

International Pediatric Fungal Network (PFN) Publication Policy

This PFN publication policy applies to all manuscripts, abstracts, or external releases of scientific data derived from the PFN database.

I. Mission Statement

The Publication Policy is designed to maintain the scientific integrity of the publications derived from the PFN and to ensure the proper recognition of all contributors. It is also responsible for approving and processing manuscripts and abstracts from the PFN. In addition, it aims to provide a vehicle for young investigators to have the opportunity to take on a leadership role for a PFN study or sub-study publication.

II. Publications Committee

- a. Membership
 - i. The PFN Publications Committee will consist of 8 members: the Director, two Co-Directors, statistician, and four principal investigators from participating sites.
 - ii. All members (except the Director and the statistician) will serve a two-year term with members rotating off in a staggered fashion to ensure continuity. The statistician will be renewed each year. The members will be considered volunteers, appointed by the Director.

b. Purpose

- i. The purpose of the Publications Committee is to:
 - 1. Review all request for data analysis and publication plans through peer review to ensure the scientific integrity of the publications derived from PFN data.
 - 2. To assist in determining fair and appropriate authorship for publications.
 - 3. Oversee primary results from each official PFN study.
- ii. The Publications Committee is also responsible for reviewing and updating the Publication Policy annually.

III. Authorship

- a. Working Group and Lead Author
 - i. The Working Group members of each project (analysis, publication, etc.) should be defined prior to the onset of the project.
 - ii. The Lead and Senior Author of the Working Group will be agreed upon at the onset of the project by all involved in the work.
 - iii. Discussion regarding authorship as well as target journal/conference should take place before project execution.
 - iv. If there is any dispute amongst authors, the Publications Committee will be the arbitrating body with final approval.

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William J. Steinbach, MD
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Co-Directors:
Theoklis E. Zaoutis, MD MSCE
Children's Hospital of Philadelphia



- b. All authors of manuscripts must adhere to the criteria outlined in the target journal.
 - i. The Author must deliver one complete electronic copy of the publication in the English language, including all figures, photographs, illustrations, drawings, charts, maps, and indexes.
- c. All authors of abstracts and manuscripts must have been actively involved in the development and execution of the project.
 - i. Authorship will only be granted to investigators directly involved with the specific project.
 - ii. All authors are required to either:
 - 1. Participate in the drafting of the manuscript OR
 - 2. Provide substantial comments to the Lead Author.
 - iii. Other involvement does not guarantee authorship (e.g. participation in data collection alone).
 - iv. Co-author on the abstract does not guarantee manuscript authorship.
 - v. Author order for a given manuscript or abstract should reflect workload, intellectual contribution, and patient enrolment. The composition of authorship should differ depending on the number of institutions involved, the number of patients accrued, and the nature of any special assessments such as laboratory studies.
 - vi. Persons who do not meet the criteria for authorship, but have contributed to the manuscripts, will be listed in the acknowledgements section.
 - vii. A statement from the Lead Author summarizing the contribution of each co-author will be submitted to the Publications Committee prior to abstract or manuscript submission (See Publications Review Form, Appendix A). If the authorship order is agreed upon by the Working Group, the order will be included as well. If the Working Group requests some input from the Publications Committee regarding the author order, it will be denoted in the cover sheet.
 - viii. Co-authors not affiliated with the PFN will need approval from the Publications Committee to be listed as authors.
- d. All authors must agree that the work, to the best of his/her knowledge is factual and original.

IV. Data Analysis

- Data analysis will generally be performed by the independent statistician for the individual PFN study
- b. If the study statistician does not perform the analysis, the study statistician must validate the analyses prior to submission of the manuscript to any journal.

V. Specimens collected through PFN study

- a. Samples will not leave Duke University.
- b. Studies can utilize the samples that are collected, but the assays or tests will be performed by Duke University researchers, and the aggregate data will be sent.

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VI. Approval of draft manuscripts

a. Before a submission of the final paper to a peer-reviewed journal, the draft will be circulated to all investigators participating in the particular study, the PFN coordinating center, the study statisticians, and representatives of the industry (when appropriate) for suggestions and comments.

VII. Journal submission and editorial changes

- a. Selection of the journal will be at the discretion of the chair of the publication committee.
- b. After a journal review of the manuscript, the dialogue between editors, reviewers, and the publications committee will be handled at the publication committee level.
- c. Correspondence from the editors, including the review, will be distributed to each of the authors listed, the PFN administration, and the study statistician.

VIII. Publications

- a. Publication review must be submitted for each publication. For example, if analysis from an abstract is developed into a manuscript, a separate Publications Review Form must be submitted.
- b. Requests for data will be made to the Publication Committee, which will work with the Clinical Coordinator to determine the best method to supply the requested data for analysis
- c. All publications (abstract, manuscripts, presentations, etc.) must be submitted to the publications committee <u>at least 30 days prior</u> to the submission date. Communication with the Publications Committee during the project well before the end of the project is greatly encouraged.
- d. The Publications Committee reserves the right to review and refuse publication of analyses derived from the PFN.
- e. The Publications Committee will review the publication and may require revisions from the author(s) before final submission. This step is to help guarantee the best science is presented.
- f. Publication data from a sub-study should not interfere with the completion of the parent manuscript, the parent study (e.g., reveal the randomization code), or publication of the primary manuscript.

IX. Publishing individual site results

- a. Rarely, the site investigators may create manuscripts detailing the study at their sites.
- b. These manuscripts must be submitted for review to the PFN Publication Committee and the PFN biostatistician prior to submission for publication.
- c. The submission of manuscripts restricted to individual size data must not interfere with the completion of the parent study or publication of the primary manuscript.

X. Policy on abstracts

a. Guidelines listed above apply when appropriate to abstracts.

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- b. No presentation of primary results from any PFN study will be made without the approval of the PFN Coordinating Center, the biostatistician, and the industry co-sponsor (if applicable)
- c. A copy of all abstracts based on PFN studies must be submitted to the PFN Publications committee and the PFN biostatistician simultaneously before submission for consideration for presentation.

XI. Authorship

- a. Order of authors will be determined by study involvement, which is generally site enrollment
- b. Only one author per study site, unless specifically determined by the Publication Committee
- c. Author for study site will be study site PI unless study site notifies the Publications Committee
- d. No more than 8 authors for brief reports
- e. No more than 12 authors for manuscripts
- f. All other study site PIs will be acknowledged in the "Acknowledgement" section

XII. Acknowledgements

a. In addition to authorship, a PFN manuscript will acknowledge all participating institutions that have enrolled patients. The listing of institutions will be in the order of the number of patients. The listing may include up to four persons per participating institution, participating PFN central unit staff, and biostatistician staff.

XIII. PFN Recognition

- a. All publications derived from the PFN database must include "International Pediatric Fungal Network" as an authorship affiliation associated with appropriate co-authors.
- b. Every publication supported wholly or in part by the PFN must include the following acknowledgement, "This publication was supported in part by the International Pediatric Fungal Network."

XIV. Violations of the Publication Policy

- a. All violations of the Publication Policy are subject to review by the Publications Committee.
- b. If the Publication Committee discovers that the Publication Policy has been violated, the Lead Author will be prohibited from publishing any data from the PFN for no less than one year.

XV. Confidentiality of Data

- a. The requestor of the data and/or author agrees to maintain in confidence the nature and details of the data set according to the Policies and Regulations set forth by Duke University Medical Center.
- b. In order to maintain confidentiality of protected health information (PHI), all data will be provided to the requestor as an anonymous data set. The sequence number to identify the patient will be maintained in a locked cabinet at Duke University Medical Center.

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Appendix A **Publication Request Form**International Pediatric Fungal Network

Date Requested:	
Requestor's Name:	Email:
Organization/Affiliation :	Phone/Extension:
B	
Planned Publication Planned Publication	
Title:	Anticipated Publication Date:
Planned Publication	·
Type:	Planned Journal/Conf:
Please provide additional details in the space provided below surrounding the overall goal of the project/publication, analysis plan, and please include a list all co-authors (in order) and a description of his/her contribution.	
goal of the project/publication, analysis plan, a	nd please include a list all co-authors
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goal of the project/publication, analysis plan, as (in order) and a description of his/her contribut	nd please include a list all co-authors ion.
goal of the project/publication, analysis plan, as (in order) and a description of his/her contribut NOTE – Attach all supporting documentation	nd please include a list all co-authors ion.

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Comments:

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