Study of Osteoporotic Fractures (SOF)
Publications Guidelines

A. GOALS

1. To encourage high quality publications and presentations.
2. To encourage broad participation by investigators in publications and presentations.
3. To encourage creative use of the data.

B. SCOPE OF THE GUIDELINES

These guidelines cover publications using data collected as part of the Study of Osteoporotic Fractures (SOF) and describe two pathways for accessing SOF data: (1) the limited public release dataset on SOF Online, and (2) additional data that are not available on SOF Online, which requires analysis plan registration and a separate Data Use Agreement. Because the study has ended, the review process has been streamlined to focus on compliance with applicable National Institutes of Health (NIH) requirements, including NIH requirements related to foreign collaborations and international data sharing and acknowledging appropriate grants. Investigators are responsible for registering an analysis plan when one is required. Manuscripts, abstracts, oral and poster presentations do not require review or approval. These policies remain in force after funding for SOF ends.

Important: Non-U.S./Foreign Collaborations
Collaborations and data sharing involving individuals affiliated with institutions based in countries of concern (China, Hong Kong, Cuba, Iran, Iraq, North Korea, Russia, and Venezuela) are not permitted and all ongoing work must cease immediately. This policy applies to all uses of NIH-funded SOF data, even if no U.S.-based SOF authors are included on the manuscripts, abstracts, posters, or presentations.

For collaborations involving individuals affiliated with institutions based in other countries outside the United States, pre-approval from the NIH is required before the start of any analyses. No work or data sharing should begin until applicable approvals are in place.

C. PATHWAYS FOR ACCESSING SOF DATA

1. PATHWAY 1: SOF ONLINE

    a) To access the limited public release dataset on SOF Online (https://sofonline.ucsf.edu), you must first request access. Once your request is approved, you can create an account and electronically sign a Data Use Agreement.
    b) For investigators affiliated with an institution outside the United States: NIH pre-approval is required before access to SOF Online datasets is granted.
    c) Public data release (PDR) datasets are accessible in the “Data & Documentation” section of the website. This section also includes links to:
        a) Data collection forms
        b) “Longitudinal Data Documentation” to browse variables in the data set
    d) The PDR datasets have the following limitations:

a) Extreme values (such as age, height, weight) that could possibly identify a participant have been removed from the datasets.
b) The datasets do not include all data generated from ancillary studies and substudies.
c) Data collected from bi-annual phone follow-up questionnaires (2009-2016) are not available.
d) Adjudicated MCI and dementia data generated from the SOF Sleep and Cognition in Older Women substudy are not available.

2. PATHWAY 2: ANALYSIS PLAN REGISTRATION

a) Investigators seeking access to the full SOF dataset must register an analysis plan by submitting an Analysis Plan Registration form to the Coordinating Center. The submission must include the research question, datasets and primary variables to be used, proposed methods, and anticipated manuscript topic.
b) Investigators using non-public SOF data must have a Data Use Agreement on file before data are shared or analyzed.
c) For analysis plans involving investigators affiliated with an institution outside the United States: NIH pre-approval is required before proceeding with analysis. On the Analysis Plan Registration Form, list all foreign collaborators' names, all institutional affiliations, countries, and their role in the project. The Coordinating Center will forward the analysis plan to the NIH for review. No work or data sharing should begin until applicable approvals are in place.

D. DATA USE AGREEMENT (DUA)

A DUA is required for all investigators who will be in contact with SOF data or will be analyzing SOF 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 SOF 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 SOF 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 SOF 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 SOF 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.

E. AVAILABILITY AND ANALYSIS OF DATA

SOF data is available to the public via the 'SOF Online' website (https://sofonline.ucsf.edu).

Limited SOF data are also available on other public resources (e.g., National Sleep Research Resource (NSSR), database of Genotypes and Phenotypes (dbGaP), NIA Aging Research

Biobank). The Coordinating Center does not share the ID link between the 'SOF Online' website and other public resources. Investigators seeking access to biospecimens, imaging files, sleep study data, or other archived materials should submit their requests through the designated public repository.

F. AUTHORSHIP

1. Definition of authorship. Authors must 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). First 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 those guidelines.

2. First authorship. First authorship will be decided on by the writing group of the project. In general, the investigator who first conceived of the project and submitted an analysis plan to the Coordinating Center should have the option of serving as first author. Conflicts in first authorship should be resolved by all members of the writing group.

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

The purpose of this section is to provide standard language for papers, abstracts, and presentations using SOF data.

1. The official name of the study for scientific purposes is the "the Study of Osteoporotic Fractures (SOF)." All papers should include "the Study of Osteoporotic Fractures" in the title or "for the Study of Osteoporotic Fractures" in the authorship line. For meta-analyses, the study should be included in an acknowledgement.

2. All study-wide papers, abstracts, and presentations (oral and poster) should include the acknowledgement: 'The Study of Osteoporotic Fractures (SOF) is supported by National Institutes of Health funding. The National Institute on Aging (NIA) provides support under the following grant numbers: R01 AG005407, R01 AR35582, R01 AR35583, R01 AR35584, R01 AG005394, R01 AG027574, and R01 AG027576.'

3. **SOF Sleep Study**: All papers, abstracts and presentations (oral and poster) that include data from the SOF Sleep Study should include in the acknowledgement: 'The Study of Osteoporotic Fractures (SOF) is supported by National Institutes of Health funding. The National Institute on Aging (NIA) provides support under the following grant numbers: R01 AG005407, R01 AR35582, R01 AR35583, R01 AR35584, R01 AG005394, R01 AG027574, R01 AG027576, and R01 AG026720.'

H. ABSTRACTS, PRESENTATIONS, AND MANUSCRIPTS

Abstracts, presentations (including posters or presentation slides), and manuscripts do not require formal review and approval from SOF. The lead author is responsible for ensuring that all co-authors review and approve the content prior to submission or presentation, acknowledging all

appropriate grants, obtaining NIH approval for any foreign collaboration before work begins, and submitting a copy of the final version to the Coordinating Center for archiving.

I. 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.

J. ARCHIVES

The Coordinating Center will maintain an archive of all SOF publications including those from meta-analyses. Lead authors are encouraged to notify the Coordinating Center when manuscripts using SOF data are accepted or published and to provide citation information or a final version when available. Final abstracts and presentations may also be submitted to the Coordinating Center for archiving.

SOF Analysis Plan Registration Form

Date:

Investigator Name:

Institutional Affiliation:

E-mail:

Other investigators who will be working on this analysis:

Are any investigators affiliated with an institution outside the United States? ☐ YES ☐ NO

If YES, NIH pre-approval is required. Please list collaborators' names, all foreign institutional affiliations, countries, and roles in the project:

1.

Proposed Manuscript or Analysis Plan Title:

1. Short background/rationale for addressing the research question:
2. Data sets to be used:
3. Primary variables to be used in the analysis:
4. Brief description of statistical methods:

E-mail this completed form (as an attachment) to Liezl Concepcion (Liezl.Concepcion@ucsf.edu).