STUDY NAME, REQUIRED ACKNOWLEDGMENTS, AND RECOMMENDED TERMINOLOGY

1. The official name of the study for scientific purposes is the "Osteoporotic Fractures in Men (MrOS) Study." When referring to the MrOS Study in the text of an abstract or paper, please refer to it as the "Osteoporotic Fractures in Men (MrOS) Study."
2. All study-wide papers, abstracts, and presentations (oral and poster) should include the acknowledgment: 'The Osteoporotic Fractures in Men (MrOS) Study is supported by National Institutes of Health funding. The following institutes provide support: the National Institute on Aging (NIA), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Center for Advancing Translational Sciences (NCATS), and NIH Roadmap for Medical Research under the following grant numbers: U01 AG027810, U01 AG042124, U01 AG042139, U01 AG042140, U01 AG042143, U01 AG042145, U01 AG042168, U01 AR066160, and UL1 TR000128.'
3. All papers, abstracts and presentations (oral and poster) that include data from the MrOS Dental Study should also include in the acknowledgment: 'The National Institute for Dental and Craniofacial Research (NIDCR) provides funding for the MrOS Dental ancillary study "Oral and Skeletal Bone Loss in Older Men" under the grant number R01 DE014386.'
4. All papers, abstracts and presentations (oral and poster) that include data from the MrOS Sleep Study should include in the acknowledgment: 'The National Heart, Lung, and Blood Institute (NHLBI) provides funding for the MrOS Sleep ancillary study "Outcomes of Sleep Disorders in Older Men" under the following grant numbers: R01 HL071194, R01

HL070848, R01 HL070847, R01 HL070842, R01 HL070841, R01 HL070837, R01 HL070838, and R01 HL070839.'

5. All papers, abstracts and presentations (oral and poster) that include data from the MrOS Hip OA Study should include in the acknowledgment: 'The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) provides funding for the MrOS Hip OA ancillary study "Epidemiology and Genetics of Hip OA in Elderly Men" under the grant number R01 AR052000.'
6. All papers, abstracts and presentations (oral and poster) that include data from projects that utilized previously extracted DNA should acknowledge Dr. Joseph Zmuda's grant (MrOS ancillary study #10) which supported DNA extraction. The following acknowledgment should be included: 'The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) provides funding for the MrOS ancillary study 'Replication of candidate gene associations and bone strength phenotype in MrOS' under the grant number R01 AR051124.'
7. All papers, abstracts and presentations (oral and poster) that include genotype data from the MrOS GWAS project should include in the acknowledgment: 'The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) provides funding for the MrOS ancillary study 'GWAS in MrOS and SOF' under the grant number RC2 AR058973.'
8. Other funding sources associated with MrOS ancillary studies that should be part of acknowledgments are included in documentation files for specific ancillary datasets. Please contact the Coordinating Center with specific questions regarding acknowledgments.
9. The Coordinating Center maintains a current list of MrOS study staff that can be included in manuscripts as part of an extended acknowledgment.
10. In all text and tables in MrOS manuscripts, the clinical centers should be referred to by city name. They should be listed alphabetically: Birmingham, Minneapolis, Palo Alto, Pittsburgh, Portland and San Diego. International sites should also be referred to by city name: Hong Kong, Göteborg, Malmö, and Uppsala.

G. DATA USE AGREEMENT

1. A Data Use Agreement (DUA) is required for all investigators who will be in contact with MrOS data or will be analyzing MrOS data for research purposes. The DUA should be signed by the institution releasing the data (California Pacific Medical Center (CPMC)) and the institution receiving the data. The DUA will cover all investigators and/or staff working with MrOS data under the direct supervision of the lead investigator of a DUA at a given institution.

There are a few exceptions. Investigators who have a subcontract or consulting agreement

under CPMC for work with the MrOS Study may not be required to complete a DUA. In addition, investigators conducting a meta-analysis, who will never receive participant level data from the MrOS Study, may not be required to sign a DUA.

The Coordinating Center will ensure that DUAs are in place with all investigators and analysts working with MrOS data. It is the responsibility of the lead investigator at a given institution to obtain the appropriate signatures at their local institution and to ensure that his/her staff comply with the terms of the agreement.

H. AVAILABILITY AND ANALYSIS OF DATA

1. Unless otherwise noted by the Coordinating Center, proposals for analysis plans can only be submitted based on data that has officially been released for analysis by the Coordinating Center. This includes data releases or supplemental data releases.
 - a) Before a new study-wide set of data is released, the Coordinating Center will make an announcement soliciting ideas for analyses using the new data. Investigators will be asked to submit 2-3 sentences describing the idea. Topics will be collated by the Coordinating Center.
 - b) After ideas are collected, a conference call will be scheduled for the Steering Committee to discuss authorship, potential overlap and/or priority of plans.
 - c) Confirmation of authorship will then be distributed to investigators and work on analysis plans for assigned topics may begin. However, analysis plans should not be submitted until the data is officially released by the Coordinating Center or an announcement is made that analysis plans can be submitted early.
2. Exceptions to submitting analysis plans before data from ancillary studies are officially released will be made on a case-by-case basis. All exceptions must be approved by the MrOS Steering Committee and a timeline for official release of the ancillary study data should be established.
3. MrOS data is available to the public via the 'MrOS Online' website (<http://mrosdata.sfcc-cpmc.net>). Recipients of the MrOS public data sets are strongly encouraged to collaborate with MrOS investigators in the analysis of MrOS data. If collaborating with a MrOS investigator (someone who has previously been an author or co-author on a MrOS publication), participation in the MrOS publications review process is required and an analysis plan proposal and all resulting publications materials must be submitted for review.
4. Analyst time is available at the Coordinating Center and Administrative Center. Analysts will be assigned by the Project Director at the Coordinating Center and the lead analyst at the Administrative Center.

I. TIMELINE FOR SUBMISSION OF ANALYSIS PLANS, ABSTRACTS AND PRESENTATIONS.

1. In order to ensure proper review of analysis plans, abstracts, and presentations, the following timeline should be followed for submitting items for review by the Publications Committee.
 - a) Analysis plans must be submitted to the MrOS Publications Coordinator at least 6 weeks before a conference abstract submission deadline.
 - b) Abstracts should be submitted to the MrOS Publications Coordinator at least 4 weeks before a conference abstract submission deadline.
 - c) Presentations (posters or presentation slides) need to be submitted to the Publications Coordinator at least 4 weeks prior to the start of the conference where the presentation will be made.
 - d) For some conferences (e.g. ASBMR), a specific timeline will be distributed by the Publications Coordinator. In this case, the timeline specified for that conference should be followed.

J. ANALYSIS PLANS

1. Submitting Analysis Plans

- a) Analysis plans must be submitted to the Publications Committee for all analyses utilizing MrOS data. The analysis plan must include all items specified on the analysis plan form.
- b) The first author must have a data use agreement on file, if necessary, before an analysis plan can be submitted.
- c) Each analysis plan should be designed to result in a single manuscript. When, in the course of the review process or analysis it becomes apparent that an analysis plan is too broad or will result in multiple manuscripts, an additional analysis plan should be submitted for each additional manuscript, and/or the original plan can be amended to narrow its scope.

2. Review and Approval of Analysis Plans

- a) Once an analysis plan is received by the Publications Coordinator, the analysis plan will be listed on the MrOS website within 48 hours of receipt, with a status of 'under review.'

- b) The Publications Coordinator will initially review analysis plans. Plans will be checked for completeness, for potential overlap with other plans, that the plan will result in only one manuscript, and that variables that will be used are in released data sets. If the analysis plan meets these requirements, then the plan will be sent via e-mail to the Publications Committee for their approval.
- c) Two primary reviewers will be assigned by the Publications Coordinator to review each analysis plan. All members of the Publications Committee can review plans and vote on approval, but the two primary reviewers will be asked to carefully review the plans and will be required to provide comments to the plan's author. Reviewers will have 10 working days to review a submitted analysis plan and forward comments to the Publications Coordinator. There will be no expedited reviews of analysis plans.
- d) If any member of the Publications Committee does not accept the plan, the first author must consider revisions and then resubmit the plan. If necessary, final approval of an analysis plan will require a majority vote of the Steering Committee.
- e) After approval by the Publications Committee, analysis plans will be posted on the MrOS website with the appropriate status. Any investigator wishing to join the writing group should contact the first author. The Coordinating Center will be responsible for keeping this list up-to-date.

3. Expiration of Analysis Plans

- a) Plans for study-wide papers remain current for 12 months from the date that "clean" data becomes available for the analysis or the date of approval of the analysis plan (which ever is later). If the Publications Committee has not received a draft of a manuscript within 12 months, the plan will be considered expired and first authorship may be reassigned (for main papers) or claimed by other MrOS-paid investigators.

4. Revision of Analysis Plans

- a) Should it become necessary to revise an analysis plan, the plan author should submit a new proposal to the Publications Coordinator that highlights the changes in the text. The revised proposal will then be reviewed as described above.

K. REVIEW AND APPROVAL OF PAPERS

1. All papers must have an approved analysis plan and current data release agreement on file (if applicable) before the paper is submitted to the Publications Committee for review.
2. Papers must be reviewed by all co-authors prior to submission to the Publications Committee.

3. Papers must be approved by the Publications Committee prior to submission for publication.
4. The approval process will proceed as follows:
 - a) A final draft of the manuscript, including figures, must be submitted to the Publications Committee for review, through the Publications Coordinator.
 - b) The Publications Coordinator will assign and notify two members of the Publications Committee to review the paper. The reviewers will come from at least 2 different units. A co-author can be one of the two primary reviewers. They must indicate approval or disapproval and suggest revisions within 10 working days of notification. A reviewer may withhold approval pending revision. There will be no expedited review of papers.
 - c) The Publications Coordinator will notify all Steering Committee members by e-mail about papers that have been submitted for review and approval. Any member of the Steering Committee may read and make comments to the first author.
 - d) If either reviewer, or any member of the Steering Committee, disapproves of the submission of a paper after a good faith effort on the part of the authors to respond to concerns, then it will be reviewed by Steering Committee. The Steering Committee may approve or withdraw submission of a paper by majority vote of all members.
 - e) A paper may be submitted for publication when all reviewers give approval. A memo will be distributed to the Steering Committee, the Publications Committee, and the first author noting the approval status.
 - f) For meta-analyses, including those utilizing GWAS data, the goal of the review is to ensure that the study and data is reported accurately and completely. Reviewers should rarely encounter a revise or reject for these types of papers when the MrOS study and data is accurately and completely described.
 - g) For any analyses that are performed outside of the Coordinating Center or Administrative Center that do not involve GWAS data, the first author is responsible for sending any code used for the analysis, including code used to create derived (calculated) variables. Coordinating Center/Administrative Center statisticians will review this code to check numbers and validate findings. Any discrepancies must be resolved before the manuscript is submitted for publication.

For all meta-analyses (those utilizing GWAS data and those not), the statistical review will check phenotypic data that is reported on the study level in a manuscript. Results from the specific meta-analyses will not be reviewed as we do not have access to data from other cohorts.

Phenotype data and code will be reviewed before sending results to the leader of the meta-analysis.

For non-meta-analyses using GWAS data, the statistical review will check the phenotypic data and code.

The MrOS Statistical Analysis Review Guidelines will be distributed to all investigators not using a Coordinating Center/Administrative Center statistician at the time their analysis plan is approved.

L. REVIEW AND APPROVAL OF ABSTRACTS AND PRESENTATIONS

1. All abstracts must have approved analysis plans and current data release agreement (if applicable) before the abstract is submitted to the Publications Committee for review.
2. Abstracts must be reviewed by all co-authors prior to submission to the Publications Committee.
3. Abstracts must be approved by the Publications Committee prior to submission to a meeting.
4. The approval process will proceed as follows:
 - a) The Publications Coordinator will assign and notify two members of the Publications Committee to review the abstract and will be required to provide comments. A co-author can be one of the two primary reviewers. They must indicate approval or disapproval and suggest revisions within 10 working days of notification. A reviewer may withhold approval pending revision.
 - b) An abstract may be submitted to a meeting once both reviewers give approval.
5. Presentations (oral or poster presentations) that contain results from MrOS data must have approval for slides and printed material. This approval will be handled in the same manner as for abstracts.

M. GENETICS DATA

1. Informed consent for genetic analyses is obtained at each MrOS clinical site for all participants at each visit when whole blood or blood blotters are collected. This information is stored centrally in a consent tracking log in the MrOS database. Sites are responsible for keeping the consent status up-to-date. The GN and GWAS datasets will be updated as needed based on the current consent status.
2. Each MrOS clinical site has site-specific language in their consent forms regarding allowable uses for genetic analyses. Allowable uses should be considered by investigators prior to submitting an analysis plan that utilizes genetics data and by Publications

Committee Reviewers when reviewing materials.

- a) Five of the six sites (Minneapolis, Palo Alto, Pittsburgh, and San Diego) have IRB approval for genetic analyses of age-related phenotypes where whole blood or blood blotters were collected (V1, V3, VS). In addition, Portland has approval for genetic analyses of age-related phenotypes on whole blood or blood blotters collected at VD.
 - b) Birmingham consent forms have specific language that limits analyses to specific, defined conditions. Appendix A provides specific information regarding allowable uses of the Birmingham data at the different visits where whole blood or blood blotters were collected. **Birmingham genetic data can only be used in genetic analyses related to these specific phenotypes and is specific to the visit(s) from which consent were obtained** (i.e. Genetic studies of sarcopenia are okay if sleep visit phenotype data is utilized; however, genetic studies of sarcopenia are not allowed if baseline phenotype is utilized.)
3. In addition to review by the Publications Committee, all genetic analysis plans will also be reviewed by the Genetics Working Group on monthly conference calls to also ensure that there are no potential areas of concern regarding consent and/or allowable uses. If a conference call is canceled, comments and approval will be obtained by email. If there are any outstanding issues that cannot be resolved by the Genetics Working Group, they will be discussed on the monthly Steering Committee conference call. An investigator from the Birmingham site will also comment on allowable uses of the Birmingham data for each genetic analyses.
 4. All genetic analysis plans should outline any restrictions to the data and/or phenotypes that can be included in an analysis after allowable uses have been considered. At the time of review by the Publications Committee or Genetics Working Group, investigators may be asked to update analysis plans to provide more information about data restrictions. The Coordinating Center will add a note to all approved genetic analysis plans that indicate allowable uses have been considered and the data and phenotypes as described in the analysis have been approved.

N. USING DATA FOR META-ANALYSIS

1. Analysis plans must be submitted to the Publications Committee for all meta-analyses that request additional MrOS data (in addition to what appears in the published manuscript). The analysis plan should specify the data or values of interest. Analysis plans for these types of requests will be used to keep track of data and manuscripts without placing additional burden on external investigators who are requesting simple data. The first author must agree to acknowledge MrOS funding sources in the manuscript.
2. Once an analysis plan is received, the Coordinating Center will initially review the analysis plan. If the request is simple (such as reformatting of a published table or reporting of effect estimates from a previously run analysis), the plan will be sent via e-mail to the

Publications Committee (and the first author of the original manuscript) to notify them of the request. A formal review from the Publications Committee is not required. Data requests identified as complex or needing substantial new analyses will be required to go through the publications review process.

3. Once data is sent to the first author, no further review is required. The first author should alert the Coordinating Center when the manuscript has been published.

O. ARCHIVES

The Coordinating Center will maintain an electronic and paper archive of all MrOS publications including those from meta-analyses. Electronic copies of the final version of all papers and abstracts, including local papers, will be posted on the MrOS website. An electronic copy of the final draft and a paper copy of the published paper will be posted on the website or sent to the Coordinating Center for posting before the scheduled date of publication.

O. INTERNATIONAL DATA: ANALYSES & PRESENTATIONS

1. The ownership of each international data set is entirely within the country of origin (i.e. Hong Kong, Sweden and the U.S.). This includes the GWAS data.
 - a) Each country shall develop and maintain internal publication guidelines for analysis that utilize data from only the country of origin.
 - b) Each country shall document their own data sets.
2. Each country maintains the right to publish data from local results before international cross-comparison analyses are completed.
3. Analyses that intend to use international cross-comparison data should submit their request through the MrOS Publications Committee. The U.S. MrOS publications approval process will be followed for international cross-calibration procedures.
4. Writing groups for analyses that use international data must include at least one analyst and one investigator from each country that contributes data to the analysis. Please note this may not be true for meta-analyses, as there may be authorship restrictions to join the meta-analysis.

MrOS Analysis Plan Submission Form

Date:

Investigator's Name:

Clinical Center:

Sponsor (if not a MrOS investigator):

Relationship to Sponsor:

Telephone:

e-mail:

Other investigators who will be working on this analysis:

Analysis Plan Title:

Data sets to be used:

Primary variables to be used in the analysis:

Does this analysis plan involve a consortium or meta-analysis project? YES NO

If YES,

1. Does this plan propose to use GWAS data? ? YES NO
2. Who is the investigator leading the analysis?
 - a. If not a MrOS investigator, please note the lead investigator's affiliations.
3. What other cohorts are involved in the consortium or meta-analysis?
4. What are the definitions of the primary phenotypes of interest?
5. Describe any authorship policies of the consortium.

Do you plan to submit an abstract based on these results? YES NO

If YES, when is the abstract due?

Who will perform the analyses?

- Coordinating Center or Administrative Center
 Other local analyst, please specify:

Is this the first analysis plan you are submitting to utilize MrOS data? YES NO

If YES, please provide 2-3 sentences about your professional background and research interests.

Please attach a 1-2 page description of your analysis plan. Please include the following:

- 1) Short background/rationale for addressing the research question
- 2) Brief description of statistical methods
- 3) Mock tables

E-mail this completed form (as an attachment) to Liezl Concepcion (lconcepcion@sfcc-cpmc.net).

Appendix A

Birmingham Consent Summary for Allowable Uses of Stored Samples

MrOS V1	MrOS V3	Dental V1	Sleep V1	Sleep V2
Other risk factors for osteoporosis Other bone diseases Osteoarthritis	Other risk factors for osteoporosis Other bone diseases Osteoarthritis	Osteoporosis Osteoarthritis	Osteoporosis Osteoarthritis Longevity Disability	Osteoporosis Osteoarthritis Longevity Disability
Heart disease	Heart disease	Heart disease	Heart disease Stroke Other diseases of blood vessels Sleep disorders Frailty Sarcopenia Eye disease Prostate disease Prostate cancer Brain function Kidney disorders	Heart disease Stroke Other diseases of blood vessels Sleep disorders Frailty Sarcopenia Eye disease Prostate disease Prostate cancer Brain function Kidney disorders
Diabetes Obesity Blood pressure	Diabetes Obesity Blood pressure	Diabetes Obesity Blood pressure Other risk factors for heart disease	Diabetes Obesity Blood pressure Other risk factors for heart disease Other metabolic disorders	Diabetes Obesity Blood pressure Other risk factors for heart disease Other metabolic disorders
Cancer	Cancer			