

# Pediatric Readiness Study Publication Policy

## I. GENERAL POLICY

Scientific contributions to the field of pediatric emergency care are made through publications in the peer-reviewed literature. Abstracts, public presentations, and sharing of data also contribute importantly to public knowledge, but do not substitute for peer-reviewed publications and are of lower priority. No participating team member may present or publish individual findings from work performed on study protocols without approval of the **Pediatric Readiness Study (PRS) Leadership Team** (7 Investigators, Study Coordinator, and 7 members of the Advisory Council).

### Goals:

- Promote efficient and quality publications of findings in peer-reviewed, MEDLINE-indexed, journals
- Policy-relevant publications
- Support broad and equitable participation in PRS through presentations and publications
- Equitable rules and guidelines for writing group (WG) membership and manuscripts
- Process for secondary manuscript proposals and prioritization of proposals
- Mechanism for resolving disputes regarding authorship and WG assignment
- Editorial support and timely review of presentations and publications

### Definitions:

- **Primary Manuscripts** – address primary aims/objectives from the NICHD R24 grant (3 aims) and HRSA grant (3 aims)
- **Secondary Manuscripts** – Secondary analyses of data from the PRS project, approved by PRS leadership, and not overlapping with primary manuscripts.

## II. PREPARATION OF WRITING GROUPS & MANUSCRIPTS

Manuscripts will be prepared and submitted in a timely manner upon completion of data collection and analyses. No results will be released, presented, or published prior to conclusion of data collection, data processing, and final analyses without approval by PRS leadership. PRS leadership will determine the priority of manuscripts and analyses to be completed. Presentation or public discussion of data prior to its formal presentation at a national meeting is prohibited.

### Data Analysis:

All statistical analyses will be performed at OHSU or University of Utah, the two institutions approved to use the data through all data use agreements (DUAs) for the PRS project. No data will be sent to external sites for analysis.

### Formation of Writing Groups (WGs):

- General guide of 12 authors per WG for feasibility, but there is flexibility with WG size as needed. All authors must meet standard authorship guidelines. All manuscripts will include a group membership byline, in addition to WG authors (detailed below).
- WGs for primary manuscripts will be comprised of the core PRS leadership team, plus 1-2 young investigators.
- WGs for secondary manuscripts can include: PRS investigators, PRS Study Coordinator, PRS staff, young investigators, and in-state contacts, with equitable representation from sites, states, and organizations. Each secondary manuscript should include at least 1 PRS young investigator. When the young investigator is the lead author, a member of the PRS leadership team who is also a co-author will mentor the young investigator in guiding the WG, including writing.

- For proposed secondary analyses, the PRS leadership team will review author recommendations from the Manuscript Form and suggest additional interested investigators to assure equity and broad representation.
- Once formed, the WG will be assigned a short name and posted on the PRS web site.
- Outside of the core study team, there will be a maximum of 3 WGs for any single person.

#### Responsibilities of WG Members:

- **Lead Author** is responsible for leading and completing all phases of the project, including manuscript preparation. Responsibilities include:
  - Conception of study idea and design, preparation of outline, plan for analyses, working with biostatistician on analyses, interpreting results, drafting the manuscript, submitting all necessary reports to PRS leadership, meeting all timelines, and journal submission/publication
  - Assignment of tasks to WG members, with clear deadlines for completion
  - Assuring that the manuscript has approval of the WG before submission of its penultimate draft to the PRS for review;
  - Authorship order (subject to review by PRS leadership). The major criterion for this determination will be the effort and contribution made by WG members. WG members who do not contribute substantially shall NOT be listed as authors.
  - Recommendation of a journal to which the manuscript should be submitted.
  - Correspondence with co-authors, communication with the PRS and biostatistician, responses to PRS questions, and correspondence with journal editors. The PRS will survey the Lead Author monthly regarding WG progress.
  - Mentorship and participation of the PRS young investigator.
- **Members** of the WG are responsible for performance of tasks assigned by the Lead Author within the allotted time period.
  - Each member is expected to participate actively and substantively in interpretation of results and preparation of the manuscript.
  - Lead Authors should re-evaluate contributions from each of the co-authors at the time of first manuscript submission. Authors who have not contributed to the writing process should be removed as a co-author.

#### Writing Responsibilities:

- Completion of the manuscript will be the responsibility of the Lead Author.
- If the WG is unable to meet the specified deadlines, the PRS will reassign the Lead Author and consider selecting new WG members.
- The Lead Author shall be responsible for submission of the final manuscript to PRS leadership for approval, then to the medical journal. The Lead Author is also responsible for all journal correspondence, manuscript revisions, and responses (the assigned biostatistician and PRS leadership team will assist as needed with addressing questions from reviewers and revisions).

#### Timeline for Preparing and Submitting Manuscripts:

- The goal is to submit manuscripts as quickly and efficiently as possible, as this is essential to having a potential impact on state/national policy and emergency care.
- For **primary manuscripts**, goal is for manuscript submission within 6 months of WG formation (including analysis, draft manuscript, WG comments, and revisions).
- For **secondary manuscripts**, goal is for manuscript submission within 12 months of WG approval, including
  - Manuscript draft disseminated to WG members within 3 months of receiving preliminary results from the biostatistician

Manuscript journal submission within 3 months of first manuscript draft (above), including PRS review/approval.

- All drafted manuscripts must be sent to the PRS for PRS and applicable data agency(ies) approval at least 30 days prior to submission date.
- Approved WGs will have an assigned biostatistician and data manager with which to work.
- Failure to meet the timeline will result in replacement of the Lead Author and/or WG members, as determined by PRS leadership, including the impact of extenuating circumstances.

#### **Adjudication of Disagreements:**

- Appeals regarding the selection of WG membership and assignment of Lead Author will be sent to the PRS leadership for resolution.
- Disagreements between authors will be settled by discussion and consensus whenever possible or, if consensus cannot be achieved, by the PRS leadership.

#### **Timeline for Study Approval:**

- The PRS leadership will discuss manuscript proposals and approved WGs monthly.
- Lead Authors will be notified of the PRS leadership decision, as well as the assigned biostatistician and data manager, within 2 weeks of the meeting date.
- Lead Authors will then be expected to disseminate this information to their WG and create an internal WG timeline consistent with the timeline expectations outlined above.

### **III. AUTHORSHIP**

- Order of authorship shall be determined by the WG Lead Author, subject to approval by the PRS leadership.
- All persons eligible for authorship according to the guidelines of the ICJME will be listed on the journal title page, followed by the designation ***“on behalf of the Pediatric Readiness Study Investigators”*** (list of PRS investigators to be included as an Appendix).
- Persons who have contributed to the completion of the study but do not meet criteria for authorship will be listed in the Acknowledgements section in alphabetical order.
- All manuscripts should include standardized language recognizing the sources of funding (NICHD and HRSA) and agency specific acknowledgements (applicable to certain data sets) – this language will be provided by the PRS team.

### **IV. ABSTRACTS AND PUBLIC PRESENTATIONS**

- **Abstracts:** Draft abstracts should be forwarded to PRS leadership for review and approval at least 4 weeks prior to the deadline for abstract submission.
- **Public Presentations:** All posters, slides, and other formal presentations should be reviewed and approved by PRS leadership at least 4 weeks prior to presentation for review and revisions.

#### **ICMJE Authorship Guidelines**

<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>