

MULTICENTER OSTEOARTHRITIS STUDY PUBLICATIONS GUIDELINES FEBRUARY 2019

(Modifications accepted by Executive/Publications Committee on February 19, 2019)

A. Goals

- 1. To encourage high quality publications and presentations produced in a timely fashion.
- 2. To encourage broad participation by MOST investigators in publications and presentations.
- 3. To encourage creative use of the MOST data.

B. Scope of the guidelines

These guidelines cover papers (including methodology and validation papers), abstracts, oral and poster presentations, letters to the editor, meeting proceedings and extended abstracts that use data collected as part of the MOST study.

Specific agreements between the Executive Committee and Ancillary Study investigators with respect to publication of ancillary study data take precedence over the policies described in this document. (For ease of presentation, hereafter the phrases "MOST study" and "MOST data" will encompass the core protocol and all Ancillary Studies.)

These policies remain in force after funding for the study ends.

Policies covering development, approval and conduct of Ancillary Studies are described in the document "MOST Ancillary Studies Guidelines."

C. Executive/Publications Committee

The Executive/Publications Committee will be comprised of the seven MOST Executive Committee members and anyone that the Executive Committee appoints. The Committee Chair will serve a 1 year term with the possibility of re-appointment. Submission of publications materials and correspondence to the MOST Executive/Publications Committee and BU Publications Coordinator should be sent via email to: <u>mostpublications@bu.edu</u>

Information about MOST Publications, Publications Guidelines, Conference Abstracts, Posters, and Presentations, Data Use Agreement, Analysis Plan Forms, Professional Conference Dates and Abstract Deadlines, PowerPoint Presentation Templates and Study Design Descriptions is accessible via the study website (<u>https://mostonline.ucsf.edu</u>) under the Publications page.

Information about Datasets and Dataset Documentation is accessible via the study website (<u>https://mostonline.ucsf.edu</u>) under the Data page.

Additionally, the MOST Public Data Sharing website provides information about longitudinal study measurements, annotated forms, variables guides, distributions and other important study documentation.

D. Types of publications

These guidelines deal with four different types of publications.

- 1. <u>Papers</u> reporting MOST data collected for the parent study or for ancillary studies. "Main papers" for the parent study will be identified by the Executive/Publications Committee and, generally, include results about the main outcomes of the study analyzed from the study-wide database.
- 2. <u>Methodology/validation papers</u> that utilize data that has <u>not</u> yet been officially released for analysis by the San Francisco Coordinating Center.
- 3. <u>Abstracts, meeting proceedings/extended abstracts, and presentations (oral and poster</u>) submitted to meetings.
- 4. <u>Letters to the editor</u> reporting MOST data collected from one or more of the clinical centers.

E. Authorship

- Authors should participate in the writing of the paper in accordance with the International Committee of Medical Journal Editors guidelines (N Engl J Med 1991;324:424-8).
- 2. Authorship of study-wide papers and abstracts:

- a. The MOST Executive/Publications Committee may assign first authorship of main papers.
- MOST investigators may propose other study-wide papers. Fellows and non-MOST scientists may serve as first authors on study-wide papers and abstracts if:
 - at least one MOST senior investigator (see section H.1.b) serves as a coauthor and "sponsor" of the project and is listed as 2nd or last author (unless the MOST senior investigator declines 2nd or last author position) and,
 - ii. no other MOST principal investigators (Peggy Cawthon, David Felson, Cora E. Lewis, Michael Nevitt, James Torner, Tuhina Neogi, Neil Segal) have interest in first authorship. Interest in first authorship must be expressed at the time of the review of the specific analysis plan.
- 3. Investigators are limited to lead roles on <u>three</u> active analysis proposals ("active" is defined as the manuscript not yet submitted for publication). Each investigator will be limited to no more than 3 abstracts per calendar year. Exceptions can be approved by the Executive/Publications Committee.
- 4. Study-wide papers, abstracts, and presentations (oral and poster) should include "for the Multicenter Osteoarthritis Study Group" in the authorship line, or "the Multicenter Osteoarthritis Study (MOST)" in the title. For abstracts and poster presentations, the study name can be abbreviated to "MOST" or "MOST Study".
- 5. Papers based on study-wide data should invite at least one clinic site investigator as author from each of the four study centers (BU, UCSF, UAB, U-Iowa).
- 6. Junior investigators at clinic sites should be actively sought for authorship.
- 7. First author responsibilities:
 - a. enlist participation from appropriate investigators from other MOST units, including the clinical centers, Coordinating Center, NIH, and analytic and reading centers.
 - b. 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 Executive/Publications Committee may mediate disagreements that cannot be resolved by the writing group.
 - c. distribute abstracts, manuscripts, presentations, letters to the editors, etc. to all co-authors for review <u>prior</u> to submission to the Executive/Publications Committee.

d. 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 Editors guidelines.

F. Official study name, required acknowledgements, and recommended terminology

- The official name of the study for scientific purposes is the "Multicenter Osteoarthritis Study (MOST)." When referring to the MOST Study in the text of an abstract or paper, please refer to it as the "Multicenter Osteoarthritis Study (MOST)." The name can be abbreviated to "MOST" or "MOST Study" for abstracts and poster presentations.
- 2. Study-wide papers, abstracts, and presentations (oral and poster) should acknowledge NIH and NIA as the MOST funding source and list the NIH grant numbers of all participating centers in an "Acknowledgement." The four grant numbers are:

National Institute on Aging Grants for MOST4 (National Institutes of Health)

• U19 AG076471 – David T. Felson, MD & Tuhina Neogi, MD (Boston University)

National Institute on Aging Grants for MOST3 (National Institutes of Health)

- U01 AG18820 David T. Felson, MD (Boston University)
- U01 AG18832 James C. Torner, PhD (University of Iowa)
- U01 AG18947 Cora E. Lewis, MD (University of Alabama at Birmingham)
- U01 AG19069 Michael C. Nevitt, PhD (University of California, San Francisco)

In addition, publications using Ancillary Study data should also list the grant numbers of the Ancillary Study.

G. Availability and analysis of data

- 1. Proposals for analysis plans can only be submitted based on data that has been cleaned and released for analysis by the San Francisco Coordinating Center. The Overview of MOST Datasets document on the MOST website under the Data page details the datasets available for analysis.
- 2. <u>IMPORTANT NOTE</u>: Refer to the Overview of MOST Datasets document posted on the study website to confirm that you are using the most recent version of the datasets available for analysis.
- 3. In general, analyses will be performed at the Boston University (BU) Analysis Center or the San Francisco Coordinating Center. Data analyses may also be performed at other participating centers with the approval of the Executive/Publications Committee. Analyses not performed at BU or SFCC will be confirmed by replication of selected results at one of these two centers.

H. Analysis plans

- 1. Submitting Analysis Plans
 - a. Analysis plan proposals must be submitted to the Executive/Publications Committee for all reports utilizing MOST data, including parent study and ancillary study papers, methodology/validation papers, abstracts, presentations (oral and poster), and letters to the editor.
 - b. Before submitting an analysis plan, investigators should: 1) review analysis plan titles on the MOST Analysis Plan Tracking Log, under the Publications page on the MOST website to determine if the analysis plan proposal may have potential overlap with an approved analysis plan, and contact the analysis plan author to discuss; and 2) discuss and develop the analysis plan with a MOST senior investigator (Peggy Cawthon, David Felson, Cora E. Lewis, Michael Nevitt, James Torner, Tuhina Neogi, or Neil Segal).
 - c. Analysis plans can propose a single question that will result in one paper or propose several closely related questions or hypotheses that will result in more than one paper. If more than one paper is planned, all papers should address the questions or hypotheses outlined in the analysis plan.
 - d. Analysis plan proposals should be submitted to the MOST Executive/Publications Committee via e-mail to <u>mostpublications@bu.edu.</u> A MOST Analysis Plan Form (Appendix A) must accompany the analysis plan. The analysis plan proposal must include:
 - i. The name of the first author. If the first author is not a MOST principal investigator, then the sponsoring MOST senior investigator must take an active role in refining the research question(s) and research method(s) <u>prior</u> to approving the analysis plan proposal for submission to the Executive/Publications Committee. The sponsoring MOST senior investigator must be listed on the analysis plan.
 - ii. The name of the senior author (if different than the MOST senior investigator).
 - iii. An initial list of potential co-authors.
 - iv. Research question and/or hypotheses.
 - v. Brief background and rationale for addressing the research question or hypotheses.
 - vi. Variables to be used in the proposed analyses.
 - vii. 1 to 2 mock tables illustrating the results of the main aims/hypotheses.
 - viii. Timeline for completion and submission of manuscript.
 - ix. Deadlines for submission of abstracts or dates of presentation and meeting or venue (if applicable).
 - x. Where analysis will be done (if analysis will not be done at the BU or SFCC analysis centers, MOST EC approval is required).
 - xi. Confirmation that the MOST senior investigator has reviewed and approves submission of the analysis plan.

- e. If the objectives of an analysis plan evolve and deviate substantially from the original plan, the first author is responsible for submitting an amended analysis plan.
- 2. Review and Approval of Analysis Plans
 - a. Once an analysis plan and Analysis Plan Form are received by the BU Publications Coordinator, or an ancillary study is approved, the analysis plan will be assigned a MOST Analysis Plan number and listed on the MOST website under the Publications link, with a status of 'under review.'
 - b. Analysis plan proposals will initially be reviewed by the BU Publications Coordinator to make sure that the analysis plan packet is complete. When the packet is complete, the plan will be sent via e-mail to 2 members of the MOST Executive/Publications Committee to check for potential overlap with other plans and assignment of reviewers. The Committee will discuss analysis plans via email and/or conference calls as needed.
 - i. Two reviewers will be assigned to review each analysis plan proposal in detail and submit a recommendation to accept, revise/resubmit, or reject the analysis plan. One of the assigned reviewers will be a methodological reviewer (Nevitt, Felson, or a study statistician), and the other reviewer will be an expert in the area of study.
 - ii. Any member of the Executive/Publications Committee can also submit comments and a recommendation to accept, revise/resubmit, or reject.
 - c. Primary reviewers will have 10 working days to review a submitted analysis plan and forward comments to the Publications Coordinator at the BU. <u>There will be</u> <u>no expedited reviews of analysis plans.</u>
 - d. Analysis plan proposals must be submitted to the Executive/Publications Committee a minimum of 5 weeks prior to an abstract deadline (a minimum of 12 weeks prior to an abstract deadline for the ACR and OARSI meetings) to allow time for review, possible revision of the plan and data analysis.
 - e. If an assigned reviewer or member of the Executive/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 by the Committee.
 - f. After approval by the Executive/Publications Committee, the approval status will be posted on the website, and the analysis plan posted with the permission of the proposer.
 - g. Any investigator wishing to join a writing group should contact the first author at the time that the approved analysis plan is posted. The first author is responsible for notifying the Publications Coordinator when authors are added to the

writing group. The San Francisco Coordinating Center will be responsible for keeping the author list up-to-date on the study website.

- 3. Expiration of Analysis Plans
 - a. Plans for study-wide papers remain current for 24 months from the date that "clean" data becomes available for the analysis or the date of approval of the analysis plan (whichever is later). If the Publications Coordinator has not received a draft of an abstract or manuscript within 24 months, the Coordinator will notify the first author and request an update. If the first author does not provide an update, first authorship may be reassigned (for main papers) or claimed by other MOST-paid investigators.

I. Review and approval of MOST papers

- 1. MOST papers must have an approved analysis plan before the paper is submitted to the Executive/Publications Committee for review.
- 2. Papers must be reviewed by all co-authors prior to submission to the Executive/Publications Committee. The first author must submit a completed MOST Manuscript Submission Form (Appendix C) confirming that all co-authors were given the opportunity to review the manuscript and the MOST senior investigator approves submission of the manuscript for review. The signed form must be submitted before the manuscript will be sent for review.
- 3. MOST papers must be approved by the Executive/Publications Committee prior to submission for publication.
- 4. The approval process will proceed as follows:
 - a. A final draft of the manuscript (including figures), a flow diagram showing subject selection for analysis, and the MOST Manuscript Submission Form (Appendix C) must be submitted via email to the Executive/Publications Committee for review.
 - b. The Executive/Publications Committee will assign one MOST senior investigator and one other reviewer (usually one of the co-authors) for a critical manuscript review. This process of assignment and acceptance by the reviewer should occur within 5 working days of receipt of the manuscript so the process of review is not delayed. The reviewer must indicate approval or disapproval and suggest revisions within 7 calendar days of notification. The reviewer may withhold approval pending revision. The manuscript will be sent to the entire MOST Executive/Publications Committee for optional review and comments. After submission of the manuscript to the reviewer, if review is not completed and returned to the first author by a total of 7 calendar days, the first author has the option of submitting the paper for publication and awaiting the MOST reviewer

comments. The first author can then incorporate MOST reviewer suggestions for revisions as appropriate at the same time as journal revisions.

- c. If either reviewer, or any member of the Executive/Publications Committee, disapproves of the submission of a paper after a good faith effort on the part of the authors to respond to concerns, it will then be reviewed by the Executive/Publications Committee. The Committee may approve or withdraw submission of a paper by majority vote of all members.
- d. A paper may be submitted for publication when the Executive/Publications Committee gives approval. A memo from the Executive/Publications Committee noting the approval status will be e-mailed to the first author.
- e. The first author is responsible for sending an electronic copy of the final version of the paper to the Publications Coordinator, and when accepted, for sending a PDF file of the published article (or a paper copy if no PDF file is available from the Journal) to the Coordinator.
- f. If analysis is not done at either BU or SFCC, the first author is responsible for sending programming code and definitions for derived variables constructed specifically for the analysis in the paper to the senior analyst at the BU Analysis Center.
- g. <u>IMPORTANT</u>: Upon acceptance of publication, the first author is required to submit his/her final journal manuscript to PubMed Central (<u>http://www.pubmedcentral.nih.gov/</u>) no later than 12 months after publication. The National Institutes of Health Public Access Policy (<u>http://publicaccess.nih.gov/</u>) ensures that the public has access to the published results of NIH funded research. Once the manuscript has been submitted to PubMed Central and obtained a PubMed Central identification number (PMCID), the author then informs the Publications Coordinator by sending an email to <u>mostpublications@bu.edu</u>.

J. Review and approval of abstracts and presentations

- 1. <u>Abstracts must have an approved analysis plan before an abstract is submitted to a scientific meeting.</u>
- 2. Drafts of abstracts must be sent to all co-authors at least 10 working days prior to the submission deadline.
- A draft of the abstract must be sent to the Publications Coordinator (<u>mostpublications@bu.edu</u>) at least 10 working days prior to the submission deadline. The Publications Coordinator will post the abstract on the study website for optional Executive/Publications Committee review.

- 4. Approval of the final abstract for submission will be the responsibility of the MOST senior investigator, who is a co-author of the abstract. <u>The first author is responsible for having the MOST senior investigator sign the Abstract Approval Form (Appendix B) and for faxing or emailing the form to the Publications Coordinator prior to the submission deadline for the abstract.</u>
- 5. The first author is responsible for sending to the Publications Coordinator an electronic copy of the final version of the abstract. The first author is responsible for updating the coordinator on whether the abstract was accepted.
- 6. The Publications Coordinator will post the final version of the abstract on the MOST website under Publications link.
- 7. Presentations to national or international meetings that contain results of MOST data must have approval for the slides or printed material. This approval will be handled in the same manner as for abstracts.
- 8. When giving a podium presentation of the results of analyses, include a slide with information about MOST Online (<u>https://mostonline.ucsf.edu</u>). The NIH requires that federally-funded datasets be available to the public and that information about how to access these datasets is widely distributed.

K. Miscellaneous (Letters to the Editor, Meeting Proceedings, Extended Abstracts, Methodology / Validation Papers)

1. Letters to the Editor

- a. Letters to the Editor using analyses of MOST data done specifically for the letter must utilize data that has been officially released by the San Francisco Coordinating Center. The approval process will be handled in the same manner as for abstracts.
- b. All Letters to the Editors related to a specific MOST publication should be reviewed by all co-authors of the publication prior to submission to the journal. Final approval of the letter to the Editors will be the responsibility of the MOST senior investigator who is co-author.
- c. The first author is responsible for sending to the Publications Coordinator an electronic copy of the final version of the Letter to the Editor.

2. Meeting Proceedings and Extended Abstracts

- a. Meeting Proceedings and Extended Abstracts utilizing analyses of MOST Data must be based on approved analysis plans.
- b. Meeting Proceedings and Extended Abstracts that are nearly identical to or minimally expand on an approved abstract do <u>not</u> need to be submitted to the Executive/Publications Committee for review prior to submission for publication. These should be reviewed by all co-authors prior to submission with final approval from the MOST senior investigator.
- c. Meeting Proceedings and Extended Abstracts that significantly expand an approved abstract <u>must be</u> submitted to the Executive/Publications Committee for review prior to submission for publication. New analyses and results not included in the abstract and substantial additional detail about methods are examples of significant expansion. The approval process will be handled in the same manner as for abstracts.
- d. In order not to jeopardize the publication of the complete manuscript in a peerreviewed journal, MOST investigators are encouraged to take a "minimalist" approach when drafting Meeting Proceedings and Expanded Abstracts. The content should closely mirror the abstract; the analyses and results should be presented with the same level of detail as the abstract. Expanding the background and discussion sections is a good alternative to expanding the methods and results section. Authors should feel free to provide half as much text as requested for the Meeting Proceedings and Expanded Abstract.
- e. The first author is responsible for sending to the Publications Coordinator the final version of the Meeting Proceedings and Short Communications.

3. Methodology / Validation Papers

- a. All methodology / validation papers must have an approved analysis plan before the paper is submitted to the Executive/Publications Committee for review.
- b. The Executive/Publications Committee will consider analysis plans for methodology and validation papers that utilize data that has <u>not</u> yet been officially released for analysis by the San Francisco Coordinating Center.
- c. The approval processes will be handled in the same manner as for other analysis plans and manuscripts.

L. Archives

BU will maintain an electronic archive of all MOST publications. The first author is responsible for sending the Publications Coordinator the final draft of the manuscript and the paper when it is accepted for publication. Electronic copies of the final version of all papers and abstracts, including local papers, will be posted on the MOST website.

The first author is responsible for submission of the published article to PubMed Central (<u>http://www.pubmedcentral.nih.gov/</u>) and notifying the Publications Coordinator when the article is submitted. It is understood that some journals (e.g. Arthritis and Rheumatism) have a policy of automatically submitting to PubMed Central and that journal policy will override MOST policy (e.g. if journal policy is to delay sending to PubMed, MOST will abide by that policy). However, the author must notify the Publications Coordinator when the article is posted to PubMed Central.

Appendix A: Analysis Plan Form Please use the interactive form for submission (<u>https://mostonline.ucsf.edu</u> / Publications/ Data Use Agreement, Analysis Plan Forms, etc.)

	Analysis Plan Form
	Email completed form to MOST Publications (MOSTPublications@bu.edu)
MOST	MOST senior investigator:
Telephone number: E-mail address:	(Felson, Lewis, Nevitt, Torner, Neogi, or Segal: responsible for analysis plan, abstract & manuscript approvals) Senior author: (If different from MOST senior investigator) Date of request: / /
Institutional Affiliation:	Month / Day / Year
1. Working title of plan:	
 c) Variables to be d) 1 to 2 mock tai e) Timeline for co 	Ind and rationale for addressing the research question/hypotheses. e used in the proposed analyses. bles illustrating the results of the main aims/hypotheses. completion and submission of manuscript. Inny abstracts based on this analysis? ☐ Yes ☐ No ↓ nit an abstract to: OARSI: ☐Yes ☐No and/or ACR: ☐Yes ☐No
If not OARSI or ACR specify:	R, what conference / journal do you plan to submit the abstract to? Please
When is the abstrac	ct due? / / Month/ Day/ Year
3. Where will analysis be o * <u>If analysis will not be d</u> BU Analysis Ce	lone at the BU, KU, or UCSF analysis centers, MOST Executive Committee approval is required
 Other investigators who 1) 	will be working on this analysis: 4) 7)
2) 3)	5) 8) 6) 9)
5. MOST senior investigat	or approval stigator (named above) has reviewed and approves submission of the analysis plan.
	cated below, your analysis plan will be posted on the MOST website, once it is approved
	is Committee. (Note: The MOST website is a restricted-access website.) proposal posted on the MOST website until the abstract or manuscript is accepted.

Appendix B: Abstract/Poster/Presentation Approval Form



PART II – MOST SENIOR INVESTIGATOR FINAL APPROVAL
I have reviewed the abstract or presentation listed above and approve it for submission to the scientific meeting.
Signature of MOST Senior Investigator:
Date:
Reminder: Signatures are required. Scan signed form and email to

<u>MOSTPublications@bu.edu</u> prior to submission or presentation. Retain the original document for your own records.

Version 7/6/16

Appendix C: Manuscript Submission Form

MOST	Email completed form to MOSTPublications@bu.edu
First Author:	
MOST Senior Inv	estigator:
MOST Analysis P	Plan Reference Number: AP
Title:	
What journal(s) w	ill the manuscript be submitted to?
Reminder:	
Submit a PART I - FIRST AL	flow diagram showing subject selection.
	rs have had the opportunity to review this manuscript and provide
comments.	(Preferred option)
	ncurrent Review by co-authors and MOST Publications Committee.
(This option) expected. The Committee R	is limited to manuscripts that are very well developed and minimal revision e MOST Senior Investigator must approve use of this option. The Publications eviewer has the option of returning an insufficiently developed manuscript for ut completing a formal review.)
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(This option I expected. The Committee Re revision witho	is limited to manuscripts that are very well developed and minimal revision e MOST Senior Investigator must approve use of this option. The Publications eviewer has the option of returning an insufficiently developed manuscript for ut completing a formal review.)
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(This option I expected. The Committee Ri- revision witho Signature of First Date: PART II – MOST S I have review Publications I approve Co applicable). Signature of MOS Date: Reminder: Signature	is limited to manuscripts that are very well developed and minimal revision MOST Senior Investigator must approve use of this option. The Publications eviewer has the option of returning an insufficiently developed manuscript for but completing a formal review.) Author: SENIOR INVESTIGATOR FINAL APPROVAL wed the manuscript listed above and approve it for submission to the MOST Committee. Incurrent Review by co-authors and MOST Publications Committee (if