SOMMA Publication Guidelines

i. Scope

These guidelines cover all papers and abstracts that use SOMMA data including primary SOMMA data, ancillary study data, raw signal data and derived variables from reading centers and central labs. The guidelines remain in force after funding for the study ends.

Use of SOMMA data for documents that will not be published, e.g. grant proposals, educational exercises, and presentations describing SOMMA, do not require analysis plans or review.

ii. Organization: Publications Committee and Reviewers

The SOMMA Executive Committee (EC) will appoint a Publications Committee from investigators who are supported by SOMMA. The EC will also appoint a Publications Committee Chair (Chair) who will generally be a member of the EC. The Publications Committee Coordinator at the San Francisco Coordinating Center (SFCC) assists the Chair and manages the publications process and keeps records of publication plans, abstracts, presentations, and manuscripts.

iii. Authors and authorship

a) Analysis plans and papers will have a **lead author** who is responsible for engaging co-authors and ensuring that abstracts, presentations and manuscripts are submitted for review by SOMMA Publications Committee. Lead authors will generally be SOMMA-supported investigators* who proposed the idea for the paper. (SOMMA supported investigators, or "SOMMA Investigators," include PIs of Ancillary Studies). Investigators who are not SOMMA investigators may be lead authors if they have a SOMMA Sponsor. (See point 4).

b) The lead author will identify coauthors. When the analysis plan is circulated for review, SOMMA investigators may ask to be included in the writing group as coauthors.

c) The following recommendations for authors who should be included or offered the opportunity to participate in SOMMA analyses should be considered:

   i) One author from each clinical center and the SFCC when analysis plans utilize study-wide data.

   ii) Russ Hepple when analysis plans utilize histology data.

   iii) One author from Adventist Health when analysis plans utilize respirometry data.

   iv) One author from the UF-Esser lab when analysis plans utilize RNAseq data.

   v) Dave Marcinek when analysis plans utilize ATPmax data

   vi) One author from the ancillary study team when analysis plans utilize data from a SOMMA ancillary

d) The lead author is encouraged to hold an initial conference call to discuss the idea and the design of the analysis.

e) Lead authors are responsible for submitting accepted manuscripts to the PubMed Central (PMC) digital archive and notifying the Coordinating Center of the PMC ID (see below Section 10: NIH Public Access Policy).

* A SOMMA supported investigator typically receives salary from the SOMMA main grant or is a P.I.s of a funded ancillary study. SOMMA-supported investigators are referred to as "SOMMA investigators." A list of "SOMMA Investigators is in the Appendix and kept by the Coordinator.

f) Authors should meet the criteria for authorship defined by the ICMJE: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html
   - Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
   - Drafting the work or revising it critically for important intellectual content; AND
   - Final approval of the version to be published; AND
   - Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

g) The lead author has several responsibilities for authorship. They should:
   - provide opportunities for potential authors to make substantial contributions that meet these guidelines. At a minimum, the lead author should distribute drafts of the paper that are open to meaningful contributions.
   - determine the order of authorship. Non-SOMMA lead authors should consult with the SOMMA sponsor in deciding the order. If any co-author has a question about the order of authorship, they should first communicate with corresponding author or SOMMA Sponsor (if applicable). The SOMMA Executive Committee may mediate disagreements about order of authorship.
     i) Lead author generally serves as first author.
     ii) There are several considerations in the selection of the senior author.
       (1) The lead author may elect to play that role, for example, deferring to junior investigator as first author.
       (2) P.I.s of SOMMA, of ancillary studies, or leaders of SOMMA laboratories may be considered for the senior position.
       (3) The author who conceived the idea may be considered for that role if they meet other criteria for authorship.
     iii) The second author should have been an active contributor to the analysis and/or writing. A data analyst for a manuscript often makes such a contribution and should be considered for the second place.
     iv) The value of an authorship position to the career of a young investigator or trainee may be considered
     v) Besides these contributions, the order of authorship may be based on contributions or alphabetically.
   - exclude potential authors who do not meet authorship criteria despite opportunities to participate.

h) In some cases, authorship for meta-analyses may be restricted based on consortium policies.

iv. Sponsors and non-SOMMA authors

a) Investigators who are not SOMMA-supported may serve as authors on papers that have a SOMMA lead author or SOMMA sponsor.

b) Non-SOMMA investigators may serve as a lead authors if they have a SOMMA investigator Sponsor.

c) Sponsors are expected to be a liaison to other SOMMA investigators. The sponsor reviews the analysis plan; reviews the final draft of a paper before submission to the Publications Committee; and is a co-author. The Sponsor assures that SOMMA is described accurately.

v. Study names and acknowledgements

a) Where word limits allow, the title of papers that are based on SOMMA data should include: the Study of Muscle, Mobility and Aging (SOMMA). Papers based on data from ancillary studies should also acknowledge the title of the ancillary study in the title of the paper.

b) All papers, abstracts and presentations should include: "The Study of Muscle, Mobility and Aging is supported by funding from the National Institute on Aging, **grant number AG059416**." The following statement should also be included: Study infrastructure support was funded in part by NIA Claude D. Pepper Older American Independence Centers at University of Pittsburgh (**P30AG024827**) and Wake Forest University (**P30AG021332**) and the Clinical and Translational Science Institutes, funded by the National Center for Advancing Translational Science, at Wake Forest University (**UL1 0TR001420**).

c) Ancillary grant numbers and other funding support should be acknowledged in papers, abstracts and presentations as needed based on data being presented.

d) The following statement may be included for journals that require a statement on data availability: "The analysis dataset for this specific manuscript is available on request from the corresponding author." The public SOMMA data release website may also be listed: https://sommaonline.ucsf.edu

e) Consider including key staff who contributed to the paper or presentation in Acknowledgements in papers and presentations. The Coordinating Center (CC) maintains a current list of SOMMA study staff and key personnel that can be included in manuscripts as part of an extended acknowledgment.[†]

f) The clinical centers should be referred to as Wake Forest University School of Medicine and University of Pittsburgh, the coordinating center as San Francisco Coordinating Center and the tissue management and repository as Translational Research Institute, Adventist Health. Geographical regions of where participants reside (if included) should be described as in and around Forsyth County, NC and Pittsburgh, PA.

vi. Data Use Agreements (DUA)

A Data Use Agreement (DUA) is required for all investigators who will be in contact with SOMMA data or will be analyzing SOMMA 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 SOMMA data under the direct supervision of the lead investigator of a DUA at a given institution.

a) There are a few exceptions. Investigators who have a subcontract or consulting agreement under CPMC for work with the SOMMA Study may not be required to complete a DUA. In addition, investigators conducting a meta-analysis, who will never receive participant level data from SOMMA, may not be required to sign a DUA.

b) The Coordinating Center (CC) will ensure that DUAs are in place with all investigators and analysts working with SOMMA 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.

[†] Journals may require signatures from staff who are included in acknowledgements.

vii. Data availability and submission of analysis plans

a) Analysis plans can only be submitted and approved for data that has been released by the SFCC.

b) Official SOMMA Data Releases occur in May and November of each year. However, if data becomes available between official releases, that data may be approved for release by the SFCC and analysis plans can be submitted at that time (e.g. if a dataset becomes available in January, authors do not need to wait until the official release in May to utilize the data).

c) There may be a call for ideas for analyses prior to the release of a dataset. Details for how review of analysis plan ideas will be conducted will be released in conjunction with each call for ideas.

d) Data from Ancillary Studies must be submitted to the SFCC for quality control checks by the SOMMA Data Manager or a SOMMA ancillary study. Analysis plans utilizing ancillary data can be submitted for review after the SFCC has approved the ancillary study data for release.

e) Data from ancillary studies may be reserved for plans by investigators for those studies for submission of 3 papers or 12 months from the date that the data become available. At that time, other investigators may submit analysis plans that include data from the ancillary study.

f) The Executive Committee may approve the use of unreleased data for specific analyses. A formal request should be sent to the SOMMA Publications Coordinator to circulate to the Executive Committee. If the Executive Committee approves the use on unreleased data for specific analyses, an analysis plan should be submitted for approval.

viii. Analysis plans

a) All analyses for papers, abstracts, and presentations must be approved by the Publications Committee.

b) Analysis plans submit a completed Analysis Plan Form (appended to this Guideline). The Coordinator will post plans (under review) to the SOMMA Online website and study Publications Box Folder within 2 working days; SOMMA investigators may ask to be included in the plan.

c) Analysis plans are intended to reflect the analyses for a single manuscript. If the analysis leads to an additional paper, an additional plan should be submitted.

   i) If analyses begin to expand the scope of the originally approved analysis plan, expansion must avoid overlap with other approved plans. Significant changes in scope (e.g. addition of an outcome or key predictor) require a modification to be submitted to the Publications Committee for review. Track changes should document the proposed changes.

d) Grants for Secondary Data Analysis: An investigator who is submitting a proposal for funding to perform secondary data analysis with existing SOMMA data, should submit an ancillary study proposal for review by the Executive Committee. After the ancillary study is approved, investigators should also submit an analysis plan (or plans if there will be more than one resulting publication) for review by the Publications Committee. This will 'reserve' the analysis plan topic for the lead investigator to begin analyses once funding is obtained. Once approved by the Publications Committee, these analysis plans will be considered 'Approved, pending funding'. Once funding is obtained, they will be considered 'approved'. If there are any changes in analyses from what was originally proposed, a modification should be submitted for approval

ix. Data analysis support and best practices

a) The Coordinating Center will assign a data analyst to work on analysis plans if centralized analysis support is required. Priority for these analysis resources will be established by the Executive Committee.

b) Data analysis may be conducted by analysts not located at the Coordinating Center.

c) Every manuscript submitted to for Publications review is required to have undergone statistical analysis review, where the major findings from the paper (including the N) are replicated independently by a second analyst. For papers with a Coordinating Center assigned analyst, this will be managed at the Coordinating Center. For papers that do not include a Coordinating Center analyst, proof of this review will be required. Statistical review for papers by outside analysts can be completed by Coordinating Center analysts; however, this step may take several weeks depending on workloads.

x. Review of analysis plans

a) Analysis plans must be approved before analyses start.

b) The Coordinator will check for completeness, overlap, availability of data and then send the plan to reviewers (members of the Publications Committee).

c) Two reviewers will be assigned who rate the plan as approve (with or without comments), revise and reconsider, or disapprove. The reviewers will prepare comments for the authors; they may choose to be identified or anonymous to the authors. One of the reviewers can be a coauthor, if that reviewer is on the Executive Committee.

d) If either reviewer rates the plan as revise and resubmit or disapprove, the plan is not approved until the author makes revisions that are approved by the reviewer(s).

e) Approvals: The lead author and co-authors will respond to comments or recommended revisions. The revised version with comments will be read by the reviewer(s) who requested re-review or disapproved. If approved, the analyses can proceed. If reviewer(s) disapproves or request another round of revision, the plan may be reviewed by the Publications Chair for a decision about approval. The Chair may also request an additional review by a member of the Publications Committee to advise about approval or refer the plan to the Executive Committee for a decision.

f) Expiration and withdrawal: If a plan does not result in draft of the paper submitted for review within 9 months after approval of the plan, the Chair or Coordinator will contact the lead author to develop a plan for completion with milestones and deadlines. If milestones and deadlines are missed, the Publications Committee Chair can, in consultation with the Executive Committee, de-list the analysis plan. The topic of the paper could then be pursued by other interested investigators.

xi. Review of papers

a) The draft of the paper that is sent to the Publications Committee should also be sent to co-authors for approval. (Journals may require documentation of approval by co-authors). Co-author review should be coordinated by the lead author.

b) Papers must be approved by the Publications Committee before it is submitted for publication in a peer reviewed journal or preprint service. Review by the Publications Committee is coordinate by the Publications Coordinator.

c) The final draft, including tables and figures will be submitted to the Coordinator. Two reviewers will be assigned for the paper, both of which may be co-authors. If two co-authors are assigned to review a paper, one reviewer should be an Executive Committee member.

d) Approvals: Recommendations about approval should consider rigor, accuracy, clarity of results, and appropriateness of conclusions. The reviewer(s) should send comments to that author to improve the quality of the paper, but avoid detailed edits and minor issues.

e) Reviewers will rate the paper as 1) approve (with or without comments), 2) revise and reconsider, or 3) disapprove (do not resubmit). The reviewers will also prepare comments for the authors that identify the reviewer, or not. If either reviewer rates the paper as revise and resubmit or disapprove, it is not approved until the author(s) makes revisions- and/or responses to the review(s).

f) The lead author and co-authors will respond to comments or recommended revisions. The revised version with comments will be read by the reviewer(s) who requested re-review or disapproved. If approved, the paper may be submitted. If reviewer(s) disapproves or request another round of revision, the plan may be reviewed by the Chair for a decision about approval. The Chair may request an additional review by a member of the Publications Committee to advise about approval. The lead author may appeal a disapproval to the Executive Committee.

xii. Review of abstracts and presentations

a) Abstracts and presentations must have an approved analysis plan and the co-authors must have an opportunity to review a draft before the lead author submits it to the Publications Committee.

b) Abstracts must be approved by the Publications Committee before submission to a conference. Abstracts should be as close to final as possible. If the Abstract's conclusion changes after Committee review it must be re-reviewed before submission.

c) One reviewer for the abstract, ideally a member of the Executive Committee, will approve the abstract (with or without comments), requests revisions and reconsideration, or disapprove. Reviewer may be a co-author if member of the Executive Committee.

d) If the reviewer requests revisions before submission, or disapproves, the lead author will respond, revise, and resubmit to the Publications Committee. The revised version may be approved for submission by the Chair.

Timelines for abstracts

e) Analysis plans for abstracts must be submitted to the Publications Coordinator at least 6 weeks before an abstract submission deadline for a meeting. Alternative timelines for major meetings (such as GSA) may be provided.

f) Abstracts should be submitted to Coordinator at least 2 weeks before the abstract submission deadline. The Chair of the Publication Committee or the Publications Coordinator may make exceptions to review within 5 working days considering availability of reviewers.[‡]

g) It is expected that authors will receive approvals and comments for abstracts, within two weeks of submitting it to the Publications Coordinator. The Reviewers will have an opportunity to let the Coordinator know their availability. Assuming reviewers are available, they should provide reviews and approvals of within 5 working days after receiving the draft.

Presentations

h) Copies of posters or slides for presentation should be sent the Publications Coordinator.

i) If a poster or presentation includes results or conclusions that are the same as an approved abstract, the Publications Committee does not need to review the presentation.

[‡] The Executive Committee or Publications Committee Chair may develop timelines and special guidelines for unusual circumstances, such as expected submission of a large number of abstracts to a meeting or opportunities for presentation on short notice.

j) If a poster or presentation includes results or conclusions that differ substantially from the approved abstract or approved draft of the paper, then those results and/or conclusions must be to be submitted to Coordinator and Chair at least 2 weeks prior to the start of the conference where the presentation will be made.

k) The Publications Coordinator and Chair should be notified about any other presentations that use unpublished SOMMA data. Slides from these presentations that are directly related to SOMMA should be submitted to the Publications Coordinating at least 2 weeks prior to the scheduled talk. A member of the EC should review the slides related to SOMMA to make sure the study is appropriately represented. The SOMMA slides presented should be archived at the SFCC.

xiii. Summary of Publications Materials Reviews (Coordinated by SFCC)

Publication Element	SFCC Review Required	Who Reviews
Analysis Plan	Always	2 reviewers from Publications Committee
Abstract	Always	1 reviewer, ideally from Executive committee; may be co-author if reviewer is from Executive Committee
Presentation, poster	Only required if conclusions change from abstract	If required, 1 reviewer, ideally from Executive Committee, may be co-author
Manuscript	Always	2 reviewers from Publications Committee; Both reviewers may be co-authors if one co-author is from Executive Committee SFCC completes administrative and statistical review

xiv. NIH Public Access Policy

The NIH Public Access Policy states that all NIH-funded studies must submit copies of their manuscripts to the digital archive PubMed Central (PMC) once accepted for publication to a peer-reviewed journal. Authors should review the journal's copyright agreement before signing and determine if they allow for submission to PMC. If not, it is the author's responsibility to negotiate with the journal to make sure this is allowable.

Once accepted for publication, the manuscript should be submitted to the NIH Manuscript Submission system at http://www.nihms.nih.gov. The manuscript will be assigned a PMCID. The Coordinating Center should be notified of the PMCID as soon as it is available. For more information on the NIH Public Access Policy, please visit http://publicaccess.nih.gov.

Guidelines for meta-analyses and genetics data to be developed when relevant to SOMMA.

SOMMA Investigators
May serve as lead authors on any SOMMA publication

Steve Cummings
Russ Hepple
Stephen Kritchevsky
Anne Newman
Peggy Cawthon
Paul Coen
Bret Goodpaster
David Marcinek,
Nancy Glynn
Dan Forman
Fred Toledo,
Barb Nicklas
Osvaldo Delbono
Jamie Justice
Mary Lyles
Ezequiel Zamora
Elsa Strotmeyer
Jane Cauley
Lauren Sparks
Erin Kershaw
Anthony Molina
Sruti Shiva
Caterina Rosano
Phil Kramer
Theresa Mau
Kate Duchowny
Nancy Lane
Leon Lenchik
Samaneh Farsijani
Ashley Weaver
Kyle Moored
Ming Xu
Andrea Brennan
Sofhia Ramos
All Coordinating Center data analyst

SOMMA Analysis Plan Form

Analysis plan title:

Date:

Lead author / proposer's name:

E-mail: Phone:

Lead author's affiliation (Clinical Center, Coordinating Center, Laboratory, Other):

Other SOMMA investigators in the writing group (this may change):

Sponsor (if the lead is not a SOMMA investigator): Sponsor email: Phone:

Data sets to be used (please be specific):

Primary variables to be used in the analysis (primary endpoint(s) and main predictors):

What is the definition of the primary endpoint (if applicable)?

Describe how the analysis plan will treat age, sex and body size in the analytic approach.

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

If YES, who is the investigator leading the analysis?

If not a SOMMA investigator, please note the meta-analysis lead investigator's affiliations.

Describe authorship policies of the consortium that are relevant to SOMMA authorship.

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

If YES, what is the deadline?

Who will perform the analyses?

☐ Coordinating Center ☐ Other SOMMA Center:

☐ Other analyst (name and email address):

Is this the first plan you are submitting to utilize SOMMA data? ☐ YES ☐ NO

If YES, to introduce you to SOMMA investigators, please provide 2-3 sentences about your professional background and research interests.

Attach a 1-2 page description of the plan. Include:

Background/rationale

1-3 aims or hypotheses

List the main variables to be included in the analyses (to identify and prevent overlapping plans)

Statistical methods for the main aims

Mock table(s) and / or figure(s)

Attach the form and description to an email to Amelia Cervantes (Amelia.Cervantes@ucsf.edu)