SPIROMICS
SubPopulations and InteRmediate Outcome Measures In COPD Study

SOURCE
SPIROMICS Study of Early COPD Progression

SPIROMICS and SOURCE

Publications and Presentations Policy

Table of Contents

I. Objectives 2
II. Policy 2
III. Tracking 3
IV. Proposal Procedures 3
V. New Manuscripts 3
VI. Requests for Data 6
VII. Special Manuscript Types 6
VIII. Authorship and Acknowledgement 7
IX. Review of Final Manuscripts Prior to Journal Submission 9
X. Abstracts for Regional, National, and International Meetings 9
XI. Invitations to Present 10
XII. Use of Data for a Grant Application or Contract Proposal 10
XIII. Presentation and Discussion of Study Data 10
XIV. Use of Study Logo, Poster Template, and Slide Template 11
XV. Administration 11

SPIROMICS and SOURCE Publications and Presentations Policy

I. Objectives

The primary objective of the Publications and Presentations Policy is to ensure the appropriate, efficient, and accurate use of data without restricting scientific inquiry. This policy is to ensure:

a. Expeditious and timely dissemination of major findings to the scientific community.

b. Accurate and scientifically sound publications.

c. Promotion of fair and collaborative authorship on publications.

In addition, this policy will describe infrastructure to support:

a. Review and oversight of proposals, manuscripts, abstractors, and presentations.

b. Opportunities for investigators from clinical centers and outside investigators with appropriate expertise to participate and be recognized in study-wide publications and presentations.

c. Creation of writing groups and an orderly system for setting priorities and providing timely review of manuscript proposals.

d. Mechanisms for appropriate tracking and reporting of all publications and presentations.

II. Policy

The Steering Committee (SC) will appoint a Publications and Presentations Committee (PPC), which will be composed of members from the clinical sites, study cores, and the Genomics and Informatics Center (GIC). The Chair(s) of the PPC will be appointed and approved by the SC. In order for any submission (manuscript proposal, abstract, draft manuscript, or final manuscript) to be reviewed, a quorum (defined as the GIC plus six entities including clinical sites, reading centers, and/or cores) must be present. If a quorum is not present, a provisional decision will be made and sent for review by the full PPC via email.

In order to fulfill the objectives listed above, it is the policy of the SC and PPC that all manuscripts deriving from study data (including questionnaire, imaging, biomarker, genetics, local, and ancillary) be proposed to the PPC for scientific review and approval. If necessary, the PPC will also establish priorities for the GIC to process, analyze, and/or verify data being reported.

All proposals (for abstract or manuscript) submitted for review must be sponsored/mentored by a study Principal Investigator (PI). Ideally, even with an active DMDA contract, a study PI should sponsor or collaborate on proposals submitted by non-study/external investigators. In cases where a non-study/external investigator does not wish to collaborate with SPIROMICS and SOURCE, they should obtain the data from a NIH or NHLBI data repository, e.g.

Biologic Specimen and Data Repository Information Coordinating Center (BIOLINCC), database of Genotypes and Phenotypes (dbGaP), or BioData Catalyst® (BDC). Given the vast expertise of the SPIROMICS and SOURCE investigators, partnership and collaboration are highly encouraged, as these efforts offer significant scientific benefits. Working together allows for the pooling of knowledge, resources, and methodologies, which can lead to more comprehensive insights and impactful outcomes in the field.

III. Tracking

The GIC will oversee and facilitate all necessary processes related to submissions, ensuring smooth management and coordination. The GIC will manage the tracking database and provide routine progress reports which will include all manuscript proposals, abstract proposals, draft manuscripts, and published manuscripts.

IV. Proposal Procedures

Proposals for abstracts and manuscripts may be submitted by any investigator, with the approval of a clinical site or core PI. The PPC may also take the initiative and recommend specific topics for papers or presentations, based on its own deliberations. Authors are required to obtain approval from the PPC before proceeding with manuscript preparation. Manuscripts should not move forward without an approved proposal.

Prior to submission of an abstract or manuscript to the PPC, investigators are encouraged to identify a relevant SPIROMICS/SOURCE Working Group for discussion. This step is considered important to (a) engage broader expert opinion and obtain relevant scientific input, (b) avoid overlap with other ongoing SPIROMICS/SOURCE manuscript proposals, (c) identify potential collaborators for data interpretation, (d) identify individuals willing to participate in a small selected writing group. Investigators can work with the GIC or directly contact a Working Group Chair to have their proposal added to the appropriate working group agenda.

A reference form, user guide, and demo of the submission process, via the GIC's web-based Carolina Data Acquisition and Reporting Tool (CDART) Manuscript and Ancillary Study Tracking (MAST) system, are available on the study website under Researchers > Publications > Policies and Forms.

V. New Manuscripts

The first author of a manuscript is generally the proposer unless the proposer indicates in writing that he or she nominates another member of the writing group to be the lead author.

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

manuscripts.

a. **Writing Groups and Authorship**

i. For all new manuscripts proposed and approved by the PPC, we strongly encourage the formation of a writing group, led by the proposer. The writing group is an opportunity for meaningful contribution/participation from investigators across SPIROMICS and SOURCE, ultimately improving the quality of manuscripts from the network. The single most important criterion for authorship is meaningful intellectual contribution to the project or manuscript in question.

a. Manuscript proposals should be circulated to the clinical center, reading center, and core PIs where the data being included in the manuscript was generated as well as to the GIC to offer the opportunity for writing group participation and authorship to a minimum of one author per clinical site, reading center, core, and the GIC. If no response to a request is received after two reminders, sent one week apart, then the proposer may proceed without involvement of that clinical site, reading center, or GIC PI. Upon request, the GIC can facilitate this effort.

b.]Ideally, manuscripts should be discussed with members (or at a minimum the leadership) of working groups and committees relevant to the topic before being sent to the PPC.

c. Exceptions to this opportunity for broad participation include 1) manuscripts utilizing data generated only at a single site; 2) highly technical reports that do not incorporate significant clinical data; 3) multi-network manuscripts that did not originate from SPIROMICS nor SOURCE (for instance, in which SPIROMICS or SOURCE is functioning as a validation cohort).

ii. The lead author (writing group chair) determines the order of authorship. In the event the lead author is relatively junior, the sponsoring site or core PI, may play a major role in this decision. A major criterion for the order of authorship is the level of effort and contribution made by the members of the writing group.

iii. 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 and timeline for writing the manuscript.

iv. All members of the writing group should review and approve the final manuscript proposal and the final manuscript draft before submission to the PPC, via CDART MAST.

v. The final draft of a manuscript, as well as the analysis dataset, should be submitted to the GIC (which may check the accuracy of the data reported and the methods of analysis), via CDART MAST which will review and move the manuscript draft to the PPC for review and approval.

vi. For all draft manuscripts, the PPC will assign two committee members to provide a detailed review. The PPC will discuss these reviews, make scientific and analytic recommendations, and vote on approval during the regularly scheduled working meetings bi-monthly.

vii. 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.

viii. **Special Considerations:** In certain instances, lead authors may have a strong rationale for a more limited writing and/or authorship group i.e., the need to maintain intellectual property (IP). Engineering, statistical, or technical reports are examples of manuscript types that may fall into this category. Similarly, in selected instances it may be appropriate to limit the number of named authors and instead include the following corporate banner statement ("*on behalf of the SPIROMICS and SOURCE investigators*"). In such instances, authors should make the request, including rationale, for limited writing group and authorship at the time of the manuscript proposal, and the final decision will be made by the PPC. Disagreement with the PPC decision may be appealed to the SC.

b. **Status Reporting**

i. The lead author (writing group chair) should 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 propose replacing the lead author with another member of the writing group. If no writing group members are interested in assuming the lead author position, other study investigators outside of the writing group may be solicited by the PPC to be the new lead author.

ii. The writing group may be asked to prepare a lay summary of manuscripts that have been accepted for publication, which can be used by the NHLBI for publicity and be available on the study website under Researchers > Publications > Published Manuscripts. The writing group can opt out of this request.

VI. Requests for Data

Manuscripts may have funding for or a need for data analyses and/or data related services to be completed by the GIC.

For all SPIROMICS and SOURCE proposals the following policies apply:

a. Data used for manuscript analyses will be provided by the GIC after approval of the manuscript proposal that specifies the dataset(s) required. Gaining access to data from another investigator directly will not be supported.

b. Policies congruent with those of the NIH for data and materials distribution will apply, implemented by the GIC through a signed and executed Data and Material Distribution Agreement (DMDA) between The University of North Carolina at Chapel Hill and the institution(s) accessing data and materials for data access and analyses.

c. The GIC reserves the right to independently validate key findings prior to publication or presentation.

d. Applicable NIH and NHLBI policies are:

   i. NIH Data Sharing Policy: https://sharing.nih.gov/data-management-and-sharing-policy
   ii. NHLBI Supplement to the NIH Data Sharing Policy: https://www.nhlbi.nih.gov/grants-and-training/policies-and-guidelines/nhlbi-policy-for-data-sharing
   iii. NHLBI 3rd Party Policy: https://www.nhlbi.nih.gov/grants-and-training/policies-and-guidelines/third-party-involvement-in-nhlbi-supported-clinical-trials-and-other-population-based-studies-awardee-contractor-third-party-related-issues

VII. Special Manuscript Types

a. **Primary:** Resulting from the primary aims and hypotheses of the study (e.g., overall recruitment effort, population description, etc.). These will be led by SPIROMICS and SOURCE leadership.

b. **Local Site:** Most manuscripts will be study-wide, i.e., will use data from the entire cohort to preserve and ensure maximum use of the full, unique cohort(s). A proposal for using only site-specific data may be considered, if appropriate. The decision to have limited authorship for local, site-specific manuscripts will be considered on a case-by-case basis by the GIC, PPC, and SC.

c. **Dissertations**: A manuscript proposal is not required for a dissertation until individual abstracts and/or manuscripts are contemplated. Once contemplated, the student is required to follow the standard process and associated policies. However, the student and their advisor are strongly

encouraged to maintain engagement with the site PI and relevant working group(s) as the dissertation progresses.

d. **Consortia**: Consortia manuscripts are analyses resulting from the pooling of SPIROMICS and/or SOURCE data with that of one or more other cohorts or where SPIROMICS and/or SOURCE data is being used as a validation cohort for an analysis conducted in another cohort. Authorship for consortia manuscripts will frequently be limited due to the number of authors from other cohorts and institutions. Consortia manuscripts for which the analysis originates from SPIROMICS and/or SOURCE investigators, regardless of the number of additional cohorts and institutions that might be included in the analysis, would go through the usual study processes described in this policy (meaning the manuscript proposal will be circulated to all SPIROMICS and SOURCE PIs). SPIROMICS and SOURCE specific authorship will be determined by those conducting the analyses with the approval of any other relevant committee in addition to the PPC. In these situations, the involvement of relevant working group(s) and/or committees is required.

i. All TOPMed consortia manuscripts are required to involve and gain approval, at a minimum, from the Biomarkers, Genetics, and Genomics Committee before the proposal will be reviewed by the PPC.

Manuscripts originating from outside the SPIROMICS and SOURCE networks are encouraged to include collaboration and/or sponsorship from study investigators. In such cases, the manuscripts will undergo the standard PPC scientific review process and be subject to PPC policies.

Manuscripts whose author(s) fail to adhere to the PPC policies will not receive support from SPIROMICS nor SOURCE in the final publication phase, may be reported to the journal editor, and may result in revocation of access to study data through the SPIROMICS and SOURCE GIC in the future.

VIII. Authorship, Acknowledgement, and Conflict of Interest

a. For primary and secondary manuscripts, proposing investigators may suggest an authorship format pending agreement by the PPC (see below).

b. A complete and up to date investigator roster should be listed in all primary and secondary manuscripts. The investigator roster is maintained by the GIC, approved by the EC, and includes members of the “SPIROMICS and SOURCE Investigators” which consists of the entire list of key personnel involved in the conduct of SPIROMICS and SOURCE, including all committee members, the GIC, the NHLBI program officer(s), clinical site, reading center, and core investigators, certified support staff, and industry partners.

c. Manuscripts reflecting local or site-specific findings are encouraged, but they should be submitted 1) after manuscripts covering the same topic based on the entire cohort have been published or accepted for publication, or 2) if the PPC does not anticipate publication from the entire cohort on the same topic.

d. Authorship format:

i. **Modified Conventional:** Masthead (indexed) author = "Name A, Name B, Name C, etc. “for the SPIROMICS and SOURCE Investigators"; the writing group for the manuscript will determine the order of the named authors. This is the preferred format for most manuscripts.

ii. **Corporate:** Masthead (indexed) author = "SPIROMICS and SOURCE Investigators"; membership of writing group is not specified in the published article.
Corporate should be used when a journal limits the number of authors or when the vast majority of the work is from a very small number of authors. This decision is at the discretion of the lead author, with review and approval by the PCC at the time of proposal and again at the review of the draft manuscript.

iii. **Modified Corporate:** Masthead (indexed) author = "SPIROMICS and SOURCE Investigators"; title page footnotes include a list of the writing group members for the manuscript; the writing group for the manuscript will determine the order of the named authors in the footnote.

iv. **Conventional:** Masthead (indexed) author = "Name A, Name B, Name C, etc."; the writing group for the manuscript will determine the order of the named authors.

e. All manuscripts should include the SPIROMICS and SOURCE Acknowledgement and Funding Statement. The statement is maintained by the GIC and is available on the study website under Researchers > Publications > Policies and Forms.

f. Conflict of Interest Statements (COI) for several study investigators are available on the study website under Researchers > Publications > Conflict of Interest Statements. The GIC request COIs from study investigators once annually and updates the study website with all of the statements received. However, if a COI is needed from an investigator and one is not available on the study website, the lead author is responsible for the request and follow-up. As time allows, the GIC may be able to assist upon request.

IX. Review of Final Manuscripts Prior to Journal Submission

Upon completion of a manuscript, the lead author should submit the final manuscript, via CDART MAST, for a review of the analyses and manuscript by the GIC and PPC. The GIC maintains oversight of all study data analyses but will not necessarily repeat analyses unless there are concerns or a repeat analysis is specifically requested by the PPC or SC. This final GIC review before journal submission is not intended to be exhaustive but rather an effort to ensure the data are accurately represented, and that authorship, funding, and acknowledgements align with study policy.

Manuscripts, particularly those deemed “primary,” may also require review by the NHLBI program officer(s) prior to journal submission. Authors will be notified during the manuscript proposal process if this will be required.

It is the responsibility of the lead author(s) to provide the GIC and thus the PPC updates, via CDART MAST, on the publication status of the manuscript after journal submission of the final status of the manuscript (i.e., journal acceptance, invitation to re-submit a revised version of the manuscript with author responses to major and/or minor reviewer comments, withdrawal, submission to a different journal, etc.).

X. Abstracts for Regional, National, and International Meetings

Authors must meet a deadline determined by the organizers of the meeting where the abstract is to be presented. Authors should allow for sufficient lead time for the required SPIROMICS and SOURCE proposal submission and abstract draft, via CDART MAST, in order to then meet the meeting organizers’ submission deadline. Abstracts must be proposed, abstract draft reviewed by, and approved by the PPC. Abstracts must be associated with an approved manuscript proposal to be reviewed by the PPC. In the event that an abstract ultimately leads to a manuscript that goes beyond the original scope of the abstract, the manuscript proposal must be revised and submitted, via CDART MAST, for review and approval.

The GIC will curate and publish a current list of all relevant meetings and their deadlines for submission of abstracts on the study website under About > News Archive. Proposals and associated abstracts should be submitted for review at least two weeks (10 business days) before the meeting organizers’ submission deadline unless special circumstances arise. Proposals and associated abstracts will be expeditiously reviewed by a minimum of two members of the PPC, who are asked to review and recommend approval, approval with modifications, or disapproval.

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

Ideally, abstracts written from an existing manuscript should be submitted at the same time as the manuscript proposal and draft. In the event an abstract is submitted to a conference or organization without prior PPC approval, the PPC should be notified so that the abstract can be reviewed asap. In the event the PPC does not grant approval of the abstract, it must be withdrawn from the conference or organization and the data not presented.

XI. Invitations to Present

An investigator receiving an invitation to speak on behalf of SPIROMICS and/or SOURCE should submit a summary of the planned presentation to the PPC for review and approval. PPC approval is not required for local clinical site talks or **local site** medical grand rounds.

When an invitation is directed to the GIC or the Chair of the SC, the respective chairs will decide who is to represent the network. Invitations will be sent to the PPC for review and approval.

When a SPIROMICS or SOURCE investigator receives a personal invitation to present, he/she should notify the Chair(s) of the PPC to ensure listing of the presentation on behalf of the “SPIROMICS and SOURCE Investigators.”

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

Requests received by SPIROMICS and SOURCE PIs or their staff to present or discuss at the investigator’s institution led meetings any previously published SPIROMICS and/or SOURCE data do not need prior approval by the PPC or the SC. Acceptance of such invitations is encouraged.

XII. Use of Data for a Grant Application or Contract Proposal

Requests for existing data which have not been previously published but which are needed for grant applications or contract proposals must be submitted to and approved by the Ancillary Studies Committee (see the Ancillary Studies Policy for more details). Grant applications requesting/requiring a letter of support (LOS), require an ancillary study proposal, via CDART MAST, and must be approved by the Ancillary Study Committee and the SC before the GIC provides a LOS.

XIII. Presentation and Discussion of Study Data

The PPC acknowledges the need for 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.

XIV. Use of Study Logo, Poster Template, and Slide Template

a. **Study Logo**
Investigators may use the SPIROMICS and SOURCE study logos as part of invited talks and local/regional presentations. If the investigator has any questions about the use of the logo, they should contact the GIC with a description of the intended use. Industry partners may use the study logos in presentations but are required to send a description of the planned use along with a copy of the presentation to the GIC. The study logos are available on the study website under Researchers > User Dashboard > Branding and Document Templates.

b. **Poster Template and PowerPoint Slide Template**
SPIROMICS and SOURCE investigators have access to these resources. Individuals who prepare presentations that may be appropriate for posting on the study website are encouraged to submit them for consideration. Investigators can access up to date Data Management Reports for tables and figures via the study website under Researchers > Documents > Study Reports. Non-study investigators and industry partners may also use these resources but must request use through the GIC. All presentations must include the appropriate Acknowledgement and Funding Statement available on the study website under Researchers > Publications > Policies and Forms. The PPC approved PowerPoint templates are maintained by the GIC and are available on the study website under Researchers > User Dashboard > Branding and Document Templates.

XV. Administration

The PPC meets twice per month to:

a. Monitor the status of study publications and presentations.

b. Review and approve proposals for new abstracts, manuscripts, presentations, and/or to review and approve final manuscripts for journal submission.

c. Discuss completed abstracts and manuscripts.

d. Formulate the content of reports to the SC and OSMB on the status of study publications and presentations.

The GIC is responsible for supporting the PPC chair(s) and managing the oversight of CDART MAST, study data, logistics, tracking, and reporting to meet the needs of the PPC.