

## FPRN Policies and Procedures

### 1) Development of the FPRN

#### a. Background

Female Pelvic Medicine and Reconstructive Surgery (FPMRS), also known as Urogynecology, was established in the US in 1976. Since then, fellowship programs to sustain this field have continued to expand. Under fellowship accreditation guidelines defined by the American Board of Obstetrics and Gynecology (ABOG) and the American Board of Urology (ABU), one third of any accredited program is dedicated to research.

To facilitate the recruitment of patients to answer clinical questions, multi-centered studies have become increasingly common. Numerous networks have been established to facilitate collaborative efforts in the development and performance of research studies. Research networks allow timely recruitment and completion of studies and increases the generalizability of results.

To promote research training and expose fellows to multi-center studies, in 2007 the Society of Gynecologic Surgeons (SGS) sponsored the creation of the first fellows multi-center research network the **Fellows' Pelvic Research Network (FPRN)** for FPMRS fellows. The idea for this research network was suggested by a fellow, Lior Lowenstein. SGS considers the FPRN an important initiative within the context of its mission statement to promote education and research in Gynecologic Surgery.

#### b. Scope

This network is open to all fellows in Female Pelvic Medicine and Reconstructive Surgery. Interested fellows from accredited and non -accredited programs across the United States and Canada are welcome to join. Fellows applying for membership in the FPRN must be prepared to be active participants in the network's research activities. All members of the network will have the opportunity to be actively involved in developing, implementing, conducting, and publishing research studies.

#### c. Mission Statement

The purpose of the FPRN is to enable fellows to work together cooperatively and conduct multi-center pelvic floor research projects. The goal of the FPRN is to imbue fellows with greater confidence, ability and efficiency in becoming accomplished researchers. Within the FPRN fellows will work and collaborate both with peers and leaders in the field of urogynecology. The network also provides the opportunity to form ties with colleagues throughout the United States and Canada that will continue long after fellowship. Participation in the FPRN should help members become more effective researchers.

The specific goals of the FPRN are to:

- 1) Create an environment for fellows to participate in collaborative research and conduct multi-center studies as primary investigators.

- 2) Enhance fellows' knowledge and skills in study design, implementation of multi-center studies, data management and statistical analysis. Participating fellows acquire experience in process of conducting successful clinical research including:
  - a. Study protocol preparation
  - b. IRB submission, with each fellow responsible for IRB submission in their own institution
  - c. Patient recruitment for a clinical study
  - d. Database creation
  - e. Data entry
  - f. Data analysis
  - g. Manuscript writing
  - h. Abstract submission
  - i. Abstract presenting at National and International conferences
  - j. Manuscript writing and publication
- 3) Provide an environment for fellows to develop professional relationships which will be sustained after graduation.

## 2) **Organization of the FPRN**

### a. **Advisory Board**

The FPRN and its research projects are operating under the mentorship and supervision of the Advisory Board which includes representatives from the SGS Executive Board and Research Committee. This group consists of experienced urogynecologists, gynecologists, and epidemiologists: Steve Young, Joe Schaffer, Rebecca Rogers, Linda Brubaker, Kim Kenton, Rajiv Gala, Vivian Sung, Miles Murphy, Tom Wheeler, and Janet Hardy. A Junior Advisory Board consisting of former fellows of the FPRN provides additional support and resource.

### b. **Steering Committee**

#### i. **Membership**

The FPRN Steering Committee consists of three fellows with positions of Chair, Secretary, and Treasurer. Terms are one or two years based on date of graduation from fellowship. New members will be elected to serve on the Steering Committee annually at the SGS FPRN meeting. The number of fellows elected will equal the number of openings on the committee. To facilitate continuity, at least one Steering Committee member being elected must be in their first year of fellowship. Fellows are elected to the Steering Committee by anonymous vote of the current FPRN fellow members and Advisory Board members present at the meeting. The positions of Chair, Secretary and Treasurer will be decided internally by the Steering Committee members. Past Steering Committee members will remain as emeritus members through the end of fellowship and also have

the opportunity to serve as Junior Advisory Board members after graduation.

ii. **Responsibilities**

The responsibilities of the FPRN Steering Committee include:

- Planning FPRN meetings at SGS and AUGS
- Administering FPRN funds, preparing budgets, meeting financial reporting requirements
- Communication with the Advisory Board
- Communication with the FPRN members
- Coordination and monitoring of ongoing research projects, including progress toward goals and conflict resolution.
- Attending all FPRN meetings

iii. **Meetings**

The Steering Committee will meet weekly through conference calls or as necessary. A bimonthly conference call will be held with the Advisory Board and Principal Investigators to provide project updates and conduct other necessary business.

c. **Project Principal Investigators**

When a proposal is selected by the FPRN for implementation as a multi-center research project, the fellow who developed the proposal becomes the project Principal Investigator (PI). PI's responsibilities include:

- Regular communications with and updates to the Steering Committee and Advisory Board
- Attending all FPRN meetings
- Accountability for use of research funding
- Accountability for meeting project deadlines, completing research project, presenting research findings at national meetings and publishing results.
- Coordination of all participating study sites
- Providing project leadership, including authorship decisions and conflict resolution
- Involvement in network will continue until completion of their project which may extend beyond graduation

PIs will have the opportunity to submit an application to be reviewed by the Advisory Board to serve as Junior Advisory Board members after graduation.

d. **Funding Committee**

The Funding Committee was established to pursue new funding opportunities to support the FPRN's research activities and meetings. The FPRN Treasurer is a member of the Funding Committee.

e. **Clinical Sites**

All members of the FPRN are expected to actively participate in at least one research project.

f. **Communication**

Communication and transparency are important goals of the FPRN. Communication within the network will be accomplished through biannual meetings and biannual conference calls. Additional communication will be performed through e-mail as necessary. All significant decisions and changes affecting the network must be approved by the FPRN membership.

**g. Meetings**

The network meets biannually at the SGS and AUGS annual meetings. These meetings provide opportunities to discuss ongoing research projects, review new proposals and select new projects for implementation. Meetings are also opportunities to further fellow education through didactic sessions and guest speakers.

**h. Committees and Subcommittees**

Committees and subcommittees may be created at the discretion of the Steering Committee. The life of the committee will be based on the underlying purpose; committees may become permanent entities within the FPRN or be temporary to focus on a specific event or issue. Membership on a committee is based on interest and appointment by the Steering Committee. Committees report to the Steering Committee. The length of term on a committee is until graduation from fellowship. New members will be appointed biannually at meetings as necessary.

**3) FPRN Membership**

**a. Overview**

- Membership is open to all interested fellows in a Urogynecology or Female Urology Fellowship . Fellows from accredited and non-accredited fellowship programs across the United States and Canada are welcome to join. Applications for membership from fellows in other disciplines who have an interest in pelvic floor disorders will be considered by the Steering Committee on a case by case basis. Fellows applying for membership to the FPRN must be prepared to be active participants in the network research activities. All members of the network will have the opportunity to be actively involved in developing, implementing, conducting, and publishing research studies. No membership dues required.

**b. Addition of new members**

- New members will be added twice yearly at SGS and AUGS meetings to allow orientation and efficient incorporation into the network and research projects.
- Invitation to join FPRN sent out to all fellows 2 months prior to meetings.
- Fellows at existing FPRN sites may join at any time or they may submit a new proposal for that site at the AUGS and SGS meetings (if no other fellows at that site are currently Principal Investigators)

**c. Members leaving network**

**a. Graduating Fellows**

1. Members may remain in the FPRN until end of fellowship or through completion of projects in which they are active.
2. Members who are graduating and will no longer participate in the network need to submit a “ transition plan” for the project at that site detailing the plans for continuation or discontinuation of the protocol at that site **(see Appendix)**

**b. Non-productive clinical site**

1. Principal Investigators (Protocol Chair) are required to provide the Steering Committee with at least monthly updates, detailing the progress of each site.
2. Members may be asked to leave the FPRN due to lack of participation. Cases will be reviewed on an individual basis by the Steering Committee.

**d. Multiple fellows at single clinical site**

There is no limit to the number of fellows that can participate from any given site. However all members at a site are expected to actively participate in meeting the recruitment goals for their site. It is up to the Protocol chair and each individual fellow to determine if they would be the Principal Investigator at their site. All participating fellows must be active in the network and involve in at least one study.

**4) Protocol Development and Implementation**

**a. Study proposals**

**Mini-proposals (see appendix)** will be accepted for possible presentation twice yearly at the SGS and AUGS meeting. With the intended purpose of enrichment of fellow education, proposals for studies will be principally derived from fellows in the FPRN. All fellows are invited to submit a proposal (however only one proposal per fellow will be accepted for review at each meeting). Fellows who are interested in receiving feedback from the Advisory Board will have to submit their proposal at least 4 weeks prior to the meeting. All proposals will be reviewed by the Steering Committee and Advisory Board. A maximum of 10 proposals will be considered at any meeting. If greater than 10 proposals are submitted, the top 10 will be selected by the Steering Committee and Advisory Board. New projects will be selected by vote of the FPRN members with input from the Advisory Board Members present at the meeting.

**b. Protocol implementation**

- i. All Principal Investigators are required to submit a final protocol which includes a budget and timeline for completion of their protocols. This has to be reviewed and approved by the Steering

Committee and Advisory Board before implementation of protocol or before distribution of funding.

- ii. All Principal Investigators will be required to strictly adhere to the guidelines outlined by their individual site's IRB/ HRRC. Each Protocol Chair must also be familiar with all participating institutions IRB requirements
- iii. Monitoring of active research projects:
  - 1. Protocol Chair to update Steering Committee monthly on progress.
  - 2. Steering Committee responsible for intervention if a project is consistently not meeting goals.
  - 3. Each protocol chair is required to present updates twice yearly at the FPRN meetings ( SGS and AUGS)
  - 4. Each Protocol Chair may be required to present an official update to the entire meeting body at the annual SGS meeting

c. **Conflict Resolution**

Any issues related to individual projects should first be discussed with the Project's PI. The Steering Committee will be available to all members if specific issues are not adequately addressed by the project's PI. Members should also feel free to contact the Advisory Board if conflicts are not sufficiently addressed by the Steering Committee.

## 5) Quality Assurance

### a. Mentorship

#### i. Protocol development

After a research proposal is accepted by the FPRN, protocol development will be completed by the project team and coordinated by the principal investigator. A member of the Advisory Board will serve as project advisor and mentor protocol development. A Junior Advisory Member will also serve in this capacity. Additionally, PIs are encouraged to seek a local faculty member for guidance in the study.

#### ii. Teleconferences

Advisors should participate in project teleconference calls to guide fellows through the process of implementing research protocols. They should serve as a resource when issues and problems arise pertaining to authorship and data analysis, for example. Participation is essential to ensuring research projects are progressing appropriately and that abstract and manuscript deadlines are met.

#### iii. Abstracts and Manuscripts

During the development of the project timeline, advisors will assist in planning where to submit abstracts and manuscripts in an effort to maximize publication of FPRN research. Abstracts and manuscripts should be circulated to advisors no later than 2

weeks prior to a deadline and all comments will be returned to the PI within 1 week to allow for revision. The advisors will circulate comments amongst themselves and provide comments on a single version of the manuscript to return to the PI.

**b. Routine study and data quality checks**

Each project site shall adhere to its own IRB requirements for research. Each site will collect data and send de-identified data to the principal investigator to be analyzed. Storage of data will be at the individual sites as well as the principal investigator site during the study period. Each site will be responsible for assuring the IRB process is strictly adhered to.

All data becomes the property of the Network at the conclusion of the study and/or upon the graduation of the PI. The data will be stored at SGS adhering to the standards of strict confidentiality as required by the PI's IRB.

**c. Dissemination of information**

A member of each project group shall be responsible for writing the minutes of each conference call and meeting and submit this to the secretary of the Steering Committee. Subsequently, the minutes will be distributed to the FPRN members and Advisory Board.

**6) Funding**

**a. Management of the budget**

The management and administration of the budget shall be the responsibility of the FPRN Treasurer with the support of rest of the Steering Committee and the Advisory Board.

**b. Study budgets**

Individual study budgets are established at the beginning of a project. Study budgets will be reassessed at the biannual FPRN meetings or as necessary. Each study principal investigator shall be responsible for maintaining their project's budget for the duration of the project. The PI is responsible for preparing study budget reports for SGS and AUGS meetings and at the request of the Steering Committee.

**c. Financial status reports**

The FPRN budget status report shall be submitted to the SGS executive committee annually before the SGS annual meeting. The FPRN financial status and budget update will be communicated to the FPRN members at the bi-annual meetings at SGS and AUGS. The Treasurer is responsible for preparing reports and presenting information on the FPRN financial status.

**d. Internal funding**

Primary funding for the FPRN is through SGS. Funding is determined annually at the SGS annual meeting. The annual request for FPRN funding will be submitted to the SGS executive committee prior to the SGS meeting. The FPRN Treasurer is responsible for preparing the

annual request for SGS funding. Accounting and disbursement of funds is through the SGS account and is managed by the Treasurer.

**e. External Funding**

The Funding Task Force shall pursue other funding sources to support FPRN meetings and research studies.

**7) Publications, Presentations and Ancillary Studies Policy**

**a. Objectives**

FPRN research results shall be submitted to professional organization meetings such as SGS and AUGS for presentation. Current recommendation is that primary abstract is submitted to SGS and secondary abstracts may be submitted to other professional organization meetings. Subsequently, manuscripts shall be submitted for publication in peer-reviewed journals.

**b. Proposal and approval process**

FPRN members are invited to propose original research ideas at the bi-annual meetings at SGS and AUGS. The proposals may be reviewed by the Advisory Board prior to their presentation at a FPRN meeting. Proposals are chosen based on scientific merit and feasibility by vote of FPRN members present at the bi-annual meetings.

**c. Selection of writing committee members and writing committee chair**

Individual research projects will internally select writing committee and chair.

**d. Authorship**

Authorship shall reflect the level of participation by FPRN members in data collection, conference calls, and writing. The first paper submitted by a research project will have the PI as first author. Criteria to gauge participation and subsequent authorship order will be established during the early stages of the project and may also include the local mentor and junior advisory board member. Generally, the last author shall be the project Advisory Board member. Secondary papers will allow other FPRN members to be first authors. Authorship of secondary papers will be based on established criteria including generation of ideas and level of effort.

**e. Preparation and submission of abstracts for national and international meetings**

Abstracts will be written by the study writing committee in consultation with the attending advisor. Prior to submission, the project advisor will review all abstracts. The selection of meeting for abstract submission will be made by the PI and project team in consultation with the project advisor.

**f. Ancillary studies and presentations**

Ancillary studies are encouraged. Ancillary study ideas may be developed during initial protocol development or subsequently

during implementation of the research project. Any member of the project team may propose an idea for a secondary study. The decision to accept a secondary study idea will be made by the project team and attending advisor. The attending advisor will mentor any secondary study arising from a research project through development and submission to meetings and journals.

## **Appendices**

- a. FPRN Proposal Submission Form**
- b. FPRN Application Form**
- c. Transition Plan Guidelines for Fellows**
- d. Governance Structure**