

PRO-KIIDS PUBLICATION POLICY

I. Introduction

The Pediatric Resource Organization for Kids with Intestinal Inflammatory Disorders (PRO-KIIDS) publication committee (PC) has five objectives:

1. To assure timely publication and accurate reporting of the results of the studies conducted by the group
2. To avoid inappropriate publication of results including those that might compromise (1) ongoing studies (such as publication of trends before they become statistically convincing) or (2) future publication in a more appropriate format or journal
3. To maintain high quality of material published
4. To prevent duplicate publication of results, by screening all projects and informing the PRO-KIIDS members of pending publications, and by coordinating efforts with other PRO-KIIDS committees
5. To assure equitable and appropriate attribution of credit to the PRO-KIIDS participating members.

Scope of Policy

All material to be presented orally or submitted for publication or dissemination that includes any PRO-KIIDS data or any aspect of the PRO-KIIDS scientific agenda must receive prior review and approval by the Publication Committee (PC) **section IX of this document.**

II. Source of Suggestions for Publications

The PC may suggest topics for abstracts, original peer reviewed papers, or reviews. In addition, all participants in PRO-KIIDS are invited to suggest topics to the PC, who shall review the request, to assure that the project is scientifically meaningful and valid, and that there is no overlap with existing writing assignments. Topics should be suggested in writing, dated, and should include a brief outline of the proposal not to exceed one page. Overlapping proposals will be granted based on submission date and focus of proposal. The final decision will be made by the PC.

The PC will maintain a list of suggested topics that should be prepared for publication and to assure that all completed aspects of the work of the PRO-KIIDS are reported to the scientific community in a timely fashion. This list will be circulated yearly to members of the PRO-KIIDS.

The scientific society or journal to which an abstract or manuscript will be submitted will be a joint decision of the authors and the PC.

III. Assignment of Writing Committees

Topics suggested for presentation or publication will be circulated to the PRO-KIIDS principal investigators. These investigators are requested to volunteer to participate in the writing committee or to suggest (and justify) names for other authors, subject to review by the PC.

If a topic is suggested by a participant of PRO-KIIDS, a writing committee will be formed and the person making the suggestion may be considered as either the lead or senior author. The writing committee will consist of the lead and senior authors and other PRO-KIIDS or additional investigators determined by these authors and the PC. The PI of an ancillary study should be considered for lead author of material derived from this study. Disputes regarding authorship will be settled by the PC. All writing committees requiring analysis of data will be assigned a member of the Steering Committee of PRO-KIIDS unless the lead or senior author are already members of the Steering Committee. The member of PRO-KIIDS who is serving as liaison to Clinipace will facilitate data retrieval from Clinipace. .

All members of the writing committee must submit current disclosures of potential conflicts of interest in a form acceptable to potential journals and professional societies as well as to the PC.

IV. Reports of PRO-KIIDS

Any written communication to a scientific meeting, journal, or lay organization that details scientific work performed by the PRO-KIIDS will fall under the auspices of the Publication Committee. All work coming from PRO-KIIDS will list PRO-KIIDS as the directing body of the work.

V. Authorship Policy

Each publication will have a primary author, senior author, and contributing authors.

It is expected that the primary author will have performed the majority of work on the project including conception of the idea, data retrieval and analysis, and writing. The senior author will have also contributed significantly to these aspects of the work. Contributing authors will be determined based upon the following: participation in PRO-KIIDS for a minimum of one year, contribution of significant numbers of patients to the work being submitted (20 patients), significant contribution to analysis and writing of the abstract/manuscript. The order of the contributing authors will be determined jointly by the primary author, senior author, and PC.

Given the large numbers of contributing sites to projects such as RISK and PROTECT it is the intention of the Publications Committee to allow single authorship from each center for analyses that examine clinical outcomes of the entire study population. In contrast it is expected that there will be sub-projects that examine specific biomarkers or other translational pathways of selected populations. For these analyses authorship will be given to those investigators who have performed the analyses, contributed to interpretation and review the final manuscript, as well as to the top 50% of centers contributing biomaterial to the study.

If an investigator moves from one institution to another and that investigator was significantly involved in a PRO-KIIDS research effort at their original institution, it is expected that the investigator that moved along with the person who took his/her place will discuss and agree on authorship from that institution. Should they not be able to reach agreement, then the Publication Committee will decide authorship.

If at a specific institution two investigators were involved in data generation then it is expected that those two individuals will discuss and agree on authorship. Should they not be able to reach agreement then the Publication Committee will decide authorship. If a sub-investigator at a site develops a specific proposal (not the site PI) and further is largely responsible for analysis and manuscript preparation, then it may be possible for there to be two authors from that site. Final decision will be made by the Publication Committee.

Acknowledgement.

For specific sub-analyses of selected groups of patients those centers and their PI who do not qualify for authorship will be given recognition at the end of each manuscript.

All works that receive funds from the Crohn's and Colitis Foundation of America (CCFA) will acknowledge that support. Individual investigators should also indicate support by grants from NIH, foundations, the pharmaceutical industry, or other relevant entities. Work performed without CCFA support that nonetheless was supported by the CCFA PRO-KIIDS infrastructure will also recognize CCFA support.

It will be the responsibility of all potential authors to provide relevant disclosure forms to the appropriate societies or publishers. Failure to do so can result in the loss of authorship rights.

VI. Schedule for Completion of Writing Assignments and Resolution of Overlaps Between Writing Committees

At the time a writing committee is constituted for a particular project, the PC will establish a timetable for the completion of the writing assignment that takes into

account deadlines for publication, the time required for data analysis, and priority of the publication. The lead author should provide the PC a general outline of the proposed publication within a month of receiving his/her assignment, to permit the PC to identify any overlap with assignments of other writing committees. The PC will report at each meeting of PRO-KIIDS the progress of various writing committees.

If the timetable is not met, after attempting to discuss the situation with the current lead and senior authors, the PC may name a new lead author or co-author for the publication being prepared.

VII. Review of Abstracts and Presentations by the PC

The following procedure will be used to expedite reviews of abstracts and presentations:

1. The lead author wanting to submit an abstract or other material for which there is an explicit submission deadline shall contact the PC. The submitted material should be provided to the reviewers (PC plus several other PRO-KIIDS members) no fewer than seven (7) days prior to the deadline for submission.
2. The members of the review committee shall review the material and notify the lead author promptly of their approval or disapproval.
3. All materials submitted for approval in this fashion will be distributed, together with notice of the disposition, to all members of the PRO-KIIDS (whether or not the member(s) is a coauthor or participant in the study).

Review of Papers by the PC

All materials, for which there is no explicit deadline, and all papers that may result in a citable scientific reference, whether or not there is a deadline for submission, must be submitted to the PC for formal review by the entire Committee. If there is a deadline for submission, it is the responsibility of the submitter to be certain that it is submitted to the PC at least thirty (30) days prior to the submission deadline. The review will be conducted as follows:

1. The PC shall appoint two to three primary reviewers, including at least one PC member. The PC will circulate the submitted material to the entire PC committee and to the PI. The primary reviewers will each send to the PC a written critique of the submitted material for distribution to the entire PC. The PIs will be given a deadline by which comments of any study personnel at their center must be received by the PC.

2. The PC shall schedule a meeting of the PC (generally by conference call), including review of papers as Agenda items. The primary reviews and any comments received from the center PIs will be distributed to the committee with the agenda. The discussion of the submitted papers and other materials will be led by the primary reviewers.
3. Three dispositions may be made: a) approval of the material as submitted (possibly with minor recommendations for revision that do not require re-review), b) non-acceptance of the material as submitted but with recommendations to the authors for revisions and resubmission, or c) to discontinue the project
4. The PC will communicate the decision of the Committee to the authors, together with a summary of suggestions for revision, if any.
5. If a scientific journal to which an approved manuscript is submitted requires revisions to the manuscript, the PC will determine whether the revised manuscript should again be reviewed the PC prior to resubmission. If the PC determines that a review of the revised manuscript is necessary, the PC will attempt to appoint the same reviewers that first read the paper to review the revision, and will make every effort to expedite repeat reviews.

Criteria for Review of Materials by the PC

Materials submitted to the PC will be reviewed for acceptability on two grounds:

1. Materials shall be evaluated for scientific accuracy, quality, importance, and style.
2. Material shall be reviewed to assure that it conforms to the assignment to the writing committee, does not encroach on assignments to other writing groups, and does not divulge prematurely the findings of PRO-KIIDS or compromise the eventual publication of PRO-KIIDS in high quality peer reviewed journals.

VIII. Maintenance of Records of Publications and Presentations

The PC will maintain a record of all official publications and presentations of PRO-KIIDS. This listing will be updated twice yearly and will be distributed to the PRO-KIIDS membership and CCFA together with copies of any papers, chapters, or abstracts accepted for publication since the last update.

IX. Publications Committee Members

Standing members: Jeffrey Hyams, Melvin Heyman, Neal LeLeiko, Wallace Crandall

PRO-KIIDS Publication Policy February 1, 2014

Term: Each member will serve a 3 year term starting January 1 of their appointed year. Members may be considered for consecutive terms by the Steering Committee of PRO-KIIDS.