Practice-based Research Network Research Good Practices (PRGPs): Summary of Recommendations

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Abstract

Introduction: Practice-based research networks (PBRNs) conduct research in community settings, which poses quality control challenges to the integrity of research, such as study implementation and data collection. A foundation for improving research processes within PBRNs is needed to ensure research integrity.

Methods: Network directors and coordinators from seven U.S.-based PBRNs worked with a professional team facilitator during semi-annual in-person meetings and monthly conference calls to produce content for a compendium of recommended research practices specific to the context of PBRNs. Participants were assigned to contribute content congruent with their expertise. Feedback on the draft document was obtained from attendees at the preconference workshop at the annual PBRN meeting in 2013. A revised document was circulated to additional PBRN peers prior to finalization.

Results: The PBRN Research Good Practices (PRGPs) document is organized into four chapters: (1) Building PBRN Infrastructure; (2) Study Development and Implementation; (3) Data Management, and (4) Dissemination Policies. Each chapter contains an introduction, detailed procedures for each section, and example resources with information links.

Conclusion: The PRGPs is a PBRN-specific resource to facilitate PBRN management and staff training, to promote adherence to study protocols, and to increase validity and generalizability of study findings. Clin Trans Sci 2015; Volume 8: 638–646

Keywords: practice-based research networks, primary care research, research methods, research guidelines

Introduction

Practice-based research networks (PBRNs) are groups of primary care practices affiliated with each other in order to ask and answer questions related to community practice[1] and are an important mechanism for conducting translational research.[2,3] Although most PBRNs are affiliated with academic medical centers, their research programs are often conducted in the offices of community-based practicing clinicians. Community-based, participatory research offers the advantage of greater external validity for translating research and evidence into practice, highlighting the potential role of PBRNs to speed the uptake of proven treatments and processes into everyday care. Yet, research conducted in such decentralized settings poses quality control challenges to the integrity of the primary care research enterprise, including implementing standardized research protocols in decentralized settings, and supervising data collection activities at multiple community-based clinical practice sites. Furthermore, the boundaries between research and practice must be emphasized to clinical practice staff who may recruit and collect data from patients while having very little research training.

To date, no comprehensive compendium of good research practices existed specifically for PBRNs. Certainly, many resources exist for planning and designing studies, as well as for training in the responsible conduct of research. However, in spite of the growing importance of PBRNs as vehicles for conducting research in real-world settings, there is little infrastructure to guide good research practice specific to the context of decentralized primary care settings, and particularly to the ethical and operational aspects of research beyond participant recruiting and informed consent issues.[4] Therefore, we were determined to develop a resource specific to the context of practice-based research that focuses on issues integral to the development, management and supervision of practice-based research, without attempting to duplicate existing resources on the responsible conduct of research or research study design issues.

Preliminary study

This project builds on a previous study "Research Culture of Practice-based Research Networks[5] that established a foundation for improving research processes in PBRNs. The study used a participatory research process to develop a self-assessment tool for PBRNs to identify strengths and weaknesses in their research practice. In that preliminary work, 75 PBRN experts ranked the items most essential for sound research processes specific to the PBRN context. PBRN survey research experts reviewed item wording, identified redundancies and gaps making many suggestions for improvement. The primary outcome of the multistep formative process was a list of 31 items representing five domains: data management, study supervision, PBRN policies, study management, and ethical considerations (Appendix).

Although the 31 PBRN research best practices were a new resource for PBRNs to self-assess their research practice and identify areas for improvement, they lacked details for specific procedures, and guidance as to how to implement the best practices. Thus, the need for more detailed research guidelines was identified. This paper reports on the PBRN Research Good Practices (PRGPs) developed to fill this gap.

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Methods

Building on the initial work to identify research best practices specific to the context of PBRNs, the PRGPs is a compendium of recommended research procedures developed by network directors and coordinators from seven PBRNs: IRENE, the Iowa Research Network; MetroNet, the Metropolitan Detroit Research Network; OKPRN, the Oklahoma Physicians Resource/Research Network; ORPRN, the Oregon Rural Practice-based Research Network; PCRC, the Duke Primary Care Research Consortium; RIOS Net, the Research Involving Outpatient Settings Network; and WREN, the Wisconsin Research and Education Network

From 2010 to 2014 this collaborative of network directors and coordinators participated in the demonstration project "Building Research Culture with Quality Improvement Strategies" (PI, Neale R18HS019601). Working with a professional team facilitator and following the Technology of Participation® strategy,[6] a minimum of two representatives from these experienced PBRN researchers produced the PGRPs compendium using the 31 PBRN research best practices as a starting point. Importantly, the PRGPs reflect the participants' wisdom and experience conducting primary care practice-based research. A companion paper describes the qualitative team process and resulting dynamics with professional facilitators that produced the PRGPs.

To increase the generalizability of the PRGPs, we sought peer review prior to dissemination at a national Webinar conducted in the fall of 2014.[7] The PRGPs were circulated for review and critique by attendees at the 2013 AHRQ National PBRN preconference workshop, by members of the North American Primary Care Research Group (NAPCRG) Committee on the Advancement of Science of Family Medicine (CASFM) PBRN workgroup, and by members of three ARHQ-funded PBRN "Centers for Primary Care Practice-based Research and Learning".[8–10] To facilitate the collaborative revision of the PRGP document, the Society of Teachers of Family Medicine (STFM) provided study team members access to a Web-based Wiki platform that incorporated basic group-level document editing and team messaging functions. Wiki working groups of 5–8 collaborators were selected for each chapter based on their interest in the chapter's topic. Dr. Nagykaldi prepopulated the Wiki with draft versions of each PRGP chapter. Each working group then engaged in an iterative editing process led by one or two group leaders, who requested the review and updating of chapter parts online, consolidated suggested changes, and released new versions for subsequent rounds of editing.

The use of the Wiki platform proved to be challenging. Users struggled with communication features in the Wiki to support a 2-level collaboration process between the reviewers and study teams to edit each chapter. The Wiki contained limited editing and annotating features that are common in other word processing software. Thus, reviewers were encouraged to highlight the portion of the text they wanted to change and to use the "comment" feature in the footnote section to suggest revisions. Direct editing was reserved for the core team only. This process was clearly less efficient and some chapter groups reverted back to circulating edited documents by email. All edits were discussed by the core team and incorporated into the PRGPs if deemed within project scope. Each chapter was finalized before assembling the entire document.

Here, we summarize the PRGPs document with an overview of each of its four chapters, and their associated appendix of "Info Links" which provide supporting details, examples, and form templates from each chapter.

Results

The PRGPs document is organized into four chapters: (1) Building PBRN Infrastructure; (2) Study Development and Implementation; (3) Data Management; and (4) Dissemination Policies, and is available at: http://www.napcrg.org/PBRNResearchGoodPractice. An outline of the recommendations from the PRGP chapters is as follows.

Building PBRN infrastructure

Rationale for chapter: PBRNs conduct research that matters in daily primary care clinical practice, help improve the safety and quality of care, and provide learning communities for knowledge transfer (translating research and evidence into practice). PBRNs require some infrastructure support to sustain their strategic plan; this includes nurturing community connections with clinical practice members and with other stakeholders and maintaining staff readiness to seek external funding. Some PBRNs may not have all of these resources in the early stages of their development. They may consider partnership with more experienced networks that can assist them to develop their own infrastructure. New PBRNs may also request infrastructure support from their institution as they support their institution's mission with the value-added activities of their network.

Based on a cursory review of PBRNs in the United States[11] three organization types seem to have emerged. Most PBRNs operate out of an academic institution (often a Department of Family Medicine) under the same legal entity. Some other PBRNs, although closely tied to academic institutions, are separate organizations with at least some private resources and personnel. A third type includes nonacademic PBRNs that often operate within specific communities and conduct community-based participatory research (CBPR) or research driven by specific community stakeholders.

PBRN infrastructure support includes a wide variety of activities which make it possible for networks to rapidly react to funding opportunities and also to proactively develop research and quality improvement programs aligned with the network's mission. Recommendations and resources in *Table 1* for building PBRN infrastructure reflect the wisdom and experience of PBRN leaders. This PBRN infrastructure supports, yet overarches the needs of a particular study. These infrastructure requirements include: (1) developing and maintaining relationships; (2) strategic planning; (3) building PBRN infrastructure; (4) PBRN staffing; and (5) PBRN funding.

Study Development and Implementation

Rationale for chapter: Investigators who conduct practice-based research often include geographically dispersed practices. This dispersion requires extra work by the investigators to educate the practice staff (nurses, nurse assistants, physicians, social workers, and other staff) in each practice so that they can complete the research tasks in a consistent manner. Conversely, the practice staff will need to educate the investigators on what is feasible in their particular busy practice. The purpose of this chapter is to outline processes to promote research quality management and quality performance.

Table 2 summarizes the recommendations and resources for study development and implementation. This chapter addresses ten topic areas: (1) preproject development; (2) research project staff roles and responsibilities; (3) staff education; (4) community partner involvement; (5) study personnel evaluation and

Recommendations
• Recruit and retain PBRN members, sustain and grow the organization in a participatory manner
- Contact members through a respected champion clinician or PBRN leader
- Invite members personally as part of a systematic recruitment process
- Help members take ownership of the PBRN through active participation
- Provide value-added resources and services to members
- Establish effective, bi-directional communication
• Define a clear mission and vision for the organization to ground all of its activities
- Organize periodic and professionally facilitated strategic planning sessions
- Find critical areas where value can be generated or provided for members
- Translate SWOT/needs assessment into goals and strategies
- Track progress and adjust approaches/resources accordingly
• Develop an organizational structure that can turn ideas into successful projects
- Create venues for soliciting project ideas from members
- Build a structure for vetting ideas based on priorities
- Establish a "web" of professional partnerships
- Develop a database for membership tracking and ongoing organizational improvement
- Establish a PBRN information management infrastructure
- Implement innovative processes for ongoing feedback to members
- Employ best practices for effective dissemination of innovations
- Explore alternative infrastructural resources (local or national)
• Provide the necessary expertise that can support the mission of the organization
- Create a strategic organizational structure based on the mission & vision
- Hire and retain qualified, passionate and respected leadership
- Design a professional development and training approach for key personnel
- Periodically evaluate needs and hire or (re)train personnel
• Ensure the long-term sustainability of the organization via infrastructural capacity
- Use creative means to acquire infrastructural support
- Diversify network portfolio and sources of support
- Strategically "market" the PBRN emphasizing the value and benefit to others
Resources
• Membership benefits
• PBRN leadership model example
• Learning community activity
• Community relationship principles
• Examples of communication strategies
• Strategic planning template
• PBRN director
• PBRN coordinator/manager
• Example of PBRN organizational structure
• Example of a practice facilitator job description in an academic setting
• Examples of training resources
• Sample budget
SWOT = strengths, weaknesses, opportunities, threats

Table 1. Recommendations and resources for building PBRN infrastructure (PRGP chapter 1).

feedback; (6) procedure manual; (7) communication plan; (8) quality management (QM) plan; (9) guidelines for audit; and (10) study closeout.

Data Management

Rationale for chapter: Data management is foundational for scientific reliability and validity. The purpose of this chapter is

Recommendations
Preproject
• PBRN establishes a relationship with the project Principal Investigator
• Project concept is developed with PBRN advice and involvement
• PBRN Advisory Board reviews and approves the project
After project award
• Evaluate the staffing needs of the project
• Delineate staff roles and responsibilities
- Prior to study launch identify a study champion who is responsible
- Site supervisors (Champions) promote a work climate that supports research by making sure clinic staff have the time required to do a conscientious job on the study
- Before study launch, PBRN consults with clinic staff to assure that they have sufficient time to complete the project
- Each study site has a designated coordinator who assists the PBRN study manager in implementing the study
• Develop a staff education plan
- Research staff receives professional development and training tailored to their research responsibilities
- Staff (research and clinical) are trained to carry out the study consistent with research ethics
- Confirm that clinic staff receive training in human subjects protection as required by their study role
- Create a process for staff performance evaluation and feedback
• Create a "Manual of Procedures"
- Emphasize the importance of consistently following the study protocol across sites
- Study managers (site coordinators or PBRN managers) use quality control mechanisms to maintain the integrity of research data
- Monitor the informed consent process assuring that consent forms are completed for each study participant
- Proactively monitor for evidence of scientific misconduct
• Community partners involvement
- Recruit partners based on interest and capacity to contribute to the project
- Provide a study orientation and education in human participant research
- Involve partners in study design, recruitment methods, data analysis, interpretation, and dissemination of the findings
• Define the groups that need a communication plan
- Develop a communication strategy for each group involved in a PBRN study
- The PI, the PBRN study manager, the site coordinator, and clinical staff communicate on a regular basis to address study progress; Site staff members are encouraged to discuss questions and concerns with the site coordinator and/or PBRN study manager
• Develop a quality management plan
• Know the guidelines for preparing for an external audit of the project
• Conduct study closeout procedures
Resources
• Example of collaboration guidelines
• Example of site feedback form
• PBRN recruiting plan examples
• Memorandum of understanding example
• Example of site confirmation form
• IRB authorization agreement example
• Time line, milestones, and measurable outcomes example
• Ground rules for conducting meetings
• Communication modes available in most PBRNs
• Example of meeting minutes
• Example of regulatory binder index (clinical trial)
• Example of regulatory binder index (retrospective chart review)

Table 2. Recommendations and resources for study development and implementation (PRGP chapter 2).

Recommendations
• Build databases appropriate to the standard and goals of each research project
- Determine data sources and format
- Develop a data dictionary and codebook
- Develop the study database
• Data storage should be secure and ensure participant confidentiality
- Limit access based on study role, use password protection and data encryption
- Obtain a data use agreement, if applicable
- Always log changes to data files with the change, reason for the change, staff making the change, and date
• Develop a data collection process
- Identify data collection components
- Establish data and task tracking
- Define methods for data collection
- Pilot test all methods before starting enrollment
• Promote timely data entry and ensure data accuracy
- Create a data flowchart
- Determine the data acquisition process
- Review data entry plan
- Develop a plan for data entry occurring in decentralized locations
- Develop a tracking system for managing the informed consent process
• De-identify the database by removing participant identifiers
- Generate a study participant identification management process
- Develop and maintain a key (master list) for de-identified data
• Establish a plan for ongoing data cleaning
• Create and implement a data transfer protocol
Resources
• Qualitative studies: sampling
• Sample database planning table
• Codebook content
• Clinic identification scheme
• Patient identification scheme
• Determine participant identifiers
• Data sharing agreement
• Record retention scheme
• Sample database planning table
• Sample criteria for data access agreements
• Sample "project-specific" data sharing form
• Qualitative data collection process

Table 3. Recommendations and resources for data management (PRGP chapter 3).

to introduce procedures to ensure safe, secure, and systematic management of all electronic and paper study documents. PBRN research involves a wide range of data sources and types. A systematic approach to collecting, transferring, entering, cleaning, confirming, and storing data will minimize potential risk to participants and improve validity and reliability of results. This resource is intended to support the training and supervision of PBRN staff who may have little prior data management training or experience. Strategies to standardize data management activities across studies are provided.

Table 3 summarizes the Recommendations and Resources for Data Management, which are organized into seven topic areas: (1) database development; (2) data storage and security; (3) data collection; (4) data entry; (5) data de-identification; (6) data cleaning; and (7) data transfer.

Recommendations
• Dissemination products should align with and help advance the PBRN mission
• Engage relevant stakeholders—clinicians, practice staff, community members, participants
• Compose a dissemination team to create the dissemination conceptual model and plan
• The dissemination plan should contain
- Type and number of dissemination products
- Develop a time line for each product
- Specify an audience for each product
- Consider feasibility and approach to monitoring dissemination outcomes
• Use existing communication standards and authorship guidelines
• Acknowledge individuals, organizations, and coalitions who contributed
• The PI and project manager should manage and monitor the time line and deliverables
• Keep a master listing of all completed or published dissemination products on the PBRN Website and newsletters
• Send congratulatory messages to authors and contributors with information on how to reference the product on their resume
Resources
• Dissemination process
• Publication policies: CaReNet PBRN
• Overview of dissemination methods
• Time line sample with milestones
• Publication time line example
• Dissemination plan template
• Publication standards and authorship guidelines
• Authorship attribution table

Table 4. Recommendations and resources for dissemination (PRGP chapter 4).

Dissemination Policies

Rationale for chapter: Dissemination of findings or outcomes from PBRN work is important to influence policy, build and sustain relationships, inform local/regional practice settings about emerging trends, acknowledge stakeholder roles/support, and improve science. Peer-reviewed manuscripts are one of numerous approaches to dissemination. The dissemination policies chapter takes a broad perspective to the challenge of effectively communicating specific messages to a range of PBRN audiences.

The composition of the dissemination team and strategies tailored to defined audiences are described. *Table 4* summarizes the recommendations and resources for dissemination, which include: (1) priorities and alignment; dissemination team; (2) plan/process/model; (3) authorship; and (4) process management.

Discussion

Calling for greater emphasis on the research enterprise, the Institute of Medicine identified deficiencies in research integrity in the areas of knowledge base of (a) research process; (b) professional development; and (c) research community.[12] Quality problems may occur in the hands of dedicated research professionals who work within a system that does not adequately prepare them or support them in their research practice. This principle provided the impetus for developing the PRGP resource: to improve the quality of PBRN research processes while also providing professional development for the PBRN community. This project was the first known effort to integrate the IOM imperatives with an organizational change strategy[13–15] to improve the quality of research performed in the primary care setting. For these reasons, developing PBRN-specific guidelines is an important step in supporting the quality of primary care research operations. Another rationale for developing guidance for practice-based research was the necessity of finding novel research methods to support practice-based translational research in PBRNs. Working at the intersection of research and quality improvement helped PBRNs innovate in what they do, as well as how they do their work. The Best Practices Research approach developed by PBRNs is an excellent example for innovation in research methodology.[16]

The PRGPs introduced in this document are offered as suggestions to approach particular steps of a project, but they are not all required for each PBRN study. The developers of the PGRPs recognize that PBRNs conduct a variety of studies under different circumstances and not all recommendations are applicable to each study and setting. By promoting PBRN research professionalism, the PRGPs provide a common language for collaborators to launch and improve their research practice.

Each PBRN that participated in developing the PRGPs has its own history, scope and possibly niche. Implementation of the PRGPs takes a commitment from all PBRNs. Some comments from our participants and peer reviewers on the benefits and future use include:

- "Very relevant as we update our strategic plan. A good benchmark for what we have accomplished, where we are today, and where we need to go in the future."
- "Online format was easy to navigate. Chapter subheadings were clear and self-explanatory. Links to additional content embedded within the chapter text was useful. This information should be useful to newly or recently established PBRNs."
- "Overall, I think the content is solid and the examples useful."
- "Our PBRN has a diverse portfolio of research studies, including survey studies, clinical trials, feasibility and pilot studies, and implementation research. Our settings are diverse as well, historically grounded in primary care practices and increasingly moving to directly engage patient groups and the community. The diversity of projects and settings has led to a variety of operational issues, leaving us feeling scattered and tugged by multiple research priorities. At times we felt like we were drowning. This project presented us with a lifeline. We had a solid foundation for our network but needed a common language and approach. We have a better roadmap to conduct our community-based research leading to increased sense of confidence and competency. Work in the "real-world" involves challenges and variables not found in academic health centers. At our institution this competency has resulted in jour PBRN being viewed as a "Go To and Can Do" research organization—knowing how to recruit, engage and retain our research partners (subjects)—practices clinicians, patients, and communities and effectively implement the research study. The "PRGPs" are currently used in our PBRN. We also plan to use them with our Consortium of Networks."

The collaboration of seven PBRN directors and coordinators/managers resulted in not only the PRGP document but also in bringing a group of different stakeholders together who might not otherwise have met. In these 4 years the group has realized the diversification of talents and capabilities of its members. It was a special opportunity to better understand the other PBRNs and their working relationships. This collaboration was mutually beneficial and has laid the foundation for working together in future research endeavors. Throughout the process, it was evident the members of the research team were committed to their work. They met monthly on Webinar-conferencing calls to work on assigned tasks, and then in person twice a year integrate work into the developing PRGPs document. The integrity and dedication resulted in a product usable by the PBRN research community.

Going forward, members of the original team identified the need for a self-audit instrument to enable PBRNs to assess gaps in their research processes. Work is also underway for additional chapters on community and stakeholder engagement, and the team has been approached to translate the PRGPs into different languages to spread the knowledge to other countries.

Conclusions

The PRGPs is the first PBRN-specific resource to facilitate PBRN management and staff training, to promote adherence to study protocols, and to increase validity and generalizability of study findings.

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Conflicting and Competing Interests

The authors have no conflicting or competing interests to declare.

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Appendix PBRN research 31 best practice checklist

Factor 1: Data management	PBRN does this well	PBRN has an SOP	Area to improve	Priority: low; medium; or high
1.1. The PBRN has procedures in place to keep research data for the time specified by NIH and IRB regulations. For example, NIH requires that data be retained for 3 years after study completion.				
1.2. Research data and documentation are stored in a secure location.				
1.3. Electronic data are frequently stored on fire-walled and password-protected hardware.				
1.4. Data analyses are conducted in collaboration with a person knowledgeable about statistical analyses.				
1.5. Paper records are kept in locked enclosures.				
1.6. All steps of the data management process are documented. For example, logging file names, printouts, variables and file changes.				
1.7. The PBRN uses data management protocols for the examination and resolution of outliers.				
1.8. The PBRN uses data management protocols to promote accurate data entry. For example, all or some proportion of data are double-coded or double-entered to check for outliers or errors.				
1.9. The PBRN uses data management protocols such as random audits for errors.				
1.10. Research staff members periodically receive professional development and training that is tailored to their research responsibilities.				
Factor 2: Study supervision				
2.1. Study orientations include a discussion on the importance of following the study protocol in order to maintain uniformity at all sites participating in a multiple-site study.				
2.2. During study orientation, the staff are clearly explained their roles and responsibilities in the study.				
2.3. During the study orientation, clinical staff are trained in how to carry out the study in a manner consistent with research ethics.				
2.4. Study managers (site coordinators or PBRN managers) use quality control mechanisms in order to maintain the integrity of research data. For example, conducting random audits, holding regular meetings with staff to review study operations and data collection procedures.				
Factor 3: PBRN policies	**PBRN does this well**	**PBRN has an SOP**	**Area to improve**	**Priority: low; medium; or high**
3.1. Study managers (site coordinators or PBRN managers) emphasize the importance of integrity in data collection and record-keeping to clinical staff members.				
3.2. The site supervisors facilitate or promote the work climate as supportive to research by making sure clinic staff have the time required to do a conscientious job on the study.				
3.3. PBRN management assures that all staff members with research responsibilities understand the importance of their role in the research process. For example, staff members are encouraged to participate in discussions of study implementation.				
3.4. The PBRN clarifies authorship policies at the start of each study.				
3.5. The PBRN clarifies publication policies at the start of each study. For example, investigators do not publish from PBRN studies independently unless permitted by the PBRN.				
3.6. Sometimes network clinicians and staff expect to be included as co-authors. The PBRN clearly addresses expectations and criteria for authorship at the beginning of the study.				
3.7. The PBRN clarifies data agreements at the start of each study regarding data ownership. For example, investigators do not analyze or publish from PBRN studies independently unless permitted by the PBRN.				
3.8. The PBRN clarifies data analysis policies at the start of each study.				
3.9. The PBRN has a data agreement (either its own or that of a professional organization) on the dissemination of results, including publications and presentations.				

Factor 4: Study Management	PBRN does this well	PBRN has an SOP	Area to improve	Priority: low; medium; or high
4.1. The PI, the PBRN study manager, the site coordinator and clinical staff communicate on a regular basis during the course of the study to address progress. For example, the Principal Investigators and staff discuss and agree upon their mutual responsibilities.				
4.2. Site staff members are encouraged to discuss study questions and concerns with the site coordinator and/or PBRN study manager.				
4.3. Each clinical site has a designated site coordinator who assists the PBRN study manager in the implementation of the research study. For example, the PBRN study manager and site supervisors monitor study progress on an ongoing basis.				
4.4. Prior to beginning or launching a new study, the PBRN consults with clinic staff to assure that they have sufficient time to complete the project.				
4.5. For each site, there is a study champion who is responsible for promoting the study to staff members.				
Factor 5: Ethical considerations				
5.1. Study managers (site coordinators or PBRN managers) monitor the informed consent process, and assure that consent forms are completed for each study participant. For example, the consent process can be monitored with a random audit to determine if signed consent forms are on file for each enrolled participant.				
5.2. The PBRN study manager monitors clinic staff education in human subjects protections to assure that all staff participating in the study have received the required training.				
5.3. The PBRN is vigilant in looking out for scientific misconduct.				

SOP = standard operating procedure.