Creation of a Collaborative Research Network for Junior Investigators

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ABSTRACT

Due to the specialized nature of Female Pelvic Medicine and Reconstructive Surgery (FPMRS), many landmark studies are the product of national collaborative research networks of established senior investigators at various academic institutions. The Society of Gynecologic Surgeons (SGS) sponsored the foundation of the first multicenter research network for fellows in 2008, the aims of which were to: 1) Create an environment for fellows to participate in collaborative research and conduct multicenter studies as primary investigators; 2) Enhance fellows' knowledge and skills in study design, implementation of multicenter studies, data management and statistical analysis; and 3) Provide an environment for fellows to develop professional relationships that will be sustained after graduation. As alumni of the Fellows' Pelvic Research Network (FPRN), our aim was to create a similar research network for junior investigators to continue to perform collaborative research.

To accomplish this goal, we assembled the **Collaborative Research in Pelvic Surgery Consortium (CoRPS).** CoRPs consists of five geographically diverse academic institutions with fellowship-trained specialists in FPMRS.

Governance of this research consortium includes a Steering Committee, a Financial Oversight Committee, two statisticians, and an administrative director. The Steering Committee is responsible for selecting and approving topics for investigation; overseeing protocol development; participating in data analysis, presentation, and publication; approving financial resource utilization; and maintaining and assuring compliance with the network's policies and procedures, by-laws, and applicable regulations. The Financial Oversight Committee oversees the administrative finances of the network and annually reports findings to the Steering Committee. Because this research network is comprised of junior investigators, we have an Advisory Board of three senior investigators with diverse experience in multicenter research network organization and participation. Administrative oversight is provided by a non-physician Administrative Director proficient in research management and operation at the Coordinating Center. Concept proposals are presented to the Steering Committee, and if approved, protocol development ensues. Full protocols must be approved through a formalized review process by the Steering Committee before being submitted for funding and IRB approval, and the committee prioritizes the order of approved protocols to be undertaken by the network. Since our inception three months ago, we have initiated one protocol and IRB approval is underway at all 5 participating sites. In conclusion, formation of a collaborative research network amongst junior investigators in FPMRS is feasible. Further, the FPRN established by SGS six years ago has achieved its three aims, as evidenced by the formation of this research consortium of junior investigators.

ORGANIZATIONAL STRUCTURE

Advisory Board
Senior research mentors who donate their time and support for CoRPS overall or individual projects

Coordinating Center
1) Provides admin support
2) Maintains data use agreement with each site

PROTOCOL SELECTION & PRIORITIZATION

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 and approved by the Steering Committee in the form of a CONCEPT PROPOSAL before it can be developed into a full PROTOCOL.

A. **CONCEPT PROPOSAL:**

1. This 3 page summary must be distributed at least 7 days in advance of a Steering Committee meeting and should include abstract, background & significance, study design, feasibility, budget, and references

2. At Steering Committee meeting, 5 – 10 minutes are allotted for presentation followed by up to 30 minutes of discussion.

3. After discussion, the investigator can withdraw the proposal from immediate voting in order to make revisions based on the Steering Committee's comments, or can elect to move forward with a vote on whether to develop the concept.

4. Opportunity to provide anonymous comments and a Yes/No/Develop Further vote is coordinated by the non-voting Administrative Director.

- A CONCEPT will be approved to advance to PROTOCOL development when it receives a 2/3 majority vote in favor. If accepted, a PROTOCOL must then be presented at the next in-person meeting (or by phone).
- If the CONCEPT PROPOSAL is not approved or the vote is to develop further, the investigator has the option of re-presenting a revised CONCEPT PROPOSAL at the next phone meeting.

B. **PROTOCOL:**

1. Once approved, a CONCEPT PROPOSAL should be developed into a PROTOCOL: 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. This document should contain the information needed to apply for grants and to generate IRBs at each participating site.

2. A PROTOCOL must be presented and approved by the Steering Committee at the next in-person meeting (AUGS/SGS) in order to be submitted for funding. A PROTOCOL is approved when it receives a 2/3 majority vote in favor. All changes made to the PROTOCOL after final approval must be presented to & approved by the Steering Committee.

3. In the case of multiple approved PROTOCOLS, the Steering Committee will be responsible for prioritizing which one to implement or submit for funding. To prioritize, each study in the queue will be ranked by each investigator using the NIH ranking system to generate an overall impact score, and the protocol that receives the best (lowest) overall impact score will move forward.

4. Only two "unfunded" PROTOCOLS may be prioritized at any one time in order to preserve infrastructure resources and maximize funding potential. There is no limit to the number of ongoing funded PROTOCOLS conducted by the CoRPS, though in general we will limit to 2 active PROTOCOLS.

C. **PUBLICATION & AUTHORSHIP:**

All sites will be recognized for participation. Authorship is based on substantial contribution to study design/data collection, manuscript preparation, & final manuscript approval. Full ranking guidelines outlined in Policies & Procedures.

GOVERNANCE & MEMBERSHIP

The CoRPS consists of 5 institutions (sites) in the United States:

- Cara Grimes, MD. Columbia University Medical Center
- Heidi Brown, MD. University of Wisconsin School of Medicine
- Danielle Antosh, MD. Houston Methodist Hospital
- Jonathan Gleason, MD. Carilion Clinic Urogynecology
- Sallie Oliphant, MD. University of Arkansas
- Statisticians: Husam Abed, MD and Thomas Wheeler, MD, MSPH

Addition of other sites must be unanimously approved by the Steering Committee after an application process is completed. Ancillary sites may be recruited for a specific protocol but are not members of the Consortium and are not entitled to a seat on the Governance Committees.

ADVISORY BOARD

- Cheryl Iglesia, MD. MedStar Washington Hospital Center
- Kimberly Kenton, MD. Northwestern University Feinberg School of Medicine
- Holly Richter, MD. University of Alabama at Birmingham

STEERING COMMITTEE

RESPONSIBILITIES:

- Selecting, designing, and approving study protocols
- Participating in data analysis, presentation, and publication
- Maintaining and assuring compliance with CoRPS By-Laws, Policies and Procedures
- Approving financial resource utilization (informed by Financial Oversight Committee)

MEMBERSHIP:

- One investigator from each CoRPS site (must hold PhD, MD, or equivalent)
- Two Statisticians (voting members)
- Administrative Director (non-voting member)
- One member is designated Chair and serves for five years.

MEETINGS:

- Conference calls at least bi-monthly; site coordinators invited to participate
- Two in-person meetings at AUGS and SGS (attendance by each site is required)
- At least one voting representative must be present from each site

FINANCIAL OVERSIGHT COMMITTEE

RESPONSIBILITIES:

- Overseeing grant applications (including budget proposals)
- Monitoring the utilization of membership funds
- Reviewing a detailed CoRPS Financial Report for Steering Committee annually
- Making recommendations to the Steering Committee regarding financial matters

MEMBERSHIP:

- One investigator from each CoRPS site (must hold PhD, MD, or equivalent)
- One member is appointed Chair by the Steering Committee and serves for two years.

SUSTAINABILITY

FUNDING

We are actively pursuing funding from multiple sources

1. **NIH:** U34 Planning Cooperative Agreement
2. **PRIVATE FOUNDATIONS**
3. **INDUSTRY PARTNERS**

CONTACT

If you would like to discuss collaboration with our network, please contact our Administrative Director, Nisha Philip, via email: np2173@cumc.columbia.edu

You can also visit our developing website: http://corpsconsortium.org/

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