



## ***PROSpect*** **The PRone and OScillation Pediatric Clinical Trial**

<http://www.PROSpect-network.org/>

### **Publication and Presentation Standard Operating Procedures**

#### **CORE PRINCIPLES**

1. Best Science: The quality of the science will be the best possible. Science must not be compromised by submitting incorrect, incomplete, unsophisticated, hastily prepared, or biased reports.
2. Authorship: Authorship shall be determined according to specific investigative effort and effort on actual preparation of a manuscript and will not be based on affiliation alone.
3. Data Availability: Each site investigator will have access to their data and documentation from their site. Access to study-wide data will be provided when approved by the publication/presentation committee providing that the integrity of the study is not compromised (e.g., inappropriate release of interim analysis results). In the interest of scientific progress, elements of data should be made generally available as soon as the key articles are published.
4. Publication and Presentation Policy – General Principles
  - a. Promotion of a collegial and cooperative culture;
  - b. Equity in publication and presentation opportunities for all actively involved investigators;
  - c. Ensure appropriate authorship for ideas contributed and work done;
  - d. Careful review of all submissions for scientific accuracy, statistical validity, and consistency in reporting;
  - e. Avoidance of duplicate publications as well as avoidance of duplication of abstract submission/presentation. However, the breadth of the study investigations will require additions to the literature in many fields; so, careful judgement must be made as to what constitutes duplication and overlap. Methods that are uniform across much of the study may be described in a special publication and will be presented in a standardized fashion in study publications.

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- f. Timeliness of preparation and reporting is essential. Incomplete/delayed work will be reassigned to another investigator.
- g. Abstracts will be submitted at least two weeks prior to the submission date to allow adequate time for review and revisions, if needed.

## **PUBLICATIONS AND PRESENTATIONS COMMITTEE (PPC)**

1. The study will create a standing committee called the Publications and Presentations Committee (PPC) composed of Dr. Curley (Chair), Dr. Wypij (DCC PI), Lisa Asaro (biostatistician and Co-Investigator), and six representatives of the Steering Committee.
2. The PPC Chair will be Martha A.Q. Curley, RN, PhD, FAAN.
3. The PPC is charged to:
  - a. Receive and initiate writing proposals;
  - b. Solicit and propose writing teams;
  - c. Review and approve outlines and/or other detailed descriptions, proposed names, and order of authors;
  - d. Negotiate timelines for writing teams;
  - e. Monitor the progress of writing teams;
  - f. Review or arrange the review of all abstracts, papers, and presentations prior to submission;
  - g. Determine the names of presentations of original material; and
  - h. Adjudicate any problems that may develop regarding publications and presentations.
4. The PPC will keep an ongoing open record of its decisions and decision processes to provide precedents for equitable future decision-making.

## **PUBLICATION AND PRESENTATION PROCEDURES**

1. Identification of Publishable Data
  - a. Potential publications and presentations and potential members of writing teams will be identified by the individual study Co-Investigators, NIH, Executive Committee, Steering Committee, and/or PPC itself. All proposals will be sent electronically to the PPC Chair for consideration.
  - b. Ancillary papers and presentations will be proposed by the study Co-Investigators at the site carrying out the work, and the writing teams will be proposed by those sites and confirmed by the PPC. Because data from the core study will normally be utilized in additional research activities, PPC approval is required for submission of these papers and presentations.
  - c. Non-study Co-Investigators may propose external papers and presentations. The Executive Committee will make the decision regarding the extent of access to the requested database elements, and the PPC will monitor and review the proposed publications unless based on data in the public domain.

## 2. Writing Teams

- a. The PPC will ensure that each site has an opportunity to participate in providing members of writing teams to proposals. The PPC will also identify writing team members in each area proposed for publication by querying each site and the appropriate project standing committees for suggestions. Writing teams will be selected to contribute based on the research element; investigator expertise; interest and willingness to participate actively in the data preparation, analysis, literature review, and writing; and site representation. Each site need not participate in the writing of each paper, as the expertise across sites varies. Ancillary study writing teams will be designated by the sites carrying out the ancillary study.
- b. When appropriate, a team leader will be designated by the PPC to initiate the process of activating the writing team.
- c. Each writing team will create outlines for proposed papers, divide the work and credit equitably among the members, and propose landmarks and completion times. The timeline will include all aspects of preparation, including PPC review.
- d. Using the *PROSpect* template, writing teams shall provide the PPC with outlines, proposed authors, journal(s) to which the project will be submitted, and proposed meetings for which abstracts will be prepared and presentations made, for each separate unit of research, which may include multiple papers. If there are questions as to the scope of an individual writing team's mandate, or competition between groups, the PPC will adjudicate by dividing the work and developing cooperative arrangements. Advance PPC approval of the plan is required.
- e. Writing teams will have restricted access to cleaned and previously vetted study data. Writing teams have the responsibility for analyzing the data in various ways and resolving conflicting interpretations. It is expected that their combined expertise will provide an agreed-upon solution in most cases of differences of opinion.
- f. Papers in preparation will be kept in an electronic file for the use of the writing team. Once accepted, they will be made available in an electronic file to all study Co-Investigators.

## 3. Authorship

- a. Awarding of authorship requires a significant intellectual and/or work contribution to performance of a study and/or preparation of the manuscript. Writing teams will normally indicate the list of authors in order as well as their proposed contribution with the outline of each proposed paper or presentation.
- b. Each paper will have a standard study designation as well as named individual authors. The "for the *PROSpect* study investigators" will be named as final author on all ancillary study publications. The *PROSpect* investigative team will include the lead

investigator from each contributing site.

- c. Sometimes authorship may stimulate invitations to present the work of the study at scientific meetings. Generally, first authors will represent the study at scientific meetings presenting original data. See below for guidance on presentations.

#### 4. Review Process for Research Papers and Presentations

- a. The PPC shall be responsible for the review of papers and abstracts before they are submitted for publication or presentation. In addition, evaluation of the content of the submission, the review shall include attention to:

- 1) Adherence to the approved publication plan;
- 2) Accurate use of the database;
- 3) Equity in allocation of credit and opportunity to participate;
- 4) Appropriate identification of the study;
- 5) Minimal or appropriate overlap with other projects and presentations;
- 6) Appropriateness and completeness of the bibliography;
- 7) Scientific integrity;
- 8) Quality of the writing; and
- 9) Adherence to research ethics in preparation and reporting of the data.

However, it is not the responsibility of either the PPC or Executive Committee to delay submission of papers or abstracts because of apparently minor problems with either the science or presentation. Peer reviewers will deal with those issues.

- b. PPC review of ancillary papers and publications will be limited to items 1, 2, 4, 5, and 7 in the list given above. If it is satisfactory, it will then be sent on to the Executive Committee.
- c. The vast majority of abstracts will be reviewed prior to submission. Occasionally, submission of an abstract must meet a deadline that precludes review prior to submission. Such abstracts must be submitted to the Chair of the PPC for tentative approval 14 days prior to submission. Complete review must then be carried out with the understanding that if there is a problem, the abstract will have to be withdrawn.
- d. The PPC will normally receive abstracts and papers in electronic form that are ready to be submitted for publication. Unless a substantial review of the content is required, the PPC will usually complete their review in ten working days and report the vote to the Chair.
- e. Presentations are normally of two types, those announcing new research results and those reviewing already published work. Presentations at national meetings usually are based on submissions of abstracts or information about new results conveyed to the organizing committee. Poster sessions and brief (e.g., ten-minute) oral presentations

will be considered the normal consequences of submitting an abstract and will not require separate approval. On the other hand, longer presentations represent invited talks and require separate PPC authorization. Authorized presenters will often be first or senior authors of papers describing the new work.

Presenting presentations of previously published material in educational settings is the privilege of all study Co-Investigators without specific approval by the PPC. “Published” is defined for this purpose as fully described in written form in a peer reviewed scientific journal, i.e., not an abstract. To facilitate presentations of this type, Co-Investigators will have access to a file of illustrative material from which to make slides.

Inclusion of results in other talks and local presentations cannot normally be monitored. The general rule is the data are confidential until published or presented (in an approved fashion), unless they represent ancillary data which are the responsibility of the site performing the ancillary study. Collegiality, on the other hand, requires that the results of the studies are discussed informally with non-study colleagues at one’s own institution to enhance the progress of science ensuring there is no release of information to the general public.

- f. The PPC will be sent a copy of all reviews of submitted papers. If a paper is rejected or returned for serious revision, the PPC will offer assistance in the re-working and otherwise support the writing team in responding to the criticisms. If a serious situation regarding the paper surfaces, the PPC will make a decision regarding reconstituting the writing team for that paper.

## 5. Approvals

The names of each writing team will be referred to the PPC Chair for tentative approval. Final approval will take place after receipt of an outline, authorship statement, and timeline approved by the PPC.

Every completed paper, presentation, and abstract must be approved by the PPC prior to submission to the journal or organizing committee.

## 6. Managing Problems

Different groups of investigators may wish to report essentially the same data. Sites may consider some of the data they accumulate exploratory rather than core and wish to report it in that manner. There may be a conflict between Co-Investigators’ division of the workload or credit. Investigators may have seemingly irreconcilable differences regarding the subject matter, discussion, or conclusions in a piece of work. Conflict may develop as to the composition of a writing team or its leadership. During the course of paper development there may be conflicts over the feasibility of adherence to timelines. There may be very serious disagreements as to the quality of a piece of work submitted for

approval. There may be a competition for resources necessary to complete works for publication. There may be other problems that cannot be foreseen.

The PPC has both the responsibility and authority to resolve all matters related to publications and presentations. Its first attempt will always be to negotiate differences. If necessary, expert outside reviewers will be asked to help. The PPC Chair will have the final say in adjudicating such matters.

If a writing team is missing deadlines or otherwise functioning poorly, the PPC Chair can meet (or have a conference call) with the writing team and subsequently present a report to the PPC that can vote to exercise the option of reconstituting the writing team or its leadership.