Proton Collaborative Group

Research. Innovation. Results.

Data Use and Publication Policy

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ROLE OF THE PCG PUBLICATIONS COMMITTEE

The role of the Publications Committee is to promote and facilitate publication of PCG study results so as to ensure PCG trial results are published in a timely manner, to ensure authorship attributions are correct, to review the science of abstracts and papers, to ensure timely reporting by assigning or reassigning responsibilities, and to develop and recommend to the Executive Council publication guidelines as necessary.

I. PCG DATA USE

A. Any researcher from a PCG member institution is able to request data from PCG studies for which they have a membership for use in analysis/publications.

B. Data Use Request Process

1. Complete the PCG Data Use Form and return to PCG HQ at HQ@pcgresearch.org.
2. The PCG Data Use Form should list ALL investigators who will be working on the project and identify who the main contact will be for the project.
3. The scientific merit and feasibility of each request will be evaluated during the review process. Requests from anyone other than the Study Chair will only be considered once the primary study endpoint(s) has been published (not applicable to the PCG registry study). PCG HQ will submit the request to the following persons for review and approval:
   - Chair of the PCG Publications Committee
   - Chair of the corresponding Disease Site Committee
   - Protocol Study Chair (Protocol Study Chairs are not permitted to approve their own data use request. In these cases, the protocol Study Co-Chair will serve as approver in his/her place. In cases of multiple co-chairs, all co-chairs will serve as the approvers)
   - Each institution's PI whose data are requested for use
4. PCG HQ will inform the researcher of approval or denial within 7 business days. If approved, PCG HQ will work with the researcher to provide the requested data within an agreed upon timeframe.
5. PCG will provide the requestor with data that is currently collected in the PCG EDC system. Data requested that is NOT currently collected, including but not limited to copies of any medical records, is not able to be obtained by PCG. In situations where this type of data is requested, PCG will facilitate an introductory contact between the requestor and the PCG site whose additional data is being requested. The site has the option to fulfill or deny the request according to their own policies and procedures. Data should be sent directly from the site to the requestor, not to PCG.

C. Appeals Process

1. In the case of denial of a data use request, the researcher may file an appeal in writing to HQ@pcgresearch.org with rationale for the appeal.
2. All appeals will be reviewed by the PCG Appeals Committee which includes the following:
   - Chair of the PCG Publications Committee
   - Chair of the PCG Executive Council
   - PCG Board President
   - Protocol PI (In instances where the protocol PI is also the researcher requesting the appeal, the Chair of the corresponding Disease Site Committee will step in as the fourth Appeals Committee member)

3. Appeals must be reviewed by all Appeals Committee members.
4. In order to reverse a data use request denial, approval from the Appeals Committee must be unanimous.
5. Decisions from the Appeals Committee are final.

II. PRE-PUBLICATION PROCEDURES

A. It is the responsibility of the corresponding author or his/her designee (ie. first author) to distribute the draft of a manuscript or abstract to all co-authors and obtain approval from them prior to submission of the manuscript or abstract.

B. After approval has been obtained from all authors and the manuscript or abstract is in its 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 a statistical reviewer, if applicable. Once reviewed, PCG HQ will notify the corresponding author of the next step (i.e., submission to journal or changes required)

C. 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 when submitting the manuscripts or abstracts.

D. The first author will provide timely notification to PCG HQ of acceptance and/or provide a copy of page proofs.

III. PROSPECTIVE TRIAL PUBLICATIONS GUIDELINES

A. The Study Chair is given priority to complete the first report of a study. This includes an initial paper reporting on the primary endpoint(s) of each protocol as specified in the protocol (survival, disease control, toxicity, quality of life, etc.). Publication of these papers will follow the traditional publication guidelines.

B. The Study Chair must have approval of their disease site/modality committee as necessary to begin to analyze and report a specific study.

C. No manuscripts may be submitted without prior approval of the Study Chair.

D. For multi-institutional studies that include collaboration between PCG and non-PCG institutions, PCG will be considered a single institution for publication guidelines.

E. *Proton Collaborative Group* and Study Number must appear in every publication using PCG data.

F. Data from study forms (eCRFs or CRFs) is entered by the enrolling institution to the PCG EDC system. In some cases, not all information is submitted via the electronic database and the investigator and/or PCG will request this information from the site to include in the data use request. For instance, some digital radiation therapy data are not sent but are considered part of the research data record. The eCRFs 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.

G. Following publication of the primary endpoint(s), analysis of secondary endpoints cannot be performed until the time of study closure unless unanimous approval has been obtained by the Study Chair, PIs from each of the participating institutions, members of the appropriate Disease Site Committee and Disease Site Chair, Chair of the Publications Committee, and Chair of the Disease Site Committee.

H. Late Manuscripts Policy

1. **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.
2. 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 have been

sent to the offenders, the Disease Site Chair will begin the reassignment process. *It is the responsibility of the Disease Site Committee Chair to reassign or drop an outdated manuscript.*

3. A list of delinquent manuscripts will be sent to Disease Site Committee Chair for review, who will then work with the Publications Committee Chair to reassign each manuscript to another author.

IV. AUTHORSHIP

A. PCG Headquarters (HQ) will identify all persons who have participated in a study so they appear on the author line. The authorship line will include physicians, statisticians, other Co-Chairs, chair of the respective disease site committee for who the trial falls under, and/or site and/or PCG staff as appropriate. PCG will request confirmation of what author should be listed from a participating site from the site PI for the specific publication in question. The corresponding author or his/her designee must request permission in writing to add additional authors.

B. **Contributions to Trial Enrollment**

1. Prospective, non-randomized studies: 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. Randomized studies: 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 enrollment of >10% of the patients accrued, not to exceed a total of four co-authors. (Two co-authors for ≥15% accrual, 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.

C. 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. The Principal Investigator can elect to continue to include as an author an investigator who has left an institution if they made significant contributions to the study provided the Principal Investigator also assigns a new authorship spot for the institution in which the original investigator left. ***If a Study Chair leaves an institution, he/she maintains his authorship.***

D. **Order of authorship for an initial paper**:

1. Primary author
2. Study Co-Chair contributing to data review and analysis
3. Other specialty Co-Chair e.g. medical oncologist, pathologist (if applicable)
4. Institutional representatives
5. 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)
6. Top six accruers among all institutions
7. Disease Site Chair

If questions arise, the Publications Committee can be consulted, and their recommendation is final.

E. **Order of authorship for a secondary analysis paper:**

1. Primary author (person who requested second analysis)
2. Study Chair(s) (study databases used in analysis, by # of patients accrued in descending order)
3. Additional authors based on their involvement in the review process.
4. Disease Site Chair(s) who oversaw the conduct of the studies

F. The Study Chair will discuss their decisions on authorship with the Publications Committee, and their decision will be final.

G. The authorship of any paper based totally on previously published PCG data is left to the corresponding 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.

H. **PCG Registry (REG001-09)**

1. First author and/or corresponding 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 which the data are 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 corresponding author's discretion.