AIBC Publication Guidance Document

**Statement of General Principles Regarding Publications**

The primary goal in conducting the Alpha-1 Biomarkers Consortium (A1BC) study is to disseminate results of the research to the scientific community. These results will include primary study outcomes, subgroup and retrospective analyses, and ancillary materials (methodology and statistical documents). The A1BC Study Group will actively plan to publish its clinical trial data in peer-reviewed biomedical journals and to disseminate learnings through submission of abstracts to national and international scientific congresses.

**A Publication Advisory Committee comprised of the Principal Site Investigators at each NIH and Alpha-1 Foundation funded site will comprise the committee** and set policy in publication planning, authoring, review, and approval of peer-reviewed pieces relating to the RENEW dataset**. A chair of the committee is chosen by 2/3 of the PI investigators** and serves as the point of contact for data dissemination plans, publication proposals, and review of all publications (abstracts and manuscripts).

**Key Principles**

a. Per International Committee of Medical Journal Editors (ICMJE) guidelines, Good Publications Practice (GPP2) and other associated guidance relating to clinical trial authorship, all individuals who have made substantial intellectual contributions to the study (in terms of the study conduct, operationalization, design) and/or the development of the resulting manuscript shall, whenever possible, be credited as authors

b. all individuals credited as authors shall deserve that designation

c. all others who contribute to a level not rising to authorship will be acknowledged appropriately

d. Site Contract publication rights shall be respected.

**Scope**

The scope of data covered under this guidance includes:

a. all data relating to the primary study endpoints

b. all analyses relating to secondary and tertiary endpoints

c. additional exploratory, post-hoc, and subgroup analyses of efficacy and/or safety data generated under sponsor-initiated protocols

d. methodology and/or technical manuscripts relating to the study.

**A *manuscript***is defined as any written document submitted to a peer-reviewed professional journal, any non-indexed periodical in the field of medicine/pulmonary medicine, any scientific meeting (in oral or written form), or for other publication, i.e., a book chapter. It does not include white papers, regulatory documents, or articles written for industry or trade publications.

***Primary manuscript***refers to publications that report any data generated per the objectives that were described in the study protocol/statistical analysis plan.

***Secondary manuscript***means analyses of exploratory outcomes generated from raw clinical study data, including imaging data, and all subgroup analyses not covered in publication of the primary manuscript, pre-specified analyses, retrospective analyses combining one or more centers.

***Review Paper***refers to statistical, study design and methodology papers, etc. or structured literature reviews that may or may not include a structured associated statistical report (i.e., a meta-analysis).

***A1BC Dataset***refers to all data collected as part of the NIH A1BC Study (but not data collected in the Alpha-1 Foundation Research Registry)

***Data and Publication Proposal form***refers to the publication plan developed by the authors, the statistical and clinical support teams and approved by the Publication Committee. This refers to the formal request for access to data to develop a manuscript for publication submission. Acceptance by the Publication Committee of a Publication Proposal will lead to generation of a Data Dissemination Plan.

**Role and Responsibilities of the Publications Committee**

1. Promote, facilitate, and monitor the timeliness of publication of clinical data.

2. Maintain absolute confidentiality of all data, manuscript concepts, ideas, proposals, and discussions.

3. Propose additional policy guidelines for authorship of publications and updates to this Policy as necessary.

4. Assure compliance with international publication policies.

5. Advise on authorship matters when necessary and requested, including availability for meetings to review and discuss proposals.

6. Review, edit, and approve publications and presentations as necessary, prior to submission and in response to reviewer comments.

7. Reviews will be conducted per the following general editorial guidelines:

a. Ensure that all publications represent the full scientific integrity of the study, are intellectually honest and balanced

b. Correct factual and conceptual inaccuracies

c. Safeguard the rights of study participants

d. Prepare comments to assist collaborators in publishing papers of the highest quality and clarity

e. Avoid conflict with and/or duplication of other publications

f. In reviews, ensure that all reviewers’ comments are addressed and responses or changes to the draft are documented.

8. Ensure that publication of review papers or retrospective study data will not threaten the timing and/or content of presentation or publication of the primary manuscripts.

9. Ensure that new data elements captured in any manuscript have that data returned to the data files for the A1BC so that other investigators can use these data elements for subsequent projects.

10. Adjudicate disputes involving publication issues.

11. Recommend ideas for dissemination of A1BC data (raw or analyzed, aggregated or sub-grouped, retrospective or prospective, published or unpublished).

12. Exceptions to this policy may be recommended by the Publications Committee and approved by the A1BC steering committee management.

**Rights of Publication: Lead Authorship for Primary and Key Secondary Manuscripts**

1. Manuscript authorship and a Data and Publication Proposal shall be approved the Publications Committee, and in accordance with the general principles set forth in GPP3 and ICMJE guidelines.
2. 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.
3. The envisioned manuscripts include the following as first steps
   1. Trial design manuscript
   2. Primary manuscript of baseline data and correlations
   3. Cytokine/MMP Biomarkers (blood)
   4. Genetics-variants
   5. Other radiology parameters
   6. Liver - FIB4, MELD, liver symptoms, and correlations with lung disease
   7. Environmental exposure
   8. Exacerbations/COVID-19 infection
   9. Comorbidities
   10. Longitudinal correlates of CT density change
   11. Comparisons to the Irish Cohort
   12. Look back at the Registry Data for 270 participants
   13. Spiromics Propensity Analysis with PiMM subjects

4) Corresponding Author/Lead Author and the Senior Author for the primary manuscript and priority secondary manuscripts shall be based on the criteria of

a. A1BC Study enrollment

b. Involvement in development of the protocol and/or Statistical Analysis Plan

c. academic standing or prominence as a recognized expert in the field of the topic of the manuscript and/or with the specific subject matter expertise related to the manuscript content

d. commitment to submission of the finished manuscript within **3 months** of the finalization and delivery of all datasets required to complete the manuscript

e. quality of the publication proposal, strategic publication objectives, quality of the data analysis methodology, authorship team, and review by the Publication Committee.

**Publication Proposal, Review, and Acceptance Process**

Any request for access to data for development of a publishable manuscript shall include the following in a written Publication Proposal submission to the Publication Committee

* 1. Hypothesis or statement of intent
  2. Definition, type and scope of data requested
  3. Statement of support requested for data compilation, analysis, provision of raw data.
  4. Statement of support available from the Lead Author or authorship group
  5. A proposed authorship listing and order
  6. Submission timing and journal target(s)

In case of conflict between two very similar requests or hypotheses, the Publication Committee will consider the order in which the manuscript proposal was received, the importance of the proposal content to excellence in clinical practice, likelihood of acceptance in higher-ranking journals, publication experience and academic credentials of lead author(s), comprehensiveness of the proposal, and alignment with the study publication strategy.

All petitioners will receive a written response outlining the criteria evaluated in the decision process.

**Manuscript Review**

1. The Lead/Corresponding author shall be responsible for soliciting review and collecting comments by each contributing author, and for ensuring that all authors are provided with the opportunity to review and comment on key revisions of the manuscript.

2. All listed authors must complete a COI form or provide a statement as per journal requirements.

3. Manuscripts must be completed and submitted within a reasonable period per the publication plan.

a. If the manuscript draft is not substantially complete per the timing established in the Data Dissemination Plan, the Publications Committee reserves the right to make other arrangements, including reassignment of the manuscript, to ensure timely submission.

b. Co-authors should be given at least two weeks (10 business days) to review a manuscript and provide revisions/suggestions. If, after the two-week review period has concluded, the lead investigator has not heard back from a co-author, he/she should adhere to the following process:

1. Send a reminder email to the co-author. The co-author should be given three business days to provide revisions/suggestions.

2. If the co-author does not respond within three business days, send a second reminder email to the co-author. The co-author should be given an additional three business days to provide revisions/suggestions. This email should include the reminder that co-authors who do not respond to a second reminder email for manuscript feedback are removed from authorship. If a Co-author is removed from authorship, then notification of the co-author, the co-author’s site Principal Investigator, and the chair of the Publication Committee will be made.

c. The Publications Committee may grant an extension when it is deemed appropriate.

4. Following submission to a journal, the lead author is responsible for:

a. Keeping the Publications Committee informed in a timely manner regarding status of journal review.

b. Forwarding copies of the journal reviewers’ response to all members of the manuscript’s writing committee.

c. Should a manuscript not be accepted, the Publication Committee and the Corresponding/Lead author shall meet to determine appropriate next steps.

**Authorship**

1. Primary Manuscripts: Authorship representation on primary manuscripts shall include the participant institution’s Principal Investigator. a. Key study participants, including Sub-Investigators, shall be considered for inclusion in the Study Group. Principal Investigators shall submit a request to the Corresponding/Lead author nominating appropriate individuals for Study Group listing.

If a site PI leaves an institution prior to manuscript submission, s/he maintains his/her authorship rights with the permission of the Publication Committee, provided s/he has accrued patients to the study and continues to work with the Study team.

2. Secondary Manuscripts: Authorship representation on secondary manuscripts shall be approved by the Publications Committee per the Publication Proposal.

3. Abstracts and Meeting presentations: The Publications Committee must approve the concept and content of any abstract submitted to a scientific conference and any data intended for use in an invited presentation. Site specific data is exempt from this requirement.

**A1BC Acknowledgment and Funding Statement**

All A1BC abstracts and papers should use this statement for Acknowledgements:

The authors thank the A1BC participants and participating physicians, investigators, study coordinators, and staff for making this research possible. More information about the study and how to access A1BC data is available at https://researchinalpha1.org/alpha1/public/Ancillary%20Studies. The authors would like to acknowledge Columbia University for sample processing, storage, and sample disbursements and the University of Alabama Birmingham for CT quality control and analysis. A1BC was supported by grants from the NIH/NHLBI (UH3HL152323), NIH/NCATS (5UL1TR001450) and supplemented by contributions made through the Alpha-1 Foundation.

**A1BC Data and Publication Proposal**Please provide a brief description of the proposal. If dependent on the Columbia University Statistical Team then you must have discussed the proposal with Dr. D’Armiento and obtained her approval. It is expected that this proposal will be 1 page or less.

**Proposed Manuscript Title:**

**Hypothesis or statement of intent:**

**Definition, type and scope of data requested:**

**Statement of support requested for data compilation, analysis, provision of raw data:**

**Statement of support available from the Lead Author or authorship group:**

**A proposed authorship listing and order:**

**Submission timing and journal target(s):**