



SPIROMICS Publications and Presentations Policy

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SPIROMICS Publications and Presentations Policy

1. Policy Objectives

The primary objective of the Publications and Presentations Policy is to insure the appropriate and accurate use of data without restricting scientific inquiry. Other objectives of this policy include:

- Expeditious and timely dissemination of major SPIROMICS findings to the scientific community.
- Accurate and scientifically sound publications from SPIROMICS.
- Encouragement of high-quality manuscripts among the SPIROMICS investigators.
- A system for fair determination of collaborative authorship on SPIROMICS publications.
- Opportunities for investigators from SPIROMICS centers and sub-sites and outside investigators with appropriate expertise to participate and be recognized in study-wide publications and presentations.
- Creation of writing groups and an orderly system for setting priorities and providing timely review of manuscript proposals.
- Appropriate tracking and reporting of all SPIROMICS publications and presentations.
- Review and oversight of proposals, manuscripts, abstractors, and presentations related to SPIROMICS

2. Policy

The SPIROMICS Steering Committee (SC) will appoint a Publications and Presentations Committee (PPC), which will include at least one interested SC member from each SPIROMICS site (with the approval of the site PI) and from the GIC. The Chair of the PPC will be approved by the SC.

In order to fulfill the objectives enumerated above, it is the policy of the SPIROMICS SC and its PPC that all manuscripts and presentations deriving from SPIROMICS data obtained from SPIROMICS participants, including questionnaire, imaging, biomarker, genetics, local and ancillary, be submitted to the committee for scientific review. If necessary, the PPC will also establish priorities for the Genomics and Informatics Center (GIC) to process, analyze, and/or verify data reporting.

All SPIROMICS manuscript or abstract proposals submitted for review must be championed or sponsored by a SPIROMICS Principal Investigator.

Manuscripts reflecting local or site-specific findings are encouraged, but they should be submitted a) after papers covering the same topic based on the full SPIROMICS dataset

have been published or accepted for publication, or b) if the PPC does not anticipate publication of main papers covering the same topic.

3. Manuscript and Abstract Process Tracking

The GIC will monitor and facilitate the necessary processes for proposal submission, and provide routine updated progress reports of all submitted and approved SPIROMICS publications and abstracts (e.g., approved, in preparation, submitted, in press, published). The GIC will also manage the SPIROMICS publications database, which will include copies of all approved proposals and published abstracts and manuscripts.

4. Manuscript / Abstract Proposal Submission Procedures

Proposals for manuscripts and abstracts may be submitted by any SPIROMICS investigator, member of a SPIROMICS Reading Center or the GIC, with the approval of the local PI. The PPC may also take the initiative and recommend specific topics for papers or presentations, based on its own deliberations.

Investigators who join a consortium should submit a manuscript proposal at the time of entry to the consortium. In addition to the required information, the manuscript proposal should also contain the name of the consortium, main goal, list of member studies, and the name of organizer and/or key members.

The process for proposal submission is available on the SPIROMICS secure area website via the entry of an online manuscript or abstract proposal form. The GIC will monitor submissions and notify the PPC of necessary reviews. The PPC will assign reviewers, discuss reviews, vote on approval, make scientific and analytic recommendations, and establish any necessary priorities needed at the GIC to process and/or analyze the data.

Authors should not proceed with a manuscript without an approved manuscript proposal. Approval will require presence of a minimum of four voting members of the publications committee. If four members are not present, a provisional decision will be made and sent for email review by the full committee.

Proposals for genetics consortia manuscripts where SPIROMICS data is pooled with multiple other cohorts will still need to be approved by both the genetics and PPC, but the overview and analytic plan may be brief.

5. New Manuscripts

The first author of a paper will generally be the proposer unless that proposer indicates in writing that he or she nominates another member of the writing committee to be lead author. Approval of the PPC is required.

In general, first authors should lead no more than three study-wide papers at any one time, unless there are special considerations. This is to ensure timely progress on the papers and to afford the opportunity for others to propose papers.

Authorship and Writing Groups:

- For each new manuscript the proposal of which has been approved by the PPC, a writing group will be determined by the proposer with input from the PPC. Unless a manuscript utilizes data generated only at a specific site, all manuscripts should be circulated to the PI's of clinical centers and cores where data to be included in the manuscript was generated as well as the GIC to offer the opportunity for authorship to at a minimum one author per center/core/GIC. If no response to a request has been received after two reminders, one week apart, then the proposer may proceed without involvement of that center/core/GIC. Ideally, manuscripts would be discussed with members (or at a minimum the leadership) of working groups/committees relevant to the topic before being sent to the PPC.
- The lead author (writing group chair) determines the order of authorship. A major criterion for the order of authorship is the level of effort and contribution made by the members of the writing group.
- It is the responsibility of the writing group chair to communicate with other writing group members, to identify data needed from the GIC, and to establish a plan for writing the manuscript.
- All members of the writing group should review and approve the final manuscript proposal and the final manuscript draft before its submission to the PPC.
- Final drafts of the manuscript should be submitted to the GIC (which will check the accuracy of the data reported and the methods of analysis), which will distribute the manuscript draft to the PPC. Upon approval by the PPC a draft will be circulated to the SC for comments by interested members and the NHLBI.
- If the writing group chair feels that some members of a writing group have shown little or no interest in participating in the work of the group or have failed to contribute to the task of preparing the manuscript, the writing group chair can ask the PPC to review the situation and determine if the author list should be revised.
- Special Considerations: In certain instances, authors may have strong rationale for a more limited authorship group i.e. the need to maintain intellectual property (IP). In such instances, authors should make the request for limited authorship, ideally, at the time of manuscript proposal. Engineering, statistical, or technical reports are examples of manuscript types that may fall into this category. Authors must include their rationale for limited authorship, and the final decision will be made by the SPIROMICS Publications Committee. Disagreements may be appealed to the SPIROMICS Steering Committee.

Status Reporting:

- The Chair of each writing group is to update the PPC on manuscript progress every six months after the manuscript proposal is approved, unless the PPC requests more frequent updates. If the PPC has not received a report from a lead author within 12 months (unless otherwise specified) or if satisfactory progress has not been made:

- The PPC may replace the lead author with another member of the writing group.
- If no writing group members are interested in assuming the lead position, other SPIROMICS investigators outside of the writing group may be solicited to be lead author.
- All members of the writing group, as well as the GIC, should see the manuscript after revisions suggested by the journal are made.
- The writing group must prepare a lay summary that will be used by the NHLBI for publicity and also be available on the SPIROMICS website.

6. Requests for Data

Some papers may have data analyses done by the GIC.

For those analyses done by the writing group the following rules apply:

- SPIROMICS data used for analyses for the paper will be provided by the GIC after approval of manuscript proposals that specify the dataset required.
- NHLBI style rules for data distribution will apply, implemented through signed data distribution agreements.
- The GIC will independently validate key findings prior to publication or presentation.

7. Types of Manuscripts

- **Mainline:** Dealing with the major hypotheses or overall aspects of the study (e.g. overall recruitment effort, population description, etc.). Analysis of these aspects of the study must be done by the GIC.
- **Secondary:** Dealing with a secondary outcome of the study, substudy or an aspect of the study that is more “select” than “general”—this decision will be a judgment call and can be debated.
- **Ancillary:** Resulting from a SPIROMICS ancillary study
- **Local:** Most papers will be study-wide, i.e. will use data from all the entire SPIROMICS data set to preserve and make maximum use of the full, unique cohort. A proposal for using only site-specific data may be considered if appropriate. Authorship for local, site-specific papers will be considered on a case-by-case basis.
- **Consortia:** Papers resulting from the pooling of Spiromics data with that of other cohorts. Spiromics specific authorship for such papers will frequently be limited (4-6 authors) due to large number of authors from other institutions. Spiromics specific authorship will be determined by those conducting the

analyses with approval of any other relevant committee (typically genetics) in addition to the PPC.

8. Authorship and Credits

- For mainline and secondary papers, proposing investigators may suggest an authorship format pending agreement by the PPC (see below).
- A full credit roster should be listed in all mainline and secondary papers. The credit roster includes members of the **SPIROMICS Research Group**. The SPIROMICS Research Group consists of the entire set of personnel involved in the conduct of SPIROMICS, including all committee members, the NHLBI project officer, industry partners and clinical and reading center certified and support staff.
- Authorship formats:
 - **Modified conventional:** Masthead (indexed) author = "Name A, Name B, Name C, etc. for the SPIROMICS Research Group"; the writing committee for the paper will determine the order of the named authors. This is the preferred format for most manuscripts.
 - **Corporate:** Masthead (indexed) author = "SPIROMICS Research Group"; membership of writing committee is nowhere specified in the published article
 - **Modified corporate:** Masthead (indexed) author = "SPIROMICS Research Group"; title page footnotes include a listing of the writing committee for the paper; the writing committee for the paper will determine the order of the named authors in the footnote
 - **Conventional:** Masthead (indexed) author = "Name A, Name B, Name C"; the writing committee for the paper will determine the order of the named authors
 - All SPIROMICS primary and secondary papers should use this statement for Acknowledgements:

“The authors thank the SPIROMICS participants and participating physicians, investigators and staff for making this research possible. The authors thank the SPIROMICS participants and participating physicians, investigators and staff for making this research possible. More information about the study and how to access SPIROMICS data is at www.spiromics.org. We would like to acknowledge the following current and former investigators of the SPIROMICS sites and reading centers: Neil E Alexis, MD; Wayne H Anderson, PhD; Mehrdad

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- All SPIROMICS abstracts should use this statement for Acknowledgements:

“SPIROMICS was supported by contracts from the NIH/NHLBI (HHSN268200900013C, HHSN268200900014C, HHSN268200900015C, HHSN268200900016C, HHSN268200900017C, HHSN268200900018C, HHSN268200900019C, HHSN268200900020C), grants from the NIH/NHLBI (U01 HL137880 and U24 HL141762), and supplemented by contributions made through the Foundation for the NIH and the COPD

Foundation from AstraZeneca/MedImmune; Bayer; Bellerophon Therapeutics; Boehringer-Ingelheim Pharmaceuticals, Inc.; Chiesi Farmaceutici S.p.A.; Forest Research Institute, Inc.; GlaxoSmithKline; Grifols Therapeutics, Inc.; Ikaria, Inc.; Novartis Pharmaceuticals Corporation; Nycomed GmbH; ProterixBio; Regeneron Pharmaceuticals, Inc.; Sanofi; Sunovion; Takeda Pharmaceutical Company; and Theravance Biopharma and Mylan.”

9. Review of Completed Manuscripts Prior to Journal Submission

Upon completion of a manuscript, the authors should submit it to the GIC for a review of the analyses in the paper. The GIC maintains oversight of all analyses of study data but may not necessarily repeat the analyses, unless there are concerns or a repeat analysis is specifically requested. Once this review is completed, the manuscript will be reviewed by the PPC. This review is not intended to be exhaustive but rather an overview to insure the SPIROMICS data are accurately represented. Approval will require presence of a minimum of four voting members of the publications committee. If four members are not present, a provisional decision will be made and sent for email review by the full committee.

Some manuscripts, particularly those deemed “core analyses,” may require review by NHLBI prior to journal submission. Authors will be notified during the manuscript proposal process if this will be required.

10. Abstracts for Regional, National, and International Meetings

Authors of abstracts must usually meet a deadline determined by the organizers of the meeting where the abstract is to be presented. Authors should allow sufficient lead time for the internal review of abstracts in order to meet that deadline. Abstracts must be approved by the PPC.

The PPC is to maintain a current list of all relevant meetings and their deadlines for submission of abstracts. Abstracts must be submitted to the committee for review at least two weeks before the due date unless special circumstances prevail. Abstracts will be expeditiously reviewed by a minimum of two members of the PPC, who are asked to recommend approval, modifications, or disapproval of the abstract.

The lead author is responsible for submitting abstracts for approval on behalf of all co-authors. In doing so, the lead author certifies that all co-authors have reviewed and approved the final version, as submitted. No person should be included as co-author if he/she did not read and approve the abstract.

It is preferable that abstracts of papers for presentations are to be prepared at the time a manuscript on the same issue is in preparation.

All abstracts accepted for presentation or publication should be submitted to the GIC for archival purposes.

11. Invited talks

An investigator receiving an invitation for a national talk on behalf of SPIROMICS should submit an abstract of the talk to PPC and must obtain PPC approval. No approval is necessary for local talks or grand rounds.

When an invitation is directed to the Chair of the SC or the GIC, the respective chairs will decide who is to represent SPIROMICS. Invitations directed to the Chair(s) will be sent to the PPC to be reviewed and approved.

When a SPIROMICS investigator receives a personal invitation to make a presentation, he/she should notify the Chair of the PPC to ensure listing of the presentation on behalf of the SPIROMICS Research Group.

All presentations in response to such invitations should be based on published SPIROMICS reports unless prior approval is granted by the PPC and the SC.

Requests received by SPIROMICS PIs or their staff to present or discuss at the investigator's institutional meetings any previously published SPIROMICS data need no prior clearance by the PPC, and acceptance of such invitations is encouraged.

12. Use of Data for Grant Application or Contract Proposal

SPIROMICS data which have not been previously published but which are needed for grant applications or contract proposals must have prior approval for use by the SPIROMICS SC.

13. Local and Regional Presentation and Discussion of Project Data

The PPC acknowledges the need of investigators and students at each site to offer informal presentations of project details within their institution. In order to facilitate this process, and at the same time to protect the integrity and confidentiality of the SPIROMICS database, the PPC requires that each such presentation be personally approved by the site's PI. International and national presentations must be approved by the PPC (see Section 9).

14. Use of Study Logo and Standard Slides

a. Study Logo

Investigators may use SPIROMICS Logo in as part of invited talks or as part of local/regional presentations. If the investigator has any questions about the use of the logo, he or she should contact the GIC with a description of the intended use. Industry partners may use the SPIROMICS logo in presentations but must send a description of the planned use and should provide a copy of the presentation to the GIC.

b. Standard Slides

A set of Standard SPIROMICS slides will be approved by the PPC and maintained on the website. All SPIROMICS investigators will have full access to use these materials. Individuals who prepare new slide materials that may be appropriate for posting on this

website are encouraged to submit these for consideration. Investigators may request slides with updated enrollment and demographic information from the GIC as needed. Industry partners may also use the SPIROMICS slides but must request these through the FNIH or GIC.

15. Administrative Procedures

The Publications and Presentations Committee will hold meetings or conference calls as needed to:

- Monitor the status of study publications and presentations;
- Approve requests for new papers, presentations, publications or abstracts;
- Discuss completed papers and abstracts; and
- Formulate the content of reports to the Steering Committee on the status of study publications and presentations.

The GIC will manage reports of ongoing and planned publications, future meetings, and other planned presentations of project data on the study website.