

## FPRN® Policies and Procedures

- A. FPRN® Overview
  - a. Scope: This network is open to all fellows in all sub-specialties of surgical gynecologic practice, including (but not limited to) Female Pelvic Medicine and Reconstructive Surgery (including OBGYN and Urology graduates), Minimally Invasive Gynecologic Surgery, Pediatric and Adolescent Gynecology, Reproductive Endocrinology & Infertility, and Family Planning. 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 Associate Members of the Society of Gynecologic Surgeons (SGS) and the collaborating Society. The application for Associate Membership in SGS is available on the SGS website under the Membership tab. Fellows applying for membership in FPRN® also 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.
  - b. Mission Statement: The purpose of the FPRN® is to enable fellows to work together cooperatively and conduct multi-center 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 gynecologic surgery. The network also provides the opportunity to form ties with colleagues throughout the United States and Canada that will continue long after fellowship.
- B. The specific goals of the FPRN® are to:
  - a. Create an environment for fellows to participate in collaborative research and conduct multi-center studies as principal investigators.
  - b. Enhance fellows' knowledge and skills in study design, implementation of multi-center studies, data management and statistical analysis. Participating fellows acquire experience in the process of conducting successful clinical research including:
    - i. Study protocol preparation
    - ii. IRB submission, with each fellow responsible for IRB submission in their own institution
    - iii. Patient recruitment for a clinical study
    - iv. Database creation
    - v. Data entry
    - vi. Data analysis
    - vii. Manuscript writing
    - viii. Abstract submission
    - ix. Abstract presentation at national and international conferences
    - x. Manuscript submission and publication
  - c. Provide a mentorship platform that brings members with research experience into contact with fellows to provide mentorship in the above clinical research process.
  - d. Provide an environment for fellows to develop professional relationships which will be sustained after graduation.
- C. Organization of the FPRN®
  - a. Advisory Board: See the Advisory Board Policy for further details.
  - b. Study Mentors: See the Advisory Board Policy for further details.
  - c. Steering Committee: See the Steering Committee Policy for further details.

- d. Project Principal Investigators: When a proposal is selected by the FPRN<sup>®</sup> for implementation as a multi-center research project, the fellow who developed the proposal becomes the project Principal Investigator (PI). PI's responsibilities include:
  - i. Regular communication with and updates to the Steering Committee and Advisory Board.
  - ii. Attending all in-person FPRN<sup>®</sup> meetings as well as virtual meetings as requested by the Steering Committee.
  - iii. Accountability for use of research funding.
  - iv. Accountability for meeting project deadlines, completing research project, presenting research findings at national meetings, and publishing results.
  - v. Coordination of all participating study sites.
  - vi. Providing project leadership, including authorship decisions and conflict resolution.
  - vii. Involvement in network will continue until completion of their project which may extend beyond graduation.
  - viii. PIs will have the opportunity to serve as Study Mentors or Advisory Board members after fellowship graduation.
- e. Fellow FPRN<sup>®</sup> Members: Any fellow in a sub-specialty training program which participates in gynecologic surgery (see above) is eligible to join the FPRN<sup>®</sup> as soon as they have matched into fellowship. Fellow members are not required to be PIs during their term in the FPRN<sup>®</sup>, but they must commit to participating in at least one active FPRN<sup>®</sup> research project within the first year of their participation in the FPRN<sup>®</sup>. Once that particular FPRN<sup>®</sup> project is no longer active (no longer engaging in any of the research processes outlined above) due to completing those processes (successful dissemination via publication and/or presentation), that fellow member does not have to participate in another project in order to be an ongoing member for the FPRN<sup>®</sup>. However, if the active FPRN<sup>®</sup> project in which a fellow member was participating is terminated early due to lack of success in moving through the research processes or designation of the research as inappropriate to continue at the individual fellow's clinical site, the PI's main clinical site, or by the FPRN<sup>®</sup> Advisory Board or governance, the fellow must select another research study in which to participate to maintain fellow membership status.
- f. Clinical Sites: Once a fellow member commits to participation in an active FPRN<sup>®</sup> research project, their home institution (the institution at which they are training as a fellow) is considered a "clinical site" for the FPRN<sup>®</sup> project in which the fellow is participating. Once that particular FPRN<sup>®</sup> project is no longer active (no longer engaging in any of the research processes outlined above), that fellow member's home institution is no longer considered a clinical site unless the same fellow or another fellow training at their institution is participating in another active FPRN<sup>®</sup> research project.
- g. Communication: Communication and transparency are important goals of the FPRN<sup>®</sup>. Communication within the network will be accomplished through biannual meetings and biannual conference calls. Additional communication will be performed through email as necessary. All significant decisions and changes affecting the network must be approved by the FPRN<sup>®</sup> membership.
- h. Meetings: The Fellow and Advisory FPRN<sup>®</sup> members of the network will meet in person biannually at the SGS annual Scientific Meeting and at the annual scientific meeting of the relevant outside organization involved in their subgroup. 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, and for fellows and advisors to connect in person for mentorship and collaboration within the network. Leadership of SGS and the outside collaborating organization will ensure space and opportunity is created/provided at their respective annual meetings for these aims to be met.

- i. Committees and Subcommittees: Committees and subcommittees within the FPRN<sup>®</sup> 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<sup>®</sup> or be temporary to focus on a specific event that would affect the direction or aims of the FPRN<sup>®</sup>, an issue that affects the research in the gynecologic surgery field, or a timely research interest. Membership on a committee is based on interest and appointment by the Steering Committee. The length of term on a committee is from appointment until graduation from fellowship. New members of committees may be appointed biannually at the in-person meetings as necessary to fill vacancies in committees that will be ongoing.
- D. FPRN<sup>®</sup> Membership
- a. Membership is open to all interested fellows matching or already training in an eligible fellowship program (see above). FPRN<sup>®</sup> members must be Associate members of SGS as well as a member of the outside collaborating organization. Other than SGS membership dues, there are no other dues to belong to FPRN<sup>®</sup>. Fellows may join FPRN<sup>®</sup> by completing the online form at <https://sgs.memberclicks.net/fprn-membership-application>.
  - b. Addition of New Members
    - i. New members will be added twice yearly at the time of the FPRN<sup>®</sup> subgroup meetings at the SGS Annual Scientific Meeting and the annual scientific meeting of the outside collaborating organization. Adding new members at these times allows for orientation and efficient incorporation into the network and research projects.
    - ii. Invitation to join FPRN<sup>®</sup> will be sent out to all matched or in-training fellows 2 months prior to biannual in-person meetings.
    - iii. Fellows at existing FPRN<sup>®</sup> sites may join at any time or they may submit a new proposal for that site at the biannual meetings of the FPRN<sup>®</sup>.
  - c. Members Leaving Network
    - i. Graduating Fellows
      1. Members may remain in the FPRN<sup>®</sup> until either graduation from fellowship or through completion of projects in which they are active.
      2. Project Principal Investigator members who are graduating and will no longer participate in the network must submit a “transition plan” for the project, including designation of a more junior FPRN<sup>®</sup> fellow member (or one eligible for membership if not already joined) as the PI at the same primary site.
      3. Fellow investigators overseeing secondary sites who are graduating and will no longer be able to participate in the network must also submit a “transition plan” for any projects at that site in which they are directly involved, detailing the plans for continuation or discontinuation of the protocol at that site (see Appendix).
    - ii. Non-productive Clinical Site

1. Project Principal Investigators are required to provide the Steering Committee with at least monthly updates, detailing the progress of each clinical site in the study (not only the primary 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.
- iii. Multiple Fellows at a Single Clinical Site
1. There is no limit to the number of fellows who can participate in the FPRN® from any given clinical site, or in the number of fellows who can be involved with a given project from one clinical site. However, all members at a site are expected to actively participate in meeting the recruitment goals for each study active at their clinical site. It is up to the Principal Investigator and each individual fellow to determine how many fellows may be involved in a given research study at their clinical site. Disputes about the responsibilities of an individual fellow if more than one fellow is participating in a single FPRN® study at a given clinical site will be settled by the PI with input from the Steering Committee if needed. As noted above, all participating fellows must be active in the network and involved in at least one study.
- E. Protocol Development and Implementation
- a. Study Proposals
    - i. Proposals (see FPRN® Proposal Submission Forms in Appendix F) will be accepted for possible presentation twice yearly – at the SGS Annual Scientific Meeting and the annual scientific meeting of the outside collaborating organization. These proposals have the intended purpose of enrichment of fellow education and protocol mentorship in advance of study selection/voting for new FPRN® projects.
    - ii. Proposals for studies will be submitted by fellows in the FPRN® with guidance from a Study Mentor. All fellows are invited to submit a proposal.
    - iii. Proposals must be submitted according to the published deadline in order to allow time for sufficient review and feedback. All proposals will be reviewed by the Steering Committee and Advisory Board.
    - iv. A maximum of 10 proposals will be considered at any in-person meeting. If greater than 10 proposals are submitted, the Steering Committee and Advisory Board will adjudicate the top 10 to be considered prior to the in-person meeting.
    - v. FPRN® will provide feedback on proposals and vote for those they believe are best suited to be funded by FPRN®. The Steering Committee will take this feedback into account, along with project feasibility, budget, available FPRN® funds, etc., in selecting new projects.
  - b. Protocol Implementation
    - i. All Principal Investigators whose projects are selected by vote at the in-person meeting for implementation will submit a final protocol including a budget and timeline for completion of their protocol in a timeframe as designated by the Steering Committee. This finalized protocol will be reviewed and approved by the Steering Committee and Advisory Board before implementation of protocol or before distribution of any associated funding.

- ii. All Principal Investigators will be required to strictly adhere to the guidelines outlined by their individual site's IRB/HRRC. Each PI must also be familiar with all participating institutions' IRB requirements and ensure no study activities at that clinical site would violate these requirements.
  - iii. Monitoring of Active Research Projects
    1. PIs will provide monthly updates to the Steering Committee regarding study progress, including updates on all clinical sites.
    2. The Steering Committee is responsible for intervention if a project is consistently not meeting goals.
    3. Each PI is required to present in-person prepared updates twice yearly at the FPRN® general meetings. If they are unable to be present, they must alert the Steering Committee of the person who will be present as their representative to give the in-person update.
    4. Each PI may be required to present an official update to the entire meeting body at the SGS Annual Scientific Meeting if requested/ appropriate. The PI shall be given appropriate notice of such a request by the Steering Committee to prepare the update and any relevant study data.
  - c. Conflict Resolution
    - i. Any issues related to individual projects noted by FPRN® fellow members participating in that project 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.
    - ii. The Steering Committee will contact the Advisory Board if conflicts are not sufficiently addressed by the Steering Committee.
    - iii. Conflicts not resolved by the Steering Committee with advisement from the Advisory Board will be placed under authority of the Advisory Board and their respective society's appropriate committee.
- F. Quality Assurance
- a. Mentorship
    - i. Protocol Development
      1. After a research proposal is accepted by the FPRN®, protocol development will be completed by the project team and coordinated by the Principal Investigator. The PI should develop the protocol under the mentorship of a Study Mentor, typically at the PIs home institution. They will serve as the lead faculty advisor for the project, and their primary role will be to mentor protocol development and to guide the fellow investigators in ongoing study implementation.
      2. When appropriate, the Study Mentor role for a project can be undertaken by more than one faculty, if the Study Mentors involved agree at the outset on authorship roles (see Authorship Policy for further details).
      3. Additionally, PIs are encouraged to seek a local faculty member for guidance in the study if the primary Study Mentor(s) is/are not at their home institution.
    - ii. Teleconferences: Study Mentors for a project 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

1. During the development of the project timeline, Study Mentors for the project will assist in planning where to submit abstracts and manuscripts in an effort to maximize dissemination of FPRN<sup>®</sup> research.
2. Abstracts and manuscripts should be circulated to the Study Mentor(s) on the project 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 project Study Mentor(s) 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

- i. Each project site shall adhere to its own IRB requirements for research. Each site will collect data and send de-identified data to the PI to be analyzed. Storage of data will be at the individual sites as well as the PI's site during the study period. Individual sites are responsible for alerting the PI if IRB requirements at their site conflict in any way with the overall study protocol.
- ii. All data becomes the property of the FPRN<sup>®</sup> at the conclusion of the study and/or upon the graduation of the PI. The data will be stored by an SGS member of the study team adhering to the local IRB requirements and adhering to the standards of strict confidentiality as required by the PI's IRB. The original study team may publish further work from this data as approved by the FPRN<sup>®</sup> Steering Committee.

c. Dissemination of Information

- i. A designated member of each project group (the group of fellows actively involved in an ongoing FPRN<sup>®</sup> study led by the PI) shall be responsible for writing minutes of each conference call and meeting and submit this to the Secretary of the Steering Committee.
- ii. Subsequently, the minutes will be distributed to the FPRN<sup>®</sup> members and Advisory Board. This may be done by the PI themselves or another fellow member active in the project as designated by the PI.

G. Funding

a. Management of the Budget

- i. The management and administration of the FPRN<sup>®</sup> budget shall be the responsibility of the FPRN<sup>®</sup> Secretary/Treasurer with the support of the rest of the Steering Committee and Advisory Board.
- ii. Conflicts regarding funding or budgets that are not addressed by the Steering Committee and Advisory Board will be under the authority of the SGS Research Committee.

b. Study Budgets

- i. Individual study budgets are established at the beginning of a project. Study budgets will be reassessed at the biannual FPRN<sup>®</sup> meetings or as necessary.
- ii. Each study PI 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 the biannual FPRN<sup>®</sup> meetings and at the request of the Steering Committee. If they do not present a budget report, they will be contacted by the Steering

Committee and, if not responsive, the Study Mentor(s) to the project will be contacted. If they are still unable to provide a budget report, the Advisory Board as a whole will become involved.

- c. Financial Status Reports
  - i. 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® fellow members and Study Mentors at the biannual meetings.
  - ii. The Secretary/Treasurer is responsible for preparing reports and presenting information on the FPRN® financial status. If the Secretary/Treasurer does not present these reports, the Advisory Board is responsible for ascertaining financial status and reporting the status to the Executive Committee.
- d. Internal Funding
  - i. Primary funding for the FPRN® is through SGS with possible contribution from an outside collaborating organization as agreed upon in a Memo of Understanding with SGS for the FPRN®.
- e. Disbursement of Funds
  - i. Disbursement of funds occurs in two steps: the first half of the funded amount is disbursed after the 1) the final protocol is reviewed and approved by the Steering Committee and Advisory Board and 2) the IRB approval letter from the primary site is received by the Steering Committee. The second half will be disbursed after the initial funds 1) have been spent, 2) the Steering Committee and Advisory Board have reviewed and approved the written progress report which will describe study progress, recruitment (if pertinent), and budget information including how funds received to date have been utilized and the plan for how the remaining funds will be used.
  - ii. Upon approval, the Steering Committee Secretary/Treasurer will forward the approved progress report to the SGS Executive Office with a request to process the remaining payment. The SGS Executive Office may request back-up documentation relevant to project expenses.
- H. Publications, Presentations, and Ancillary Studies Policy
  - a. Objectives
    - i. FPRN® research results shall be submitted to professional organization meetings such as SGS or an outside collaborating organization's annual scientific meeting for presentation.
    - ii. The current recommendation is that the primary abstract is submitted to the SGS Annual Scientific Meeting and secondary abstracts may be submitted to other professional organization meetings. Subsequently, manuscripts shall be submitted for publication in peer-reviewed journals. All SGS research group papers (FPRN®, CoRPS, SRG) are to be submitted to the Publications Committee for review before being submitted to a journal. Publication should reflect that the project is a study from the Fellows' Pelvic Research Network (FPRN®).
  - b. Proposal and Approval Process
    - i. FPRN® members are invited to propose original research ideas at the biannual meetings of the FPRN®. The proposals will be reviewed by the Steering Committee and Advisory Board prior to their presentation at an FPRN® meeting.
    - ii. Proposals are chosen based on the vote of FPRN® members present at the biannual meetings and on the website after the FPRN® meetings, the Steering

Committee, and Advisory Board. FPRN® members are asked to vote for projects based on scientific merit and feasibility of the projects proposed. If a vote of FPRN® members present cannot provide study selection, a “runoff” vote may be held amongst FPRN® members.

- iii. If a conflict of interest within the voting FPRN® members present or the Study Mentors make fairly adjudicating a tie or voting conflict impossible, the Advisory Board may be granted authority to adjudicate study selection by the Steering Committee.
- c. Selection of Writing Committee Members and Writing Committee Chair: Individual research project groups will internally select a writing committee and chair.
- d. Authorship
  - i. In general, all fellows that are part of an FPRN® network study and have put forward appropriate effort as designated by the PI should be listed as authors on the project.
  - ii. The PI is typically the first author, unless they have transitioned supervision and completion of the project to another fellow after graduation under advisement of the Steering Committee. Removal from authorship or order of authorship is under first authority of the PI, but conflicts can be adjudicated by the Steering Committee if the PI is unable to resolve these or is themselves involved in an authorship conflict. To minimize disputes on authorship, an FPRN® author agreement form is required for each participating PI and Study Mentor due within 6 months of proposal approval by the FPRN®.
  - iii. The Study Mentor for the project will be included as an author on the manuscript if they participated in the following areas: study design, data collection, manuscript/abstract review or editing. Additional project advisors (secondary study mentors), may be included as authors in an order agreed upon from the outset of the study. The mentor at each ancillary site for other authors involved in FPRN® multi-center studies will NOT be included in study authorship. Generally, the last author shall be the project’s primary Study Mentor. 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.
  - iv. Authorship conflicts that are not able to be resolved by the PI and/or the Steering Committee should be adjudicated with advice from the Advisory Board. Conflicts that cannot be adjudicated by the above groups will be reviewed and settled by the SGS Research Committee and designee from the outside collaborating organization.
- e. Preparation and Submission of Abstracts for National and International Meetings
  - i. Abstracts will be written by the PI or writing group designee. Prior to submission, the project Study Mentor(s) will review all abstracts. The selection of which meeting to submit the abstract to will be made by the PI and project team in consultation with the project Study Mentor(s). Final manuscript drafts must be reviewed and approved by the Steering Committee prior to dissemination.
  - ii. Failure by the PI to prepare an abstract or manuscript in a reasonable timeframe (following study data collection completion) will be reviewed by the Steering Committee, and if deemed necessary, the Steering Committee will request that



the PI transfer the project to another fellow PI who can complete the project for scientific presentation in a timely fashion.

iii. As the goal of the FPRN<sup>®</sup> is scientific dissemination, the goal of every FPRN<sup>®</sup> project is presentation and publication.

iv. The Steering Committee may ask the Advisory Board to intervene or advise as needed for lack of scientific dissemination in a timely fashion.

f. Ancillary Studies and Presentation

i. Ancillary studies are encouraged. Ancillary study ideas may be developed during initial protocol development or subsequently proposed during implementation of the research project. Any member of the project team may propose a secondary study.

ii. The decision to accept a secondary study proposal for implementation will be made by the project team and the project Study Mentor(s). The Study Mentor on the project is responsible for mentorship of any secondary studies arising from a research project through development and submission to meetings and journals unless they elect to designate another advisor for this secondary project who is more able/appropriate to mentor the secondary project.

I. Appendices

a. Appendix A: FPRN Governance Structure

b. Appendix B: FPRN<sup>®</sup> Advisory Board Policy

c. Appendix C: FPRN<sup>®</sup> Steering Committee Policy

d. Appendix D: FPRN<sup>®</sup> Authorship Policy

e. Appendix E: FPRN<sup>®</sup> Transition Policy

f. Appendix C: FPRN<sup>®</sup> Proposal Submission Forms

i. [AUGS-SGS FPRN<sup>®</sup> Subgroup Proposal Submission Form](#)

ii. [FMIGS-SGS FPRN<sup>®</sup> Subgroup Proposal Submission Form](#)