Proton Collaborative Group

Research. Innovation. Results.

Data Use and Publication Policy

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ROLE OF THE PCG PUBLICATION COMMITTEE

1. Promote and facilitate the use and publication of PCG trial results in a timely manner.
2. Assure authorship lines are correct to ascertain appropriate contribution credit is recognized.
3. Review the scientific use of data use for abstracts and papers.
4. Assure timely reporting by assigning or reassigning responsibility.
5. Update guidelines as necessary.

GENERAL CONSIDERATIONS

1. The Study Chair is given priority to complete the first report of a study.
2. There may be a Radiation Oncologist Co-Chair when appropriate; a Medical Oncologist or Surgical Oncologist could be Co-Chair when appropriate.
3. PCG Headquarters (HQ) will identify all persons who have participated in reviewing a study so they appear on the author line. The authorship line will include physicians and statisticians as appropriate. Clinical Research Associates and/or Data Managers will be recognized by acknowledgment when appropriate. The first author must request permission in writing to add extra.
4. The Study Chair must have approval of their disease site/modality committees as necessary to begin to analyze and report a specific study.
5. No manuscripts may be submitted without prior approval of the Study Chair.
6. Initial papers reporting the primary endpoints of each protocol are routinely assigned to the Study Chair. These endpoints are those initially specified in the protocol. They might include disease endpoints, toxicity endpoints, quality of life endpoints and any other ancillary endpoints. Publication of these papers will follow the traditional publication guidelines.
7. For multi-institutional studies that include collaboration between PCG and non-PCG institutions, PCG will be considered a single institution for publication guidelines.
8. Data from study forms is sent from the enrolling institution to the PCG HQ via electronic case report forms (CRFs). Not all information is submitted via the electronic database. For instance, some digital radiation therapy data is not sent but is considered part of the research data record. The electronic CRFs are used as the basis for the analysis of PCG studies, with the analyses performed by the PCG HQ team in collaboration with the protocol Study Chair, Co-Chairs and statistician, as applicable.
9. Special considerations are noted below for the PCG Registry Study.

DATE USE

Any researcher is able to request data from PCG studies for use in analysis/publications. Membership is not required but will be considered in determination of the request.

In order to request data:

a) Contact PCG HQ (hq@pcgresearch.org) to obtain the Data Use form.

b) Complete Data Use Form and return to PCG HQ.
c) PCG HQ submits the request to the following for their review and approval:
   - PCG Publication Committee chair
   - Protocol Study Chair
   - Each institution's lead PCG representative (Executive Board Member) whose data is requested for use.

   The scientific merit and feasibility of each request will be evaluated during the review process.
d) PCG HQ will inform the researcher of approval or disapproval and work with the researcher to provide the data needed within an agreed upon timeframe.

Requests from anyone other than the Study Chair will only be considered once the primary study analyses have been published (not applicable to the PCG registry study).

Appeals Process

If a request for data is denied, the applicant may appeal the decision. The appeal will be reviewed by the protocol Study Chair, Publication Committee Chair and Disease Site Committee Chair. Their decision will be final; no further appeals will be accepted.

AUTHORSHIP

1. Contributors who register ≥ 10% of the evaluable cases of a nonrandomized study will be listed as co-authors. The designated author is the choice of the institution's principal investigator. If fewer than three institutions contributed ≥ 10% of the cases, then the top three accruing institutions will be listed.
2. Contributors who randomize ≥ 10% of the evaluable cases on a randomized study will be listed as co-authors. The designated author is the choice of the institution's principal investigator. If an institution places a large number of cases on the study, that institution will get an additional co-author for every 10% of the patients accrued, not to exceed a total of four co-authors. (Two co-authors for ≥ 15% accrual and three co-authors for ≥ 25% accrual and four co-authors for ≥ 35%.) If ≥ 10% of cases creates an author line that is too long, then we will revert to the 15% rule for case accession.
3. The authorship line of an overview paper will consist of the following: The first author, study chairs from each study, and the top six total accruers, and the appropriate disease site or modality chair. The number of authors from the institutions depends on the percent of total accrual.
4. Membership and authorship representation rests with the institution. When an investigator leaves an institution, it is up to the Principal Investigator to assign someone to the authorship spot allocated for that institution. ***If a Study Chair leaves an institution, he/she maintains his authorship.***
5. If a pathologist has been involved with the study, he should be listed as a co-author.
6. If the PCG Group Chair or Associate PCG Chair has made a substantial contribution to a study, their name may be included in the author line.
7. **The order of authorship for an initial treatment paper** for studies will be: primary author, Study Co-chair contributing to data review and analysis, other modality chair e.g. pathologist (if applicable), and the institutional representatives. The remaining Study Co-chairs not contributing to data review and analysis will be placed in an appropriate position as determined by the Study Chair or Disease Site Chair (if applicable), followed by top six accruers among all institutions and the Disease Sub-site Chair. If questions arise, the publications committee can be consulted and their recommendation is final.
8. **Secondary analysis authorship lines** will be identified as follows: first author (person who requested second analysis), Study Chair(s) (study databases used in analysis, by # of patients

accrued in descending order), and site chair(s) who oversaw the conduct of the studies. Additional authors based on their involvement in the review process.

9. Every paper must include an appendix or table of all contributors to the study. (This does not apply to abstracts.)
10. Disease Site or Modality Committee Chairs may not publish a review article from material appearing in any PCG minutes without the permission of the Study Chair.
11. The Study Chair will discuss their decisions on authorship with the Publications Committee's and their decision will be final.
12. *Proton Collaborative Group* and Study Number must appear in every publication using PCG data.
13. The authorship of any paper based totally on previously published PCG data is left to the first author's discretion. It is recommended that PCG authorship guidelines be followed, but it is not required. Any paper that publishes any new data (i.e. data that has not previously been published in a source that is suitable for reference and citation) must follow PCG authorship guidelines exactly.
14. **If a manuscript is overdue**, that author loses authorship rights on that and any other pending manuscript and cannot take on new responsibilities within the Group.
    - List of delinquent manuscripts will be sent to Disease Site Committee Chair for review and it would be up to them to work with the Publications Committee Chair to reassign the manuscript to another author.
    - After PCG HQ reminds the first author that a manuscript is due six months after an abstract is presented at a meeting and after the 3 follow-up warning letters to the offenders, the Site Chair begins the reassignment process. *It is the responsibility of the Disease Site Committee Chair to reassign or drop an outdated manuscript.*

REGISTRY PROCEDURES (REG001-09)

It is not always applicable to use the above guidelines for publications using PCG registry data. The following is an abbreviated list of authorship requirements.

1. First author may be the person who requested and conducted the analysis.
2. The PCG name must appear in the title of every publication using PCG data.
3. At least one member from each institution from where the data is used (Investigator with the largest contribution per center) and the REG001-09 Study Chair must be listed.
4. The order of authorship and the addition of any other authors listed are at the first author's discretion.

PRE-PUBLICATION PROCEDURES

1. It is the responsibility of the first author to distribute the draft of a manuscript or abstract to all co-authors and obtain approval from them for submission of the manuscript or abstract.
2. Once all authors are in agreement and the manuscript or abstract is in the final version, it is to be submitted to PCG HQ for review and approval prior to final submission. PCG HQ will forward to appropriate reviewers and statistical reviewer, if applicable. Once reviewed, PCG HQ will notify the first author of the next step. (i.e.: submission to journal or changes required.)
3. Papers and abstracts may be submitted to journals or meetings only after publication review by the PCG office. All authors should copy the PCG HQ Director when submitting the manuscripts or abstracts.
4. The first author will provide timely notification to PCG HQ of acceptance and/or copy of page proofs.