Southern Illinois Practice Based Research Network

Policy & Procedures

Article 1. Name
The name of the organization shall be the Southern Illinois Practice Based Research Network (SIPBRN).

Section 1.01 Mission
The mission of the Southern Illinois Practice Based Research Network is to improve the health and well-being of patients in Southern and Central Illinois by applying scientific methods to questions important to primary care clinicians, their patients and their communities.

Section 1.02 Goals
To maintain and grow the SIPBRN by creating and maintaining relationships with primary care clinicians and their practices throughout Southern and Central Illinois for the purpose of conducting practice-based research.

Article 2. Membership

Section 2.01 Overview
Membership in the SIPBRN is voluntary and is open to primary care physicians in ambulatory practices (family medicine, pediatrics, internal medicine). Physician assistants and advanced nurse practitioners who work in these offices are also eligible to participate.

Section 2.02 Recruitment
Membership recruitment will be overseen by the Network Director. SIPBRN members are encouraged to assist with recruitment.

Section 2.03 Member Responsibilities
A. Members will comply with the policies and procedures of the SIPBRN.
B. Any research done in collaboration with SIPBRN shall be done according to a separate grant or research agreement.
C. Members may choose which research protocols to become involved in.
D. The member engaging in research will abide by HIPAA rules concerning patient confidentiality.
E. The member engaging in research will comply with all rules and requirements of the applicable Institutional Review Board (IRB) for all human subject research.
F. The member has the option of serving on the steering committee.
G. The member’s practice will assign a staff representative as a main contact to the SIPBRN.
Section 2.04 Withdrawal from SIPBRN

The clinician may withdraw membership at any time although it is expected that he/she fulfill any obligations (such as turning in study data) prior to withdrawal of membership.

Article 3. Organization
The SIPBRN is a collaboration between the Southern Illinois University School of Medicine and the community providers participating in the network. The SIU School of Medicine is the sponsoring organization for the SIPBRN. A steering committee will be made up of the Network Director, five to seven clinician representatives and a community representative.

Section 3.01 Network Director
The Network Director will be an MD, DO or PhD and is appointed by the School of Medicine. The Network Director will be accountable for management of the network and is the liaison between the School of Medicine and the steering committee. Duties include:
A. Participation in network meetings
B. Fiscal management including overseeing the general budget as well as individual study budgets
C. Personnel management
D. Leading reviews of proposed projects in light of research network’s mission and assisting with development and submission of grant applications
E. Oversight of outreach and recruitment of new members
F. Presentations at appropriate forums and leading an annual meeting of members

Section 3.02 Network Coordinator
The Network Coordinator will run the day-to-day operations of the network. Duties include:
A. Research Manager
   The Network Coordinator will identify potential grant opportunities, assist with development and submission of grant applications, develop project-specific protocols and procedures, train and supervise research support staff, and help with management of study budgets.
B. Infrastructure administrator
   The Network Coordinator will create and distribute a PBRN newsletter or periodical mailings (either print or online), organize and schedule meetings, conduct conference calls or teleconferencing relevant to the network.
C. Assistant to the Network Director
   The Network Coordinator will assist with recruitment of new PBRN members, maintain a database/directory for tracking both research activities and member information, and serve as the liaison between the community and the network.

Section 3.03. Steering Committee
The steering committee will consist of the Network Director, five to seven community clinicians, with at least one member from an FQHC and at least one member from a private practice, and a community representative. Committee members will serve for 2 year terms that are renewable. Initially half of the members will serve a one year term as determined by random draw. The Network Director will serve as the Chair of the steering committee for the
first 2 years; afterwards the Chair will be selected by the committee. The committee will meet at least quarterly and as needed between quarterly meetings. Duties include:
A. Develop and review network policies and procedures
B. Assist in recruitment and maintenance of provider network
C. Select research projects and help develop and implement the projects
D. Oversee regulatory compliance
E. Oversee grant submissions

**Section 3.04 Other Network Staff**
Other staff will be employed depending on the needs of the Network and specific projects. This will include research and IT support staff and will be funded through project grants.

**Article 4. Research Policy**

**Section 4.01 Research Priorities**
(a) The SIPBRN Network Director, steering committee and members determine the research priorities of SIPBRN.
(b) Study proposals submitted to SIPBRN must be aligned with SIPBRN’s mission and research priorities.

**Section 4.02 Submitting a Research Proposal**
(a) Any SIPBRN member may propose a research project. Proposals may be sent to the Network Director or to a member of the Steering Committee.
(b) All research projects will include at least one SIPBRN member as primary investigator or co-investigator.
(c) The SIPBRN steering committee will review all proposals for the following criteria:
1) It must be related to practice
2) Results would improve or change the way one would practice
3) It must be feasible (practical)
4) There must be a clinician champion for the project
5) It must be fundable
If the criteria are met, study approval will be by simple majority of steering committee members.

The Network Director and Coordinator will assist the PI in obtaining funding for the project as needed. Only approved projects with adequate funding will be implemented.

**Section 4.03 IRB**
All research projects that are accepted and performed within the SIPBRN will be approved by the Institutional Review Board (IRB) of the SIU School of Medicine and any other IRB board representing any outside partner.

**Section 4.04 Human Subjects’ Protection and HIPAA Training**
Key personnel who substantially participate in research projects (eg. Gather data, obtain patient consent) must complete human subjects’ protection and HIPAA training.
Section 4.05 Conflict of Interest
All SIBPRN members are required to complete and submit a Conflict of Interest Disclosure for review and approval when planning to participate in research.

Section 4.06 Study Conduct
(a) Once a study proposal is accepted by the SIPBRN the Principal Investigator (PI) must first meet with the SIPBRN Network Director and Coordinator to identify SIPBRN assistance/resources required for the project. On certain projects the network staff may help with study protocols, staff training, data collection, etc.
(b) For each project the PI and SIPBRN Director will jointly develop a study implementation plan that will include clear lines of accountability for aspects of the study (e.g., financial and administrative management).
(c) SIPBRN will enter into a Memorandum of Understanding with study site clinicians.
(d) Network clinicians will be responsible for patient recruitment and informed consent in their offices.

Section 4.07 Data Collection and Maintenance
(a) For each project the SIPBRN and Clinic sites will enter into a Business Associate Agreement and/or Data Use Agreement to reflect their understandings and obligations with regard to Protected Health Information.
(b) The Principal Investigator is ultimately responsible for all aspects of a project and its research with assistance from the Network staff. This includes oversight of data management, the accuracy of the data results and interpretation of the data.

Section 4.08 SIBRPN Study Responsibilities
(a) SIPBRN will maintain regulatory oversight for all SIPBRN studies.
(b) The SIPBRN Network Director must approve modifications to study protocols.
(c) SIPBRN has the authority to establish and enforce administrative procedures that minimize the vulnerability of SIPBRN in the financial and administrative management of federal research grants.
(d) At any time, if deemed warranted, the SIPBRN Network Director or Steering Committee member can terminate SIPBRN’s involvement (resources, assistance, etc.) if patient safety is at risk, inappropriate or unethical research methods are being conducted or the best interests of SIPBRN are neglected or unattainable at the time of the research project.

Article 5. Publication and Presentation Policy
SIPBRN Network Director will review and approve all manuscripts to ensure that SIPBRN is credited for its involvement and the quality of the manuscript is appropriate. The Principal Investigator retains all rights and privileges to the manuscript. All manuscripts, publications and presentations must acknowledge the SIPBRN in their work.

Article 6. Communication
Written and oral communication will be done through the office of the Network Director. A list serve will be available for electronic communication.
Article 7. Annual meeting
The Southern Illinois Practice Based Research Network will host an annual meeting for all network members. The planning of the meeting is the responsibility of the steering committee. The purpose of the meeting is to disseminate findings from any completed projects and to expand clinicians’ knowledge of practice-based research.