The Perinatal Research Consortium By-Laws/Policies and Procedures

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The Perinatal Research Consortium
By-Laws

The Perinatal Research Consortium (PRC) is an integrated system of research centers with sufficient patient volume and expertise to perform research requiring large and diverse patient cohorts. PRC members strategically apply their combined expertise through well-organized, well-structured, and stimulated opportunities for research. The PRC has developed a centralized contract/budget mechanism and Central IRB process. This centralized and collaborative approach provides a one-stop resource for research sponsors and grantors, develops a distinct identity dedicated to perinatal research, and promotes greater thinking and results through group effort. This collaboration expands the patient base diversity and volume, strengthens the capacity of key institutions and forms relationships that expand opportunities for innovation and discovery bringing this consortium to the forefront of women's health research. The Perinatal Research Consortium can accomplish more than each organization would be able to accomplish separately.

Vision: The Perinatal Research Consortium (PRC) is a destination research consortium that develops and performs the highest quality research in Perinatal and Women's Health and serves as a research resource for individual researchers, institutions and sponsors.

Mission:

1) To provide the intellectual capital to optimize conceptual and design elements needed to develop important and innovative Perinatal and Women's Health research.
2) To provide infrastructure and operational expertise needed to efficiently and economically implement and complete research protocols with a variety of study designs and diverse populations, whether investigator initiated, cooperative trial group derived or industry sponsored.

Goals:

- To develop and evaluate new technologies to improve health care for women and their infants
- To engage in research that has the potential to change clinical practice
- To perform work that translates basic discoveries into clinical care
- To train and develop research scientists
- To strengthen inter-institutional collaborations
- To maintain flexibility in pursuing various sources of funding
- To be efficient and pragmatic in the business of research, so that the PRC provides a positive revenue stream to its member institutions

A culture has been developed where research is an expected part of patient care. This has required that all physicians become accustomed to following clinical investigational protocols and consider all patients potential study subjects. This culture is supported by a central infrastructure, along with the participating institutions' clinical and scientific commitment to women's health, and has created environments that enable the development and evaluation of new and technologies, the performance of clinical research leading to evidence based changes in practice, the training and development of research scientists, and collaborations with superior basic scientists. The PRC assures continuation of successful past performances and serves as a springboard for future research growth.

BY-LAWS

I. Governance and Structure

The PRC consists of nine major institutions with large perinatal clinically based programs on the East Coast:

A. Columbia University Medical Center, New York, New York
B. Christiana Care Health System, Newark, Delaware
C. Drexel University College of Medicine, Philadelphia, Pennsylvania
D. New York Presbyterian Queens, Queens, New York
E. Rutgers Biomedical Health Sciences, New Brunswick, New Jersey
F. Saint Peter's University Hospital, New Brunswick, New Jersey
G. Virtua Medical Group, Marlton, New Jersey
H. NYU Winthrop Hospital, Mineola, New York
I. Temple University, Philadelphia, PA

Each of these sites has significant high-risk obstetrical patient volume. The delivery volume at each site in the calendar year of 2016 was as follows:

PRC Sites	**Deliveries**
Columbia University Medical Center, NY	6,719
Christiana Care Health Systems, DE	6,345
Drexel University College of Medicine, PA	1,908
New York Presbyterian Queens, NY	4,322
Rutgers Biomedical Health Sciences, NJ	4,190
Saint Peter's University Hospital, NJ	5,688
Virtua Medical Group, NJ	7,635
NYU Winthrop Hospital, NY	4,785
Temple University, PA	2,741
Total	44,333

The large patient volume, including approximately 45,000 deliveries annually and expertise in the area of perinatal medicine has uniquely positioned the PRC for basic and clinical research involving a broad range of women's health problems.

II. Steering Committee

A. The Steering Committee is the governing body of the PRC.

The Steering Committee shall consist of:

1. Two investigators from each PRC member institution
    a. One of the members of the Steering Committee must be the designated Site-PI for the MFMU Network (if the site is an MFMU satellite site).
    b. The second member of the Steering Committee will be selected by the participating site, but the individual must hold a PhD, MD/DO degree, or equivalent.

2. Epidemiologist-biostatistician (voting member)
3. Administrative Director (non-voting member)

B. Steering Committee Responsibilities:
   1. The Steering Committee is primarily responsible for:
      -Selecting and approving topics for investigation
      -Approving protocol development
      -Designing and approving study protocols
      -Participating in analysis and publication
      -Developing and approving PRC policies and procedures (By-Laws)
      -Assuring compliance or PRC By-Laws and applicable laws
      -Approval of financial resource utilization
   2. Each member of the Steering Committee has voting rights (with the exception of the Administrative Director) and responsibilities. The Steering Committee chair only votes in the event of a tie and votes during the prioritization process.
   3. All Steering Committee members must be present (either in person or by conference call) to cast a Steering Committee vote.

C. Steering Committee Schedule and Attendance
   1. The Steering Committee will convene quarterly, with additional conference calls as needed.
   2. Dates for meetings will be selected and announced six months in advance to ensure Steering Committee member attendance.
   3. Should a Steering Committee member find it impossible to attend a Steering Committee meeting, he/she may propose an alternate investigator to attend on his/her behalf with the approval of the Steering Committee chair.
      a. If both investigators are unable to attend and unable to send an alternate investigator to attend on their behalf, one time per year a Site may use the Chair as their proxy at the meeting. Site coordinators cannot serve as a proxy.
      b. If the Chair is used as proxy for two meetings per year, the Site will be placed on probation.
      c. If the Chair is used as proxy for three meetings per year, the Site will be asked to leave the PRC without reimbursement of their membership fee.
   4. Two thirds of the Sites, at least six, must be present in order for voting to take place at the meeting. Two thirds of the number of investigators present will be needed to approve an administrative vote.
   5. Designated site coordinators are expected to attend each Steering Committee meeting as they provide significant insight and valuable input regarding the practicality of study designs and feasibility of implementation.

D. Steering Committee Member Replacement
   1. If an approved Steering Committee Member can no longer perform his/her duties as a voting member, the member site shall recommend another investigator to the Chair of the Steering Committee for approval.
   2. Before approval can be granted, the recommended investigator's CV must be submitted to the Chair of the Steering Committee for review.

E. Monthly Conference Calls
   1. Monthly calls will be one hour in length, and a Doodle Poll will be used to determine the best day and time for the majority.
   2. The call may be as early as 6 AM and end as late as 7 PM.
   3. One representative from each Site must attend the call.

III. Financial Oversight Committee

A. The Financial Oversight Committee oversees the administrative finances of the PRC, and at minimum, annually report their findings, in writing and verbally, to the Steering Committee.
B. It is composed of one representative appointed by the Chief Executive Officer of each member organizations/member and a site Principal Investigator (PI) of each organization/member.
C. The chair of the Financial Oversight Committee shall be elected by a majority vote of the board members and serve for two years. The chair of the Financial Oversight Committee shall serve on the Member Review Committee and shall not be the chair of any other committee in the PRC.
D. The Financial Oversight Committee shall be responsible for:
    - Monitoring the utilization of membership funds
    - Reviewing a detailed PRC Financial Report
    - Making recommendations to the Steering Committee regarding financial matters.
E. The Financial Oversight Committee shall meet twice a year in person or by telephone, when necessary at the call of the Chairperson or request of the Steering Committee, and report to the Steering Committee no less than once a year.

IV. Administrative Infrastructure

The Columbia University Department of Obstetrics and Gynecology serves as the Coordinating Center for the PRC, and as such provides overall guidance and administrative oversight. This administrative infrastructure identifies opportunities for collaborative research, facilitates the coordination of these initiatives, and fosters efficiencies and scientific interaction.

POLICIES AND PROCEDURES

I. Proposal Development

A. Investigators have the opportunity and responsibility to propose new areas of research to the Steering Committee for review and consideration. An idea must first be presented to the Steering Committee in the form of a concept before it can move forward to be developed into a full protocol.
B. Concept Proposals:
Concept proposals must be distributed at least 10 days in advance of a Steering Committee meeting to the members of the committee for review. The written concept should be no more than 2-3 pages and include the following sections:
    1. Abstract—brief summary of the proposed research including primary hypothesis and research question;
    2. Background and Significance—brief summary of supporting research and preliminary studies;
    3. Study design—preliminary description of how the study will be executed including the study population, inclusion criteria, exclusion criteria, randomized groups (if applicable), and methods. A sample size calculation should be included;
    4. Feasibility
    5. Budget—a rough estimate of the total cost of the study should be included;
    6. References.
C. Full Protocol:
Once a concept has been accepted by the Steering Committee, it should be developed into a full protocol. The full protocol is a very detailed expansion (15-30 pages) of the concept, which must convey a clear and complete account of how the study will be implemented.

D. One hour will be allotted to each concept/protocol presentation (with approximately 30 minutes for presentation and 30 minutes for discussion). After a concept/protocol has been presented, one of the following will occur:
    1. The investigator can withdraw the concept/protocol from immediate voting in order to make revisions based on the Steering Committee's comments;
    2. The concept/protocol can move forward to a vote;
        a. If the concept/protocol is accepted according to the guidelines below, a full protocol must be presented at the next Steering Committee meeting;
        b. If the concept/protocol is not approved, the investigator has the option of re-presenting a revised concept/protocol at the next meeting.

II. Concept/Protocol Approval Policy

A. A concept proposal will be approved to advance to protocol development when it receives a 3/4th majority vote in favor. Voting occurs by secret ballots that are counted at the meeting immediately after they are cast. The outcome of the vote is announced at the meeting. A full protocol must then be presented at the next scheduled Steering Committee meeting.
B. A final protocol must be presented and approved by the Steering Committee at the next meeting in order to be submitted for funding. A final protocol is approved when it receives a 3/4th majority vote in favor. All changes made to the protocol after final approval must be presented and approved by the Steering Committee.
C. The Steering Committee will be responsible for prioritizing the next protocol to implement or submit for funding, when multiple proposals have been approved to move forward.

III. Prioritization

A. At the end of each Steering Committee meeting, the committee will prioritize the next protocol to be submitted for funding. Only two protocols may be in this phase at any given time.
B. Each study in the queue will be ranked by each investigator with a score between 1 and 5 (with 1 denoting the study that shall move forward next). Ranking should be based on scientific and clinical importance, and feasibility.
C. The protocol that receives the majority vote will move forward.
D. The chair of the Steering Committee will participate in the prioritization vote.
E. Only one "unfunded" protocol may be prioritized at any one time in order to preserve infrastructure resources, and maximize funding potential. The Steering Committee reserves the right to approve more than one "unfunded" to move forward with the approval of the Administrative Director and the Financial Oversight Committee.
F. There is no limit to the number of ongoing protocols conducted by the PRC.

IV. Publication/Authorship Policy

A. All changes made to this Publication/Authorship Policy must be approved by the Steering Committee of the PRC.
B. All centers should be recognized for their participation in a protocol if the journal allows. Thus, all publications generally will include-**1 or 2 authors per center, at the discretion of the PI (If conflict, Publications Committee will be used for mediation. If still not resolved, the PRC Chair will make the final recommendation.)**
    1. **The parent center will be allowed no more than 4 authors (see below: IV. C) plus a resident/fellow; and**
    2. **Statistician is not included in this limit; and**
    3. **The policy will be the same for abstracts and manuscripts. Special consideration will be at the discretion of the Publications Committee.**

C. Authorship credit shall be based on **ICJME's 4 Main Criteria for Authorship:**

1. **<u>Substantial contributions to</u> the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND**
2. **Drafting the work or revising it critically for important intellectual content; AND**
3. **Final approval of the version to be published; AND**
4. **Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved; AND**
5. **The PRC will also include a center as an author if the center acquired IRB approval with intent to participate in the study as well as meets all other publication criteria.**

D. Each protocol will have a primary PI. This PI will be the first author on the primary manuscript.

E. The subsequent authors will be listed as follows:

1. The remaining participating center PIs, based on ranking (see below: IV. K),
2. Chair of the Steering Committee,
3. "for the Perinatal Research Consortium" **if patients are recruited for OR "and the Perinatal Research Consortium" if the PRC gave guidance, depending on the project. The Publications Committee will review and make sure it is consistent.**

F. The PRC agrees that all studies conducted by any consortium site that raises religious concerns will not publish utilizing corporate authorship. Inclusion in these publications will be up to the individual authors and sites.

G. Investigators may relinquish their authorship to a colleague from their institution who serves as local project director for the protocol.

H. If a journal editor requires fewer authors than submitted, the primary author and the Steering Committee Chair will choose the authors. Alternatively, corporate authorship (Perinatal Research Consortium) is an option for any publication where religious constraints are not present.

I. The support of the study sponsor must be acknowledged on all manuscripts at the foot of the title page as "this work was supported by …".

J. Others who contributed significantly to the work, but are not authors, will be named in the Acknowledgements. These contributors are included by center, which is listed in order of its rank (see below: IV. K). A total of five study-affiliated personnel not listed as authors, prioritized by the site investigators may be included. For each protocol, the order that participating institutions and their personnel are listed in the Acknowledgements is based on the order of the institutions in authorship.

K. Center Ranking will be based on recruitment. At the discretion of the protocol PI, with approval from the Steering Committee Chair, a site may be moved down in ranking for recurrent data quality concerns or protocol violations. The Steering Committee can approve authorship for consultants who have made significant scientific contributions to the study as authors on manuscripts.

L. Investigators may move away from the consortium site. The site's new and former investigator should determine authorship. In general, authorship should be given to the investigator who participated in the study the longest and/or most actively. The Steering Committee Chair will decide authorship if there is a disagreement between the old and new site investigator.

M. Two presenters are allowed per concept.

N. Any investigator presenting to the PRC must comply with the PRC Publications Policy (even if there are prior agreements at local site). A proposal is considered to be bound by the aforementioned rules if there is a vote and the Steering Committee agrees to move forward.

Addendum: A writing group for the PRC should accommodate one person from each site and be comprised of those who are interested in the study. The Writing Group will be first set of authors.

IV. Voting Principles

A. **When voting to move a proposal forward the vote should be based on the science and whether it is good for the overall PRC.**
   1. **Is it a valuable contribution to science?**
   2. **Is it good for the PRC?**
   3. **Is it good for my Site?**

B. **Before a vote, the science, the value to the PRC, as well as the feasibility of the proposal, should be discussed before the vote. If the proposal is not feasible, it will not go for a vote.**

C. **Prior to presenting to the Steering Committee for a vote, the investigator should examine feasibility by possibly doing a pilot study, surveying the Sites beforehand, or developing a Working Group to help craft the proposal for the Steering Committee.**

D. **Each member of the Steering Committee has voting rights (with the exception of the Administrative Director).**

E. **The chair votes in the event of a tie. The chair may also vote as a member of his/her site but no more than two votes may be cast from any site.**

F. **If a site investigator is absent from a Steering Committee meeting and/or absent from an Administrative Board vote, he/she may appoint an alternate investigator to attend the meeting and vote in his/her place.**

G. **If only one board member is present for the Steering Committee meeting, only one vote for the site may be cast.**