PBRN Research Good Practices (PRGP)

Welcome!

The *Practice-based Research Network (PBRN) Research Good Practices*, or *PRGPs*, were developed for the specific context of multi-site research conducted in the clinical practice setting. This *PRGP* document is the culmination of a mixed-methods research project in which over one hundred researchers contributed their experience, expertise and wisdom to identify research best practices, and then to detail recommendations and strategies to support the primary care research enterprise.

The *PRGP*s are organized into four chapters, and each is divided into two sections: the main body, and an addendum with hyperlinked "Info Links" that provide supporting details, examples and form templates.

Chapter 1: Building PBRN Infrastructure.

Chapter 2: Study Development and Implementation

Chapter 3: Data Management

Chapter 4: Dissemination Policies

The team that developed the *PRGPs* is listed on the next page. We hope this will be a valuable resource for practice-based researchers.

Anne Victoria Neale (Wayne State University), on behalf of "the Team"

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PBRN Research Good Practices (PRGP)

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Executive Summary

From 2000-2014 a collaborative of network directors and coordinators from 7 PBRNs worked with a professional team facilitator to produce this detailed document expanding upon the 31 research best practices for PBRN research. The end result is that *PBRN Research Good Practices (PRGPs)* document which is organized into four chapters: 1) Building PBRN Infrastructure; 2) Study Development and Implementation; 3) Data Management, and 4) Dissemination Policies. An appendix of "Info Links" which provide supporting details, examples, and form templates follows each chapter. The recommendations from each *PRGP* chapter are summarized as follows.

1) Building PBRN Infrastructure

Practice-based research networks (PBRNs) conduct research that matters in daily 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, three organization types seem to have emerged. Most PBRNs operate out of an academic institution (often Departments 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 non-academic 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. These infrastructure requirements include: 1.1 Developing and Maintaining Relationships; 1.2 Strategic Planning; 1.3 Building PBRN Infrastructure; 1.4 PBRN Staffing; and 1.5 PBRN Funding.

Recommendations 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.

Table 1. Recommendations for Building PBRN Infrastructure

- 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

2) Study Development and Implementation

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) 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 a busy practice. The purpose of this chapter is to outline processes to promote research quality management and quality performance.

This chapter addresses ten topic areas: 2.1 Pre-Project Development, 2.2 Research Project Staff Roles and Responsibilities, 2.3 Staff Education, 2.4 Community Partner Involvement, 2.5 Study Personnel Evaluation and Feedback, 2.6 Procedure Manual, 2.7 Communication Plan, 2.8 Quality Management (QM) Plan, 2.9 Guidelines for Audit, and 2.10 Study Close-out. Table 2 summarizes the Recommendations for Study Development and Implementation.

Table 2. Recommendations for Study Development and Implementation

Pre-project
- 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(s) 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 close-out procedures

3) Data Management

Data management is foundational for scientific reliability and validity. The purpose of this chapter is 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 that may have little prior data management training or experience. Strategies to standardize data management activities across studies are provided.

This chapter addresses seven topic areas: 3.1 Database Development; 3.2 Data Storage and Security; 3.3 Data Collection; 3.4 Data Entry; 3.5 Data De-Identification; 3.6 Data Cleaning; and 3.7 Data Transfer. Table 3 summarizes the Recommendations for Data Management.

Table 3. Recommendations for Data Management

- 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

> - o Develop a plan for data entry occurring in decentralized locations
>   - o Develop a tracking system for managing the informed consent process
> - De-identify the database by removing participant identifiers
>   - o Generate a study participant identification management process
>   - o 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

4) Dissemination

Dissemination of findings or outcomes from PBRN work is important to: 1) influence policy, 2) build and sustain relationships, 3) inform local/regional practice settings about emerging trends, 4) acknowledge stakeholder roles/support, and 5) improve science. Peer-reviewed manuscripts are one of numerous approaches to dissemination. This chapter takes a broad perspective to the challenge of effectively communicating specific messages to a range of PBRN audiences.

This chapter covers five topic areas for the development of dissemination policies. These include: 4.1 Priorities & Alignment; 4.2 Dissemination Team; 4.3 Plan/Process/Model; 4.4 Authorship; and 4.5 Process Management. Table 4 summarizes the Recommendations for Dissemination.

Table 4. Recommendations for Dissemination

> - 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
>   - o Type and number of dissemination products
>   - o Develop a timeline for each product
>   - o Specify an audience for each product
>   - o 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 timeline 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

5) Discussion

This document was created to improve research integrity in PBRNs by addressing the unique challenges experienced in practice-based research: distributed or decentralized of practice sites, relative isolation of participating clinicians, low numbers of eligible patients per site, lack of dedicated research staff onsite, competing demands of clinical care and the overarching accountability to improve patient outcomes in short timeframes.

PBRN Good Research Practices (PGRPs) in this document are offered as suggestions to approach particular steps of a specific 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. Table 5 contains a list of resources ("info links") corresponding to each chapter.

Table 5. PRBN Research Good Practices (PRGPs) Resources (see Info Links after each chapter)

Building PBRN Infrastructure
- Benefits of PBRN Membership
- PBRN Leadership Model example
- Learning Community Activity
- Community Relationship Principles
- Communication (Information, Marketing) Strategies
- Strategic Planning Template
- Research Project Funding resources
- PBRN Director responsibilities
- PBRN Coordinator/Manager Sample Job Description
- Example PBRN Organizational Structure
- Practice Facilitator Sample Job Description & training resources
- PBRN Budget Category Example

Study Development and Implementation
- Study Personnel Evaluation and Site Feedback Form
- PBRN Recruitment plan examples
- Example Memorandum of Understanding
- Example Project Confirmation form
- IRB Authorization Agreement
- Example Communication Planner
- Ground Rules for Conducting Meetings
- Communication Modes Available in Most PBRNs
- Example Meeting minutes
- Example Regulatory Binder for Clinical Trials
- Example Regulatory Binder for Retrospective Chart Review

Data Management
- Qualitative Studies: Sampling
- Sample Database Planning Table
- Clinic Code and Patient identification Examples
- Record Retention
- Codebook Content
- Participant Identifiers
- Data Sharing Agreement
- Data Access Agreement
- Project specific Data Sharing Form Example
- Qualitative Data Collection

Dissemination Policies
- *CaReNet* Publication Policy
- Examples of Dissemination Products and Methods
- Sample Timeline with Milestones
- Example Dissemination Plan Template
- Lead Author Definition
- Strategy to Develop Pipeline of Clinician Researcher/Author

Summary of Utility and Value

As **L.J. Fagnan**, Director of the Oregon Rural Practice-based Research Network (ORPRN), stated recently: "We now have a better roadmap with which to conduct our community-based research leading to an 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 ORPRN being viewed as a "Go-To and Can-Do" research organization – knowing how to recruit, engage and retain our research partners (practices clinicians, patients and communities) and effectively implement the research study."

Paul Smith, the former Research Director of the Wisconsin Research & Education Network (WREN), also noted the value of the *PRGPs* for PBRN operations: "WREN participated in developing the original 31 best practices specific to the context of practice-based research, and we had kept the results to help us identify areas we needed to improve. We have already changed some of what we do including database management and how we interact with participating practices. I personally have benefitted from many PBRN researchers that have gone before me and this provides an opportunity to "give back" to the field and contribute to the success of future generations of PBRN researchers. Now at the dissemination phase, I look forward to others helping us fill gaps and build further on our work."

All the authors of this document agree with both LJ and Paul, that the work of creating the *PBRN Research Good Practices* document is not complete – there are gaps to be addressed and PBRN pearls of experiences need to be incorporated. We need you to share your wisdom and expertise. Join with us to refine this "living document" as a guide for PBRNs of all types across the globe.

CONTENTS

CHAPTER 1: BUILDING PBRN INFRASTRUCTURE

PBRN infrastructure support includes a wide variety of activities that make it possible for networks to rapidly respond to funding opportunities and also to proactively develop research and quality improvement programs aligned with the network's mission. PBRNs require some infrastructure support to sustain their strategic plan when funding lapses. PBRNs may not have many resources early in their development, and 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. PBRN infrastructure described in this chapter supports, yet overarches the needs of a particular study.

1.1   DEVELOPING & MAINTAINING RELATIONSHIPS

1.1.1 Recruit Clinician Members

- Identify potential member(s) through clinical outreach efforts and/or member referral (e.g. student preceptors, residency sites, personal contacts, local professional organizations).
- Recruit potential members through personal contacts from PBRN leadership, most often a respected, well-known clinician.
- Arrange a face-to-face meeting with potential member(s) to explain the network, share previous research efforts, discuss primary care issues identified by the clinician and identify areas of mutual concern for future research. New PBRNs may want to describe the PBRN concept and provide examples of exemplary PBRN studies. See Example of Membership Benefits (1.1.1.1)
  - o Interpersonal relationship building is key in PBRN research as clinician members may act as "research champions" for individual projects, helping to recruit research participants and/or coordinate research efforts for specific research projects.
- Provide clear, consistent, and respectful communications, which is essential for building and maintaining lasting research relationships as member effort and engagement are primary resources of PBRN infrastructure and research collaborations.

1.1.2 Retain Clinician Members

- Develop a strategy to retain members by identifying and prioritizing the interests/concerns of clinician members.

- o Form a decision-making structure such as a Board of Directors to continually assess topics of relevance to network.
  See PBRN Leadership Model Example (1.1.2.1)
- o Allow decision-making structures with key stakeholders, such as, a Board of Directors constructed of PBRN members and community leaders to play a role in decision-making.
- o Promote the opportunities for input from member clinicians.
  Learning Community Activity (1.1.2.2)

- Articulate overall mission of the PBRN to focus on value to clinicians.
- Prioritize research and educational topics based on clinicians' high value interests.
- Assure opportunities for members to participate in project development.
- Provide members a role in the decision-making processes of the network and its projects.
- Disseminate research findings in functional, and accessible formats for clinician members (e.g. newsletters, websites, etc.).
- Sponsor an Annual PBRN Member Meeting (or Convocation) to bring members together to recognize contributions, enhance existing relationships/partnerships, and for shared learning opportunities (i.e. primary care plenary speakers and/or workshops designed to provide tools, interventions, and/or information to clinicians).
  - o Provide Continuing Medical Education for the event.
    See Learning Community Activity (1.1.2.2)

- Develop a PBRN membership database including useful information on practices and clinicians. Update the membership database periodically (annually) to ensure that member outreach activities are efficient. A database for collaborators and community stakeholders can also be developed to keep track of relationships with other organizations and PBRNs.

1.1.3 Recruit Non-clinical Community Members

- Define community stakeholders (e.g. identify local concerns, ethnicities or diagnoses).
- Make personal contact with community leaders and members in areas where PBRN members plan to conduct research.
- Arrange face-to-face meetings with community leadership and members to explain the network, share previous research efforts, discuss community involvement in research efforts, and respond to community concerns for present and future research.
  See Community Relationship Principle (1.1.3.1)

1.1.4 Retain Non-clinical Community Partners

- Develop a strategy to retain community partners by identifying and prioritizing community members' values and concerns.
  - Include non-clinical community partners in a decision-making structure such as a Board of Directors to continually assess topics of relevance to network.
  - Provide opportunity for input from community partners.
- Articulate overall mission of the PBRN to focus on value to communities.
- Make sure PBRN activities are congruent with community standards and cultures.
- Prioritize topics based on what community members identify as important.
- Assure opportunities for community participation in project development.
  - In community-based participatory research, strive to achieve community engagement as defined by the specific project. For example, see Norman et al., "Testing to prevent colon cancer: How rural community members took on a community-based intervention". Ann Fam Med., 2013, 11(6): 568-70. http://www.annfammed.org/content/11/6/568.long

  - Recognize the contributions of community partners on an annual basis.
- Provide opportunities for community partners to participate in the network's decision-making processes.
  - Example: form decision making structures with key stakeholders, such as a community advisory board constructed of community leaders, or a patient advisory board.
- Disseminate findings in formats that are most accessible and useful to community members (i.e. culturally appropriate and in an appropriate language)

1.1.5 Develop Systems for Clear, Consistent and Bi-directional Communication

- Consider bi-directional communication plans for the variety of PBRN stakeholders
  - Include PBRN clinician members, non-clinical community patterns, health policy makers, sponsors, and other PBRN collaborators.
- Design the communication to close research feedback/dissemination loop.
- Inform members about current issues and research in primary care with priority given to topics that clinician and community members identify as important.
- Use websites, list-serves and social media to communicate with all stakeholders. Note that some will prefer paper methods of communication.

- Insure that stakeholders can respond easily to both participation requests as well as information dissemination.
  See [Examples of Communication Strategies (1.1.5.1)](#)

1.1.6 Developing Cross-PBRN Collaborative Relationships

As PBRN research matures, a variety of networks collaborate with each other nationally. Multi-network collaborations can include the same type of networks (e.g., family medicine-focused PBRNs) or trans-disciplinary collaborations (e.g., PBRNs working in the areas of pharmacy, pediatrics, or dentistry).

A growing number of funding announcements and research contracts call for regional or national-level collaborative work. Along with the sophistication of their research methods, PBRNs increasingly need to improve their capacity for multi-center and multi-disciplinary collaborations to remain competitive.

Examples of such large-scale collaborations include P30 Centers with PBRN membership representing various regions of the country, Agency for Healthcare Research and Quality (AHRQ) Task Order partnerships, and funding announcement-specific research groups (e.g., practice improvement or facilitation research, health extension infrastructure building projects).

More recently, PBRNs located in the United States also collaborate with networks or PBRN researchers from other countries, including Canada, Mexico, the United Kingdom, and other European countries.

1.2 STRATEGIC PLANNING

1.2.1 Devise Mission, Vision and Operative Policies

Once a cadre of dedicated members has been recruited, planning activities should include the development of mission, vision, and operating policies. These will be working documents that can be modified as necessary to fit the needs of the growing PBRN.

- Plan activities to develop a PBRN vision statement.
- Decide on needed PBRN operating policies and procedures.
- Develop the PBRN mission, vision statements and policies and procedures.
- Review and modify the PBRN mission and vision statements as needed.
- Review and modify the PBRN policies and process as needed.
- A Memorandum of Understanding is useful for documenting the PBRN's operating policies. Suggested topics for inclusion:

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- o PBRN Purpose/Mission statement;
- o Decision making process
- o Project selection/approval
- o Project leadership/operation
- o Resource allocation
- o Staff responsibilities
- o IRB approvals
- o Data ownership
- o Community role
- o Dissemination
- o Process for amending the MOA.

Mission Statement example: "The mission of the Oklahoma Physicians Resource/Research Network (OKPRN) is to support primary care clinicians through a professional network for peer learning, sharing of resources for best practices and practice-based research."

Vision Statement example: "Working with our partners and through the excellence of our members, OKPRN will help our State achieve safe and high quality primary healthcare for all Oklahomans."

1.2.2 Ongoing Strategic Planning Steps

- Include staff in discussions to inventory PBRN processes (e.g., vision, mission, policies and procedures under which you operate; by-laws). Discuss what is or is not working well.
- Determine what is missing in these processes (e.g., vision, mission, policies and procedures).
- Review information from PBRN database, or notes/committee or board minutes in order to identify specific areas of interest (what works or does not work) and changing needs of membership.
- Organize a professionally facilitated half-day to one-day session (retreat) for network leadership to present these results and brainstorm about next steps.
- Summarize these in a brief report.
- Set clear goals for developing your infrastructure.
- Revisit PBRN mission and vision statements and determine how infrastructure development could be aligned.
- Write specific objectives to accomplish the goals for the PBRN infrastructure.
  - o Designate workgroups of 3-5 invested members that can develop specific objectives based on the overarching goals of the PBRN.

- o   Ask each workgroup to summarize their recommendations.
- Allocate resources (both capital and human) to accomplish your objectives.
  - o   Complete a horizon- (environmental) scan of current PBRN resources and capabilities.
  - o   Determine gaps in resources based on accomplishing the set goals.
- Follow-up on PBRN goals on a regular basis to determine progress.
  - o   Develop specific measures and systematic processes (e.g. yearly review or leadership retreat, annual network report, etc.) to assure continuing progress and to address gaps.
    See [Strategic Planning Template (1.2.2.1)](#)

1.3   OVERVIEW OF INFRASTRUCTURE TO SUPPORT PBRN OPERATIONS

Developing ideas into successful projects is a systematic process that involves several steps. A clear vision and mission and a sound strategic plan for network operations must be translated into professional resources, effective administration, and structural investments.

1.3.1 Create Venues for Soliciting Project Ideas From PBRN Members

- Build "bottom-up" organizational structure to ensure buy-in and participation.
- Develop a process to generate project ideas and capture feedback directly from PBRN members.
- Provide multiple, easy means for members to suggest projects and propose PBRN research (e.g., listserv, website, personal networking).

1.3.2 Build Organizational Structure for Vetting Project Ideas

- Create a committee or advisory group that receives project ideas and research proposals.
- Capture ideas in a structured format (e.g., concept paper or idea form).
- Establish a process for the committee to evaluate and rank-order ideas based on their relevance to PBRN mission, importance, feasibility and impact on various audiences.
- Send recommended projects to PBRN leadership or board of directors.
- Facilitate communication of PBRN members with researchers interested in similar topics.

1.3.3 Establish Professional Partnerships for Conducting Research

- Develop multidisciplinary teams with expertise in biostatistics and epidemiology.

- Seek collaborative opportunities in Institutes for Clinical and Translational Science (ICTS) programs or "cores" or professional centers on your campus that offer a variety of resources and expertise for projects in their scope of work.
- Establish relationships with state and professional healthcare entities (e.g., public health departments, Medicaid programs, professional academies, quality improvement organizations, medical associations and nonprofit organizations) by joining their initiatives or joint funding opportunities.
- Invite the participation of academic residency programs in your state or area and establish a mechanism for collaboration (e.g., via shared board or committee work).

1.3.4 Design an Information Management Infrastructure

- Adopt a consistent process for managing electronic file folders to improve efficiency.
- Consider file folders for each project that include the following:
  - Study application documents
  - IRB applications and approvals
  - Project outcomes data and analyses
  - Financial management
  - Administrative project management
  - References and publications
  - Reports, presentations and manuscripts

- Schedule regular data file back-ups.

  - Consult with your information technology (IT) support to assure regular back-ups of data files on shared, secure file server and other databases used to collect/store information.

- Store electronic study data efficiently and effectively

  - Store longitudinal project data in a separate project folder or in data sub-folders characterized by the following:

    - Group study data according to collection type (e.g., baseline survey, focus group, etc.).

    - Use undiscoverable codes that link raw outcomes data and analyzed data, according to an IRB-approved process.

  - Develop study record keys that provide links between participant identifiers (demographics) and unique participant IDs.

- - Store on a separate medium with controlled access (e.g., physical and electronic protections).

- Keep paper copy of study records and patient identifiers in locked filing cabinet separate from coded study data.

- Organize contextual clinic data as relevant to the study.

- Create/maintain a file containing elements defined in the manual of procedures.

- Maintain a text file describing location of all study data.

1.3.5 Develop and Maintain a PBRN Membership Database

- Create a database of PBRN members and their respective practice information.

- Maintain a database of clinician and practice name, location, practice description including type, patient population by gender, ages, insurance type, etc.

- Track research participation of practices by project in the database

- Track special circumstances or unique practice aspects such as special populations or services.

- Track practice coordinator's (or office manager's) name.

1.3.6 Adopt Low-Tech Electronic Research Tools, When Appropriate

- Make low-tech electronic research tools available to PBRN research projects, when a robust data collection apparatus is not necessary, such as:

  - Stand-alone local databases for small projects (e.g., Microsoft Access and Excel)

  - Shared available publicly web-based survey tools (e.g., SurveyMonkey, Qualtrics)

  - Other electronic resources that facilitate simple data collection and storage

1.3.7 Develop a Robust Shared IT Infrastructure for Large Projects

- Implement a clinical study management platform (see Chapter 3).

  - Best practices for implementing REDCap are available in a video-based detailed tutorial online (http://www.project-redcap.org/videos.php

- Use a clinical study management system to design a more comprehensive study data infrastructure, enroll and manage participants, collect data (e.g. surveys and forms) and prepare data for analyses.

- Coordinate hosting and infrastructural management of these databases with each individual organization's IT professionals.

1.3.8 Explore Alternative Resources

- Work with the PBRN's institution association (e.g., Clinical and Translational Science Institute or research core) to determine available local resources for conducting PBRN research.

- Review resources from the AHRQ PBRN Rapid Learning Resource Center to support surveys, databases, and other concepts.

1.3.9 Implement Processes for Ongoing Feedback to PBRN Members

- Expect PIs, the network director, and other PBRN leaders to provide ongoing feedback to members.

- Provide a final report to the PBRN membership at the end of the project.

- Establish suitable venues for providing feedback that members can use easily and regularly, in a time-sensitive manner, to receive updates, (i.e., network newsletters, listserv announcements, presentations at network meetings and convocations, and personal feedback from PBRN staff, including practice facilitators).

- Ensure that the content, frequency, amount, and method of feedback are optimized for the PBRN audience(s) considering member preferences and constraints.

- Use regular project feedback to capture ideas for future research and quality improvement activities or gather lessons learned from the accomplished project.

1.3.10 Employ Best Practices for Disseminating Innovations

- Build on best practices in innovation dissemination, see for example, the Cooperative Extension Service of the USDA: http://www.annfammed.org/content/11/2/173.full

- Develop a customized approach for disseminating findings and resources within and beyond the PBRN (regionally) in a systematic manner.

- Disseminate all deliverable products beyond academic publication and presentation.

- o Schedule presentations with stakeholders to share study findings and successes.

- Routinize dissemination as an integral part of most PBRN projects.

- Consider the preferences of target audiences and stakeholders, the availability and feasibility of the most effective methods, the dissemination time frame, and sustainability of the dissemination effort through partnering with other invested organizations for dissemination.

- Leverage the potential of practice facilitators (also called "health extension agents") who can significantly accelerate the spread of new information, techniques/approaches, and healthcare resources (e.g., health information technology or best practices).

- Make effective use of information technology by combining "high tech" (e.g., web-based multimedia and social media platforms) with "high touch" personal communication and relationship building, e.g., practice facilitation strategies.

1.4   STAFFING THE PBRN

1.4.1 Leaders and Staff

PBRN staffing is pivotal to achieving success in the work of a PBRN. In order to register a PBRN with AHRQ, the network must have a director and a mission statement. Other critical PBRN roles include the coordinator or manager, staff, or practice facilitators or site liaisons.

- PBRN Director (1.4.1.1) The PBRN Director is responsible for overall PBRN operations and management, and sets the direction for the PBRN mission, goals, oversight, opportunities and collaborations. The Director identifies research investigators to work with the PBRN, reports to a governing board, and reports to institutional entities.

- PBRN Coordinator/Manager (1.4.1.2) Recruit a PBRN Coordinator/Manager to manage the daily operations of the PBRN including hiring, training and oversight of staff; assigning staff to projects; and coordinating roles to complete activities of PBRN research.

- Recruit PBRN staff; this may include research associates and research assistants who are vital to supporting the work of the network.

- As the network grows in complexity and funding, consider adding a grant manager, statistician, data manager, or IT specialist as needed.

- Develop an organization chart that depicts staff relationships and roles. Example of PBRN Organizational Structure (1.4.1.3)

- Practice facilitators (PF) and Other Similar Terms (1.4.1.4) Practice facilitators (PFs) can function as study coordinators/research assistants, practice enhancement experts, or both. PFs can also function in a manner that is similar to that of agricultural extension agents, who share ideas and successful approaches across individual teams within a region they serve or beyond the region by working with other agents (cross-pollination).

- Consider staff training at one of the approved sites for Practice Facilitation training. With both web-based didactic and experiential learning components, the program is taught by professionals with educational and executive experience, along with national experts as guest speakers. See, for example, http://www.millardfillmorecollege.com/practice-facilitator

- The curriculum is based on the modules of the Practice Facilitation Handbook: Training Modules for New Facilitators and Their Trainers. June 2013. Agency for Healthcare Research and Quality, Rockville, MD. See http://www.ahrq.gov/professionals/prevention-chronic-care/improve/system/pfhandbook/practicefacilitationhandbook.pdf

1.4.2 Training and Professional Development

PBRN staff will likely have a variety of training and research experiences. In addition to study-specific training as described in this document, opportunities for general training and professional development enable staff to further develop interests and skills that may benefit their role within the PBRN, propel career goals, and lead to increased personal fulfillment.

- Provide PBRN staff with study-specific training
- Provide PBRN staff with professional development, e.g.
  - AHRQ training resources (online and in-person)
  - Professional meetings (e.g., annual PBRN Conference)
  - Local training and professional development (e.g. survey research procedures or data base management)
  - Institutional mentoring & career development
  - National practice facilitator resources and training

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1.5   PBRN FUNDING

1.5.1 Infrastructure Costs

- Identify external funding for the research work that the PBRN proposes to complete.
- Explore a variety of funding sources to eventually have a diverse portfolio of grants and contracts from federal sponsors, state sponsors, foundations and industry.
- Realize that some PBRN activities require personnel time, travel, meeting costs, and robust communication systems with current and potential membership that are beyond the scope of any individual grant (especially those that are focused on building relationships and trust in the communities it serves, and collecting data to describe the attributes of its membership and communities).
- See Resource: Green LA, et al. Infrastructure requirements for practice-based research networks. *Ann Fam Med*. 2005, 3 (Suppl 1): s5-s11. http://www.annfammed.org/content/3/suppl_1/S5.long
- See Sample Budget (1.5.1.1)

1.5.2 Infrastructure Funding Sources

- Identify infrastructure funding that may be available through different state or federal organizations. Potential sources include: the Agency for Healthcare Research and Quality (AHRQ), the Patient-Centered Outcomes Research Institute (PCORI), local and state health foundations, state Medicaid agencies, and various professional organizations at the local and federal level. Since it has been generally difficult to find support dedicated to build and maintain infrastructure, many forming PBRNs capitalized on funding opportunities for startup research or quality improvement projects to begin building their networks. At the early stages of PBRN development, it is beneficial to collaborate with other established PBRNs on such projects, until the emerging network is strong enough to attract PBRN funding on its own.

Thinking broadly about infrastructural funding can be helpful. Beyond traditional research support, participation in local or regional healthcare QI initiatives in a contractual service provider relationship may also garner some support for building a network. Experienced PBRNs tend to diversify their portfolio and tap into resources for state and federal QI initiatives (e.g., Patient-Centered Medical Home (PCMH) certification programs, meaningful use initiatives, maintenance of certification support, and various quality assurance and measurement projects).

- Seek sustainable funding sources from within your institution. Target departments within your institution with a focus on primary care or with a focus on community outreach. Examples include, but are not limited to academic departments, centers; and the office of the President.

1.5.3 Infrastructure Funding Strategies

- Advocate for the value of the PBRN to the parent institution when seeking internal support. For example,
  - PBRNs can assist academic health centers to realize their core mission (e.g. to improve population health) by linking them to community-based health entities.
  - PBRNs can provide an excellent venue for academic institutions to operationalize community engagement in their CTSA programs
  - PBRNs can be particularly effective in facilitating public-private partnerships between health entities that generally have little contact (e.g., health departments and private clinics).
  - PBRNs can meaningfully and effectively involve medical students and residents in research that matters in practice
  - PBRNs can extend the resources and expertise of academic institutions to rural and underserved areas through their web of personal relationships
- Promote PBRN benefits to the institution by preparing communities to participate in research projects;
  - Build relationships to benefit the institution's clinical operations, e.g. by serving as the basis for medical referrals or telemedicine arrangements.
- Develop a 5- or 10-year plan when seeking institutional funding.
- Address gaps and resource needs when creating an institutional request and include those with the request.
- Request free access to personnel with expertise in grant management, budget management, human resources, grant writing, communications, and/or web development.
- Ask your institution to provide access to staff or a research assistant to assist or facilitate with data collection, data entry, meeting scheduling, IRB preparation, and Continuing Medical Education (CME) credit applications.
- Consider that requested resources could include computing server space, IT infrastructure, computers and software, and many other shared resources.

1.5.4 Research Project Funding

- Review Requests for Applications (RFAs) and Program Announcements (PAs) available on Grants.gov, which reflect both specific research requests as well as the opportunity to design and propose projects based on local interests, unique characteristics, and needs.
- Register on listservs that provide funding opportunity announcements
- Realize that most PBRN research is funded through specific project applications to federal granting agencies such as the Agency for Healthcare Research and Quality (AHRQ), the National Institutes of Health (NIH), the Patient-centered Outcomes Research Institute (PCORI), or organizations dedicated to a particular problem such as the American Cancer Society (ACS).

Info Links for Chapter 1 start on next page.

1.1   DEVELOPING & MAINTAINING RELATIONSHIPS

Benefits of PBRN Membership (1.1.1.1)

- Increases research and development collaboration between primary care clinicians and academic institutions
- Broadens the technological resources available to primary care practices.
- Introduces innovations in primary care systems and delivery of care.
- Reduces the isolation of rural primary care clinicians, or those in small practice settings.
- Exposes medical students to opportunities in primary care research.
- PBRN communication and listservs provides communication with academic primary care faculty and other specialists.
- Access to innovations such as new technologies; the opportunity to have a practice facilitator (Practice Enhancement Assistant – PEA) in your practice; and the opportunity to contribute clinical questions to the ClinIQ (Clinical Inquiry) process in which these questions are researched and answered by residents in state residency programs.
- Early opportunity to participate in developing an extension service for primary care.
- See Resource: Refer to a seminal paper on systematic PBRN best practices method. Mold JW, Gregory ME. Best practices research. Family Medicine, 2003; <u>35</u>(2): 131-134. <u>http://www.ncbi.nlm.nih.gov/pubmed/12607811</u>

[BACK TO 1.1.1 RECRUIT CLINICAL MEMBERS]

PBRN Leadership Model Example (1.1.2.1)

The Oklahoma Physicians Resource/Research Network (OKPRN) is a 501(c)(3) charitable organization. The OKPRN Board of Directors includes 15 members representing a variety of primary care and community health stakeholders. Over 50% of members are primary care clinicians from the PBRN. The Board meets quarterly. It is led by the President and includes a treasurer. The PBRN research director and network coordinator also attend these meetings. The work of the Board is regulated by specific by-laws that are reviewed and updated periodically. Board members review projects and make a final decision about pursuing particular opportunities. They also review PBRN operations, advise PBRN leadership about strategic planning and help determine the proper allocation of resources. The Board is ultimately responsible for the effective functioning of the organization. Several Board members are tasked to lead Committees (e.g., Nominations Committee, Programs Committee, Project Development and Advisory Committee) that address specific areas of OKPRN's operations.

Learning Community Activity (1.1.2.2)

One example of a Learning Community activity would be submitting a "question of the month" to the membership that can spark conversations. These could be around best practices that could initiate other discussions and foster a learning community among the PBRN membership. Another example includes a Local Learning Collaborative (LLC) that consists of 3 geographically close clinicians who can meet over lunch or breakfast for an hour a month to discuss individual progress toward a clinical goal, and may share individual performance data. Consider including clinical staff assisting in the quality improvement process.

Community Relationship Principles (1.1.3.1)

Interpersonal relationship building is essential in PBRN research as community members may act as cultural liaisons, assist with community recruitment, spearhead research coordination efforts for specific research projects, and champion research to community members who are less enthusiastic about the research enterprise. Clear, consistent, and respectful communications are essential for building and maintaining lasting research relationships in communities as PBRN research takes a long-range perspective designed to improve health outcomes within localized communities throughout the states in which they are located. Contemporary researchers are encouraged to consider the realities of historical trauma or negative perceptions about research and/or researchers when working with local/community populations (who have been historically marginalized) in order to help facilitate culturally appropriate and sustainable relationships.

Communication (Information, Marketing) Strategies (1.1.5.1)

Examples of communication strategies and messages

- Develop communication strategies and messages based upon what clinician and community members value. Messaging can be effectively delivered through:
    o Personal outreach efforts
    o PBRN website
    o Listserv messages
    o Newsletters
    o Social media such as Facebook and Twitter

- o Facsimile
- Make communications informative and inspire better organized discussions about primary care delivery and research by including materials such as:
  - o Reports of on-going or finalized research projects
  - o PBRN publications
  - o Links to relevant research from outside of the network
  - o Information about changes in health care policy
  - o Information about changes in primary care service delivery
  - o Information about events – Annual meetings, relevant speaking engagements, trainings and workshops

[BACK TO 1.1.5 DEVELOP SYSTEMS FOR CLEAR, CONSISTENT AND BI-DIRECTIONAL COMMUNICATION]

Strategic Planning Template (1.2.2.1)

WSU DFMPHS Strategic Implementation Table

DFMPHS Goal: Contribute to a healthier Metro (Greater) Detroit and Michigan

Goals	Team leader/ (Bold) team members	Strategies	Target completion date	Enabling activities	Measures of Progress	Start Date	Projected Completion Date	Actual Completion Date	Outcomes	Resources	Cross-cutting Themes

Cross cutting themes:

1. Increase diversity in faculty, staff, and learners.
2. Disparities/community health.
3. Innovation
4. Faculty development

Resources:

1. Dollars
2. Philanthropy

Revised 2/14/13

[BACK TO 1.2.2 ONGOING STRATEGIC PLANNING STEPS]

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PBRN Director (1.4.1.1)

The director is responsible for ensuring that proposed projects are evaluated in light of the network's research focus and mission, resources, and other concurrent projects. The director is responsible for leading regular meetings and for the daily administration of the PBRN, such as personnel and financial management.

- *"The Director is typically a physician but may be a PhD researcher or other senior administrator*."
- *"The director is operationally responsible for the PBRN and is the individual accountable for management of the network."*
- *"She or he often provides or arranges for mentorship and project development assistance for network members who have research questions and need help developing them. Outreach and recruitment of potential new network members, writing press releases, and giving talks … are the director's responsibility*."

See Resource: Green LA, White LL, Barry HC, Nease DE, Hudson BL. Infrastructure requirements for practice-based research networks. Ann Fam Med. 2005, 3 (Suppl 1): s5-s11.

[BACK TO 1.4.1 LEADERS AND STAFF]

PBRN Coordinator/Manager (1.4.1.2)

The PBRN coordinator/manager is the key staff person responsible for day-to-day operations of both the network and the projects within the network, and is critical to the success of the network. Successful coordinators often have training and experience in both health care management and research project administration. From Green et al. (2005) above.

Sample Job Description:

Coordinator/Manager

POSITION INFORMATION: Under the direction of the PBRN leadership, manage, coordinate and develop programs and initiatives for the network.

REPRESENTATIVE DUTIES (Example from OKPRN):

1. **Direction**

- Provides direct administrative, fiscal management and database support for the practice-based research network programs and initiatives. Manages the day-to-day activities of the program.
- Ensures fiscal viability of programs within the network and works with leadership to plan long range financial development of new initiatives.
- Manages the administrative requirements of the non-profit tax status (i.e. governance per the by-laws, assuring required meetings and elections, keeping appropriate minutes, filing required financial reports and tax returns, etc.).
- Maintain Policies and Procedures Manual. Update by-laws that were initially written and filed with the IRS.
- Proactively addresses issues involving programs under the PBRN umbrella.
- Provides clearinghouse function for questions, concerns, and suggestions from Organization members.
- Maintain Organization website.
- Recruit, maintain and update annually the network membership database.
- Hosts, maintains, and updates network listserv.

2. **Fiscal/Budget**

- Oversees fiscal management to include negotiating service contracts and purchasing supplies and equipment for operations activities.
- Plans financial criteria for program and monitors progress.
- Develops, manages and reconciles budget.
- Develops budget for all grant submissions.

3. **Community Liaison**
- Works collaboratively to facilitate PBRN involvement with other networks on campus and within the community and state.
- Identifies new opportunities and develops programs and initiatives to take advantage of those opportunities.
- Oversees and coordinates charitable contributions program (primarily member contributions initially) and/or member dues.

4. **Report Preparation**
- Assists with preparation of applications for continuing education credits for meetings and other projects.
- Assists with preparation and submission of grants and contracts

5. **Activity Coordination**.
   - Coordinates activities with OKPRN members. Plans, organizes, and otherwise assists with statewide, network meetings. Attends national and international meetings to network with other PBRNs
   - Organization of annual OKPRN meetings

6. **Communication**.
   - Interfaces with PBRNs to develop business and marketing plans and strategies for networks on campus, in the community, and statewide.

7. **As Needed**.
   - Performs various tasks as needed to successfully fulfill the function of the position.

[BACK TO 1.4.1 LEADERS AND STAFF]

Example of PBRN Organizational Structure (1.4.1.3)

Info 4: ORGANIZATIONAL STRUCTURE

Institutional Oversight

Network Director

Steering Committee

Network Manager

Day-to-day management of functions and finances
Develop timelines, strategic plans, goals
Review, monitor, report on grants & projects,
Manage personnel assignments and workflow
Maintain institution and regulatory compliance

Director of Research

Research Associate

Implement projects
Coordinate Steering Cmte
Oversee students and RAs
Prepare/submit reports
Network admin support

Grants manager

Professional development
Org development
Policy and planning consult

Future Positions

Data Systems Mgr

Statistician

Qualitative Research Associate

Implementation at sites
Site training and QA
Triage & Coord site and core needs
Oversee IRB, HIPAA, regulatory

HIPAA/IRB Coord

Research investigators

Communications

Projects coordinator
Web and communications
Network liaison and trainer
Professional development

Practice facilitators
(4 FTE)

Core area Implementation
Site training and QA
Regulatory

2nd Site Manager

Research Assistant

Investigator liaison
Study design assistant
Direct future research direction
Identify and seek funding

[BACK TO 1.4.1 LEADERS AND STAFF]

Example of a Practice Facilitator Job Description in an Academic Setting (1.4.1.4)

TITLE: Research Project Coordinator / Practice Facilitator

LOCATION: Family Medicine PBRN City metro area

HOURS: 40 hours per week, Mon-Fri   **PAY RANGE:** $x-y / year

MINIMUM QUALIFICATIONS: at least Bachelor's Degree or related training and 12 months research experience.

JOB FUNCTION: Coordinates and administers multiple projects for implementing new methods and research findings into community practices.

PREFERRED QUALIFICATIONS: Primarily healthcare or research experience preferred. Prefer Master's Degree in Nursing, Education, or Health Promotion Science and experience training medical office personnel. Must hold a valid driver's license and have dependable transportation for which mileage traveled will be reimbursed through project resources at the current state level. Must have experience and expertise in using information systems including but not limited to project management software, Excel, Word, e-mail, Internet information retrieval, and the ability to acquire some level of proficiency in navigating and interacting with electronic health record (EHR) systems.

Practice Facilitators (PFs) are individuals who develop a relationship with a group of practices over a sustained period of time, in order to help them evaluate and improve the quality of care they provide. This is accomplished through practice record reviews and feedback, patient surveys, staff training, "cross-pollination" (e.g. sharing of ideas among the eight practice members), coordination of quality improvement initiatives, and provision of specific materials and resources (flow sheets, computer training, etc.). PFs accomplish several other useful tasks as well. These tasks can be divided into three categories: facilitation of research, facilitation of practice enhancements (implementation), and facilitation of communication. Each full-time PF is assigned to several practices (depending on projects), visiting each practice regularly on a predictable schedule, generally spending a half day to a full day assisting the practice with identified objectives and obstacles, and meeting with the physicians and key support staff. They spend one day per week discussing the needs of their practitioners and learning more about how to address them with other PFs (office day). PFs based in other parts of the state usually meet by teleconference.

[BACK TO 1.4.1 LEADERS AND STAFF]

Examples of Training Resources (1.4.2.1)

<u>AHRQ Resources</u>
The Agency for Healthcare Research and Quality (AHRQ) hosts annual meetings, webinars, listservs and events targeting PBRN training needs. The AHRQ-funded PBRN Resource Center (PBRN RC) is a vital resource for PBRN literature, toolkits, FAQs, and assistance to PBRNs. Regular team meetings within individual PBRNs serve as opportunities to identify and select trainings, and to share experiences and knowledge across the team.

- Facilitator Training/Certification - The practice facilitator role within PBRNs is crucial to the implementation of projects. AHRQ's Practice Facilitation Manual ("*Developing and Running a Primary Care Practice Facilitation Program: A How-to Guide*") provides tools for running practice facilitation programs. Training should be reinforced through regular team meetings focused on practice facilitator issues, with at least annual focused training. Opportunities to shadow or participate in a forum with facilitators from other PBRNs will greatly enhance facilitator skills.
- In 2014, several PBRNs have developed a standard, national practice facilitator training curriculum and certification process. Centers for Excellence in Facilitation will be available nationally to help train facilitators, including training modules that will include didactic and hands-on shadowing work. Practice facilitators should have opportunities to access other PFs within their PBRN as well as other PBRNs. PFs also require a direct supervisor who monitors work and provides regular feedback and guidance, and challenges the PF to grow. The PFs also need access to other expertise within the network, and to the Director.

<u>Local Training & Professional Development</u>
Local training and professional development opportunities exist in the form of formal education, in-service trainings, programs offered through PBRN institutions (including human resources departments), departmental presentations (e.g. Grand Rounds), or independently. Local organizations focused on primary care often offer training sessions unique to topics of interest to primary care research and PBRNs, for example CER/PCOR research methods, practice transformation, health IT "meaningful use", motivational interviewing, and patient-centered care. PBRN member clinics may receive training around concepts like Lean Six Sigma, and PBRN staff could benefit from being knowledgeable in those areas.

<u>Institutional Mentoring and Career Development</u>
PBRN culture supports the advancement of junior investigators, staff and practice facilitators. Many opportunities exist to benefit from the knowledge and experiences of mature PBRNs. The organizational structure of each PBRN should support the learning and development of each individual.

[BACK TO 1.4.2 TRAINING AND PROFESSIONAL DEVELOPMENT]

PBRN Budget Category Example (1.5.1.1)

Fiscal Year 2012	
Income	
Starting Balance	
2/6/2012 - Deposit (Donations)	
Deposit (Protect Contract)	
Deposit (T-Shirt Sales) 8/6/2012	
Deposit (donation) 8/6/2012	
Deposit - OU Norman Maintenance Fee	
Total	
Administrative Contract Expenditures	
January, 2012	
February, 2012	
March, 2012	
April, 2012	
May, 2012	
June, 2012	
July, 2012	
August, 2012	
September, 2012	
October, 2012	
November, 2012	
December, 2012	
Total	

Miscellaneous Expenditures	
3/16/2012 - Office Depot (100 Folders)	
3/29/2012 – Food for Board Meeting	
Catering (Retreat)	
Speaker at Retreat	
Catering (Retreat)	
Impressions Printing (OKPRN Pens)	
Office Depot (certificates)	
Cimarron Screen Printing (T-Shirts)	
Triangle A&E - Poster	
Website (Hosting.com)	
US Postal (Letters for 501c3 disclosures)	
Legal Services	
US Postal (Certificates)	
Food for Board Meeting)	
MTM Midwest Trophy	
QuikPrint (Brochures)	
QuikPrint (Brochures - tax)	
Food for Board Meeting	
Total	
Total Ending Balance	

CHAPTER 2: STUDY DEVELOPMENT AND IMPLEMENTATION

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) 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 a busy practice. The purpose of this chapter is to outline processes to promote research quality management and quality performance.

2.1   PRE-PROJECT DEVELOPMENT

2.1.1   PBRN Establishes a Relationship with a Principal Investigator (PI)

- If the PI is a member of the PBRN, proposal development may begin
- If the PI is not a PBRN member, inform the PI about how the PBRN works, e.g.:
  - PBRN mission, operations, and collaboration guidelines
  - Awareness of the cooperative, participatory nature of practice-based research and the concerns of working with a busy practice
  - Rules of engagement for successful collaboration
  - Consider developing a Collaborative Guidelines document that can be provided to interested investigator
    Example of Collaboration Guidelines (2.1.1.1)Example of Collaborative Guidelines (2.1.1.1)

2.1.2   Develop Project Concept with PBRN Advice

- PI provides a brief concept paper project description that includes:
  - a statement of the research question and need for study
  - the approach and methods
  - a summary of the PBRN member involvement
  - project staffing
  - a timeline
  - budget for participating practices and subject compensation
- Faculty and research team at PI's institution review proposal to insure PBRN goals, objectives, and resource allocation are consistent with this project. Questions to be considered include:
  - Is this a researchable study question?
  - Is this research likely to fill a gap in current scientific knowledge concerning primary care patients?
  - Will this project be of interest to PBRN clinicians and their patients?

- o Might this research have a meaningful impact upon the field?
- o Is there a summary of current literature?
- o Is this a replication of a previous study? If so, will the study provide important new information?
- o What is the theoretical background of the research question?
- o What is novel or innovative in this research question?
- PI develops a more complete proposal using feedback to submit for the appropriate PBRN approvals

2.1.3 PBRN Initiates Project Development

- Ideas for projects may be solicited from PBRN members and external sources.
  - o Ideas may be presented to the PBRN from PBRN members
  - o Ideas may be presented to the PBRN from external sources, including Principal Investigators (PI) who wishes to use PBRN resources
    - ▪ Working with non-PBRN PIs enhances further networking and collaboration for the PBRN (and the potential for more external funding)
  - o Ideas should be ranked on importance, feasibility, and personal interest by the PBRN membership
  - o Resource: See Dolor RJ et al. Guidance for researchers developing and conducting clinical trials in PBRNs. *J Am Board Fam Med*, 2014; 27 (6). doi: 10.3122/jabfm.2014.06.140166
- Have available reviewers for potential new projects, such as the PBRN leadership group. (2.2.1 Evaluate Staffing Needs)
- Give new project proposal to review group
- Review new project ideas while taking into consideration the following:
  - o Applicability and feasibility to primary care
  - o The "fit" of the proposed study with PBRN mission, goals and scope
  - o The potential burden on the PBRN member's practice staff
  - o Whether the research question addresses a clinical need
  - o The interest of PBRN members
  - o Likely access to the target patient population
  - o Likely success of the recruitment strategy
    - ▪ Consider travel costs and potential issues (e.g., weather, or holidays) that might impact recruitment in proposed practices
  - o The adequacy of potential funding sources
  - o Whether the PBRN has the necessary resources, including time to commit to the study, available staff, and specific expertise or other resources

2.1.4   Advisory Board Review and Approval

- PI submits a research proposal to PBRN Board of Directors for approval, as appropriate:
  - o Include executive summary outlining impact to PBRN member's practice, preliminary findings, and other important information
  - o Invite PI to present study and answer questions
- The PBRN Board of Directors will assess suitability of the project by considering the following:
  - o Applicability and feasibility for primary care
  - o The potential burden on the PBRN member's practice staff
  - o The potential impact of the research question on a clinical need
  - o Determine which practice staff need education in human subjects research

2.1.5   PBRN Provides Budget Requirements

- PBRN submits a detailed budget plan with justification to the PI once a preliminary protocol has been approved and potential funding source(s) identified.
  - o Allocate PBRN collaboration funding
  - o Allocate scope of work funding
  - o Assign costs by category (i.e. personnel, payments to participating PBRN member practices, etc.)
  - o Ensure adequate budget for recruitment, longitudinal follow-up, data collection, data management, data cleaning, etc. Many of these costs are often underestimated and critical to the success of the project.
  - o Confirm budget is sufficient to cover PBRN tasks, including core activities like staff management
  - o Decide if any "in-kind" (cost sharing) agreements will occur.

2.1.6   PBRN Staff Supports PI with Grant Application

- The PBRN designates a staff member to coordinate grant proposal application activities such as the following:
  - o Obtaining letters of support (e.g., potential participating PBRN member practices, other PBRNs, community partners, department head of the principal investigator, and consultants).
  - o Gathering information and draft documents from collaborators.
  - o Obtaining standard descriptions for use in the grants (e.g., PBRN descriptions, research environment, completed studies and resources).
  - o Obtaining Biosketches from collaborators and key personnel.

- o Working with institutional budget office to finalize budget requests.
    - o Guiding subcontractors through completion of required documentation.
- PI sends drafts for comments and makes revisions.
    - o PBRN director and staff review drafts to:
        - Locate any changes in methods, measurements, hypothesis and analyses.
        - Identify staffing changes that would impact the budget and budget justification.
- PI and collaborators obtain respective institutional approval of budget.
- PI compiles final document and submits funding application.

2.2   RESEARCH PROJECT STAFF ROLES AND RESPONSIBILITIES

The time between proposal submission and funding may be a year or more and changes may have occurred within the PBRN that may impact the ability to accomplish the project as proposed. Many grant proposals go through two or more submissions before funding (or are never funded). Once a project has been funded and an award made, the PBRN must determine the specific staffing requirements and the roles and responsibilities that are necessary to accomplish the project goals.

2.2.1 Evaluate Staffing Needs

Evaluate staffing needs based on study protocol, budgeted effort and current commitments. See PBRN and study terms and respective definitions below:

Primary Term	Definition
Clinician	A person qualified in the clinical practice of medicine who works directly with patients.
Collaborators	Investigators from sites different from the study coordinating site.
Community Partners	An agency or practice with little research expertise that works with the PBRN engaging in the research process.
Data Entry Staff	People who enter data from paper forms into computers.
Department Head	The academic department head of the principal investigator.
Education	The general process for improving knowledge, skills and attitudes
Participant	Person who signs the informed consent document to participate in a study.
Patient	A patient waiting or under medical care and treatment who could be a potential subject.
PBRN Board of Directors	A committee comprised of clinicians and other professionals that govern the function of the PBRN.
PBRN Director	The person who manages the organized PBRN group.
PBRN Member	Typically an outpatient primary care practice with one or more providers. The word, "member" can refer to a person or a practice, depending on the

	context.
PBRN Member Site Liaison	The contact person at the PBRN member practice for a specific research project.
PBRN Staff	PBRN administrators, secretaries, and other support people, but usually not physicians.
Personnel	A general term that may be synonymous with the investigators, research assistants, and secretaries working on a specific research study. At other times, "personnel" may refer to the PBRN staff or to other people.
Practice Lead Clinician	The clinician champion in a member practice.
Practice Staff	People who work at a PBRN member practice, including nurses, medical assistants, secretaries, and administrators, but not physicians.
Research Coordinator	Someone on the research team who coordinates the interactions between the research team and the PBRN members.
Staff	PBRN staff or practice staff or study staff, depending on the context.
Study Staff	The principal investigator and his or her assistants.
Subcontractors	The Institutions where the collaborators work.
Training	The process for improving specific skills and supporting knowledge to enable the performance of specific tasks.

Specific positions within the PBRN research team and PBRN member staff that need to be considered include:

- Principal Investigator (PI) or co-PIs: Responsible for the management and integrity of the design, conduct, and reporting of the research project and for managing, monitoring, and ensuring the integrity of any collaborative relationships. The PI/co-PIs are generally the individual(s) who originate the proposal and write the majority of the proposal. They are ultimately responsible for timely reports to the funding agency, as well as many tasks outlined below.
  - Responsible for the direction and oversight of compliance, financial, personnel, and other related aspects of the research project and for coordination with school, department, and central administration personnel to assure research is conducted in accordance with Federal regulations and University and sponsoring agency policies and procedures.
  - Reports to designated official (i.e. dean, department chair, division chief).
- Co-investigator: Has similar responsibilities to that of the PI on research projects. While the PI has ultimate responsibility for the conduct of a research project, the co-investigator is also obligated to ensure the project is conducted in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research.

- Project manager: Responsible for the planning, execution, and finalization of projects according to deadlines and budgets. Includes acquiring resources and coordinating the efforts of the research team and third-party contractors or consultants to deliver projects according to plan. Also defines the project's objectives and oversees quality control throughout its life cycle.
- Consultants: Responsible for providing professional advice or services as fits with project needs.
- Project Coordinator: A project coordinator from the PBRN will be assigned as the manager for each project. Specifically, the Project Coordinator would have the following roles:
  o Convene and attend study meetings.
  o Communicate with other PBRN member staff about study implementation and requests for information.
  o Serve as the PBRN contact for the PBRN member's practices and the research team and/or PI.
  o Assist with creation of study protocols and procedure manuals, and any additional study documents (recruitment materials: flyers, posters, one page overviews, etc.)
  o Maintain study documentation (electronic and hard copies).
  o Obtain IRB approval.
  o Monitor compliance with human participants research education of key personnel for project (including PBRN research team and PBRN member staff).
  o Monitor the informed consent process for the PBRN member site
  o Assist Project Manager with other duties as assigned.
- Statistician: Responsible for duties related to the collection, management, preparation, analysis, interpretation and presentation of data in the research project.
- Data entry staff: Responsible for entering and verifying study data.
- PBRN Member's Practice
  o PBRN member lead clinician: Person at the practice who actively promotes the study and the benefits of conducting the research to other practice staff.
  o PBRN member liaison: Practice staff person who manages on-site study implementation with the help of a PBRN site liaison and serves as the key PBRN member contact for the PBRN.
    ▪ Represents the mission of the PBRN.
    ▪ Maintains timely and ongoing communication with the PBRN.
    ▪ Completes project specific and general PBRN related tasks as assigned.
    ▪ Recruits practice staff as needed to complete PBRN projects.
    ▪ Oversees implementation of PBRN projects on site, ensuring completion and accuracy of all study tasks.

- Promotes importance of conducting PBRN research projects with clinicians and other PBRN member staff.
- Assists with scheduling PBRN meetings and education at the PBRN member practice.
- Attends project specific education and meetings and other PBRN meetings as required.
- Hire personnel as needed.
- Consider sharing a portion of full-time equivalents (FTEs) for roles, e.g. statistician.
- Assign roles with appropriate job descriptions.
- Reassign personnel as appropriate.

2.3   STAFF EDUCATION

2.3.1 Develop a Staff Education Plan

- Create an education program for all staff involved in the study.
  - o Develop a flexible education program tailored to individual learning needs and the specific roles and responsibilities of each member of the research team.
  - o Select education/training program segments that staff will complete based on their roles.
  - o Provide education/training tailored to multiple staff roles.
  - o Cross-train staff, if possible.
  - o Mirror the education with the approaches, culture, and methods staff will use throughout the study, when possible.
  - o Use experiential education approaches, when possible (e.g. role playing or a "hands-on" computer experience)
- Inventory available resources/needs
  - o Assess prior experience of staff.
  - o Identify areas in which there may be gaps in resources, attitudes, skills, and knowledge.
  - o Determine skills-training needs as well as educational development needs.
  - o Identify tangible (computer systems, finances) and intangible (relationships, skills, experience) resources.
- Decide if staff education/training will be in-house or outsourced (e.g., hire an expert consultant or send staff to an education program).
- Select the location for education/training (in-person, online, or combination of both).
- Select educator and education team.

- Set the education schedule;
  - o Decide frequency and duration of education
  - o Ensure adequate time for education
- Incorporate education refreshers

2.3.2 Educate and Monitor in Ethical Issues in Human Subjects Research

- Identify all staff named on a protocol subject to ethics (IRB) review
- Assure that key personnel complete IRB education required by institution or funding agency
- Resources for Responsible Conduct of Research:
  - o Consider requiring completion of CITI education (Collaborative Institutional Training Initiative) (https://www.citiprogram.org/default.asp); there may be additional education required by VA or NIH.
  - o See also the "new investigator's guide" on the Univ. Wisconsin Health Sciences Institutional Review Boards Knowledge base website: https://kb.wisc.edu/hsirbs/
- Study PI ensures that all staff has appropriate human subjects education
  - o Routinely monitor research activities to assure proper procedures for handling data, consenting subjects, confidentiality, etc.

2.3.3 Data Collection Education

Develop educational experiences for the research team on using data collection instruments properly/reliably. This includes "assisted" survey completion (e.g. participant fills in the survey in the presence of, or with the help of, study personnel).

- Provide a clear and feasible survey protocol to minimize undesired between-individual and between-group differences (administration bias).
- Emphasize the importance of following the protocol and the impact of various errors on outcomes or analyses.
- Provide written instructions and step-by-step didactic and experiential training on the protocol adherence.
- Verify adherence to the protocol and resulting quality of survey data with periodic reviews to identify gaps in data reliability.
- Promptly communicate concerns about survey administration and/or data quality to make necessary changes or adjustments.
- Use participant tracking that follows good safety and confidentiality practices for research data.

- Be alert to the following issues specific to paper surveys:
  - Paper surveys generally require more detailed participant instructions at the time of administration to explain branching logic.
  - Check each survey for legibility and completeness before the participant leaves.
  - Study personnel should be educated specifically about maintaining the confidentiality of survey data while transporting and temporarily storing paper instruments. Resources may need to be provided to achieve this.
- Education/training should include actions to take when electronic surveys are temporarily unavailable, or initiated surveys can't be completed or duplication occurs due to technical problems (e.g. network or server issues)

2.3.4 Data Entry Education
- Complete training in study specific database use (e.g. REDCap, Excel, Access) for data entry staff. (see Chapter 3 on Data Management)
- Receive ongoing training in the nature and format of the data to be entered.
- Identify the research team member to whom questions should be directed, and encourage regular contact.
- Adhere to guidelines to maintain confidentiality in handling paper and electronic data.
- Report any issues regarding study database to research team.

2.3.5 Adherence to Study Protocol

Develop and make available to staff study-specific protocols and a manual of procedures that includes an education plan and specifies a quality management (QM) plan:
- Provide documentation of study protocol education and maintenance (e.g., may include Good Clinical Practice, human subject protection education, applicable licensure for staff, HIPAA compliance education).
- Perform quality control and quality management as specified in QM plan and provide feedback of findings.
- Complete site delegation of responsibilities log and appropriate training for specific role (often used for clinical trials).
- Facilitate monitoring of study protocol by outside entity if indicated.

2.4   COMMUNITY PARTNER INVOLVEMENT

Community partners may include agencies and practices with little research experience and expertise. Each of these may require specific recruitment, engagement, and education based on their project participation.

- Recruit community partners based on their interest, willingness, and capacity to contribute to the research project.
- Provide an orientation regarding study purpose and protocols.
- Allow opportunity for community partners to give feedback to research team regarding study process/protocol.
- Educate community partners on proper and reliable use of data collection instruments.
- Develop a process for recruiting/hiring community partners.
  - Involve community in research team meetings as appropriate; includes sharing materials such as grant application and other data collection instruments.
- Ensure that community partners have completed appropriate education in human subjects research.
  - See CITI research ethics training: https://www.citiprogram.org/
  - The PI will assess relevant education modules and facilitate IRB education for community partners. This information should be presented at the time of recruiting community partners.
  - The research team will create a tracking database for compliance with IRB education (cannot expect community partners to do this).
- The research team will develop and arrange protocol education/training for community partners using the following steps:
  - Create standards to ensure adequate level of education.
  - Conduct the educational experience.
  - Follow-up to ensure appropriate levels of compliance (oversight or mentoring from research team as necessary/appropriate).
  - Ensure that partners are familiar and competent with all aspects of data collection including consenting, measurement/assessment, equipment maintenance, interviewing techniques, distribution of incentives, record keeping (tracking), etc.
- Involve community partners in data analysis, interpretation and dissemination of findings.

2.5   STUDY PERSONNEL EVALUATION AND FEEDBACK

- Understand your organization's performance evaluation requirements.
- Conduct performance evaluations for all personnel who work on research studies.
- Conduct performance evaluations using the following good practices:
  - Conduct performance evaluations in a private location.
  - Conduct performance evaluations regularly during the probationary period.
  - Conduct performance evaluations annually; be sure to provide intermittent feedback to reduce any surprises on the evaluation.
  - Allow for employee reflection and self-evaluation.
  - Provide a copy of the performance evaluation to the employee.
  - Place original performance evaluation in employee's personnel file.

- Provide feedback to site coordinators/PBRN member site liaisons regarding their performance. See Example of Site Feedback Form (2.5.1)

2.6   PROCEDURE MANUAL

2.6.1 Create a "Manual of Procedures"

- Facilitates consistency in protocol implementation and data collection across participants and clinical sites.
- Include the following in the manual of procedures, but it is not limited to the following components:
  - Provide operational definitions of the data
  - Describe all Case Report Forms (CRFs)
  - Describe internal and external quality control procedures
  - Describe procedures for adverse and serious adverse events reporting
  - Include Delegation of Responsibilities log
  - Include recruitment/participant screening log and enrollment log
- Recruitment Plan/Screening
  - Recruitment activities and materials must be IRB- approved
    - See Recruiting Plan Example (2.6.1.1)
- Recruiting PBRN members:
  - Initial communication with lead clinician and PBRN member site liaison
  - Follow-up with 1-page written summary of project overview and tasks

- As requested, make presentation to decision-makers practice administration and staff
- Obtain decision on willingness to participate, often formalized with a signed memorandum of understanding (MOU) that clearly outlines the purpose of the project, responsibility and expectations of all parties, timeline, and payment schedule
- See MOU Example (2.6.1.2)
- Provide recruitment and protocol education as needed
- Recruiting Clinicians
  - Provide clinicians with study funding update and written summary of work involved and impact on staff
  - Request confirmation of interest
    - See Confirmation Request Form Example (2.6.1.3)
  - Send follow-up as necessary
  - If not enough participation make personal phone contact
- Recruiting Research Subjects
  - Discuss subject recruiting plans with PBRN members; in-person or by phone
    - Will space be provided for onsite recruiter?
    - Will practice staff assist with recruitment?
    - Explain need for HIPAA-compliant recruiting strategy.
    - If expecting offices to recruit participants, funding must be provided to the practice to support their efforts, in addition to funding for the PBRN staff to coordinate and manage the study.
  - Determine best recruitment method(s) for specific site (direct mailing on practice letterhead with clinician signatures, face-to-face, local media, flyers/brochures, telephone)
- Provide description of randomization process
- Regulatory/Institutional Review Board (IRB) documents for human subjects research
- Determine IRB(s) of record
- Determine if IRB of record has procedures for multi-site research
- Complete your Institution's IRB application requesting review for multi-site research when appropriate
- In the U.S., obtain IRB Authorization Agreement (AA) from your IRB office for an individual protocol for each participating PBRN practice that does not have its own IRB. Note that international PBRNs will follow their country's specific procedures.

- o The IRB AA provides a mechanism for a practice engaged in research to delegate IRB review to an IRB of another institution. http://www.niaid.nih.gov/LabsAndResources/resources/toolkit/Pages/faq.aspx
    - See IRB AA Example (2.6.1.4)
- Obtain Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule Waiver of Authorization from your IRB office if appropriate for the study
    - o The HIPAA Privacy Rule establishes the conditions under which protected health information may be used by covered entities for research purposes
    - o The HIPAA Privacy Rule protects the privacy of individually identifiable health information
- If applying for HIPAA waiver, the following elements must be present:
    - o an adequate plan to protect the identifiers from improper use and disclosure;
    - o an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
    - o adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
- Obtain Federal-wide Assurance (FWA) if needed. (Some universities require this for all projects, regardless of the funding source). Some institutions may consider filing a Federal-wide Assurance (FWA) for the protection of human subjects. Electronic filing instructions are found at http://ohrp.cit.nih.gov/efile/FwaStart.aspx
    - o FWAs require an institution or physician office to follow the federal regulations governing human subjects in all research
    - o Challenges may occur while assisting a PBRN office site in obtaining a FWA:
        - Lack of oversight for the ethical conduct of research in the office setting
        - Administrative concerns about liability associated with obtaining a FWA
        - Few resources to access and complete FWA paperwork
        - Low level of knowledge about basic research processes and human subjects protection among office staff
        - FWA renewal process is every three years
- Work with the local PBRN member site liaison to complete the applicable IRB application(s) if necessary. Significant amounts of time may be required to complete the application, respond to IRB requests for revisions or clarifications, and to receive IRB approval. Allow up to 8-12 weeks (or longer) or full board approvals.
- Documentation of IRB approvals

- If required, provide record of IRB approvals for off-site PBRNs to the IRB of record office.
- Complete IRB continuation applications, and closure forms as appropriate.
- Complete IRB reportable event forms, as appropriate.

2.6.2 Study Procedures/Timelines

- Provide a comprehensive overview of study procedures/protocols including major steps in the study:
  - Detail the timing for each step, what is to be done, and which study personnel are involved and/or responsible.
  - Consider using a Gantt-type timeline to depict how activities interact with each other. See Timeline Example (2.6.2.1)
  - Display study procedures/protocols in the form of a graphical representation of timeline with key milestones.

2.7   COMMUNICATION PLAN

2.7.1 Define the Groups that Need a Communication Plan

- Consider the following when developing a communication plan:
  - Specific research team members who need to share and track study progress
  - Specific grant and research-related departments within your institution that provide a support service to the investigator (e.g., a scheduling hub, Office of Sponsored Programs, compliance office, local university IRB if central IRB not used, central university research office responsible for tracking database, subject billing office, etc.)
  - Lead clinicians and collaborating practice staff at PBRN member practices
  - Services from the funding agency project officer responsible for study monitoring, event adjudication, statistical analysis, manuscript preparation, etc.
  - Internal quality improvement group responsible for study review
  - Data Safety Monitoring Board, an external group of experts who monitor patient safety and treatment efficacy data while a clinical trial is ongoing
  - Study subjects (e.g. PBRN member's practices, clinicians, patients)
  - Progress Reports to funding agency

2.7.2 Develop Communication Strategy for Each Group Involved in PBRN Study

- Convey communication principles:
  - Timely and effective communication between relevant groups or individuals
  - Timely notices for materials/meetings
  - Establish ground rules at first meeting (2.7.2.1)
- Create a detailed list of items to be communicated, to whom they are communicated, and when they are to be communicated.
- Establish regular opportunities for communication.
  - For example, at study outset, PI initiates a monthly meeting, lead clinicians to provide feedback and troubleshoot potential problems; then periodically as needed
- Determine preferences for communication method(s) (2.7.2.2)
- Document meeting content/results:
  - Write and distribute minutes to all concerned parties shortly after meeting See Example of meeting minutes (2.7.2.3)
- Archive agenda, minutes, and supporting meeting documents.
- Follow-up and resolve action items in minutes.

2.7.3 Identify Individuals to Execute the Communication Strategies

- Confirm roles and responsibilities of PBRN member site liaison and lead clinician regarding communication expectations.
- Identify an information technology contact person from PBRN member's practice, if appropriate.
- Identify the lead clinician contact person from PBRN member's practice.

2.7.4 Communicate Updates Regularly

Examples of communication updates are: project progress, enrollment numbers, and problems to be addressed by site

- Provide regular updates to PBRN member's practice; determine the preferred mode of communication with each PBRN member.
  - See, for example: Bertram et al. Communication is the key to success in pragmatic clinical trials in practice-based research networks (PBRNs). *J Am Board Fam Med,* 2013; 26: 571-578. http://jabfm.org/content/26/5/571.full.pdf+html
- Schedule regular research team meetings (weekly initially and decreasing frequency as appropriate).

- Schedule meetings far in advance, and cancel if not needed.
- Provide agendas for meetings.
- Provide research team members with updates of study, e.g., number consented or enrolled.
- Distribute meeting minutes to all interested parties.
  - Identify action steps and person responsible to complete actions; include due dates if possible

2.8   QUALITY MANAGEMENT (QM) PLAN

Quality management involves detailed documentation of study progress, and maintaining organized project files; this is required if the study may be audited by an external monitor
- Involve statistician in developing QM plan.
- Monitor data quality frequently at the beginning of the study.
- Review detailed study data of first few subjects (depends on rate and total enrollment, 5-10 for a large study, 2-3 for a smaller study).
- Decide number of charts to be reviewed annually (10% is a common amount).
- Randomly select charts to be reviewed.
- Monitor quarterly or as needed thereafter.
- Identify problems or trends discovered from the audit.
- Summarize subject records and regulatory files reviewed.
- Present pertinent findings to staff.
- Report findings to IRB or study sponsor if required
- Develop solution to issues discovered as part of the quality management review
- Disseminate solutions at staff meetings, through written reports, etc.
- Ensure solutions are implemented
- Review plan annually for need to revise/delete current tools

See Example of Regulatory Binder Index (Clinical Trial) (2.8.1)

See Example of Regulatory Binder Index (Retrospective Chart Review) (2.8.2)

2.9 GUIDELINES FOR AUDIT

2.9.1 Guidelines for External Audit Readiness

- First audit visit:
  - o Obtain any institution-specific electronic access needed for external monitor to review electronic health record (this process may take several weeks)
  - o Request medical records department pull paper charts used as source, if electronic review is not possible
- Subsequent visits:
  - o Review previous monitoring visit follow up letter and verify that all action items are complete
  - o Review quality management reports and verify that all issues have been resolved
  - o Review documents prior to monitor visit
  - o Review site specific education log to make sure all personnel are up to date on Human Subject Research Protection and HIPAA education and any other site or project specific education (For example, may need NIH specific education or shipment of biological specimens education if specimens are collected and shipped)
  - o Review study personnel signature/responsibility log for any updates
  - o Review personnel licensure and CVs for current versions, per funding source requirement
  - o Review any protocol deviations to ensure proper sponsor and IRB notification
  - o Review study product (i.e. medications, vaccines) accountability log for accuracy
  - o Verify study product storage temperature logs are accessible and temperatures are within range
  - o Review any outstanding serious adverse events for follow-up documentation
  - o Review regulatory binder for any needed updates/deletions (For example, current versions of all IRB approved materials, IRB approval documents, study correspondence from sponsor)
  - o Review labeling and storage of research samples for protocol adherence.
  - o Verify research sample storage temperature logs are accessible and refrigerator/freezer temperatures are within range
  - o Secure private space for monitor, with wireless capabilities and access to fax and copy machine to review subject materials, as needed (if monitor will need to travel to other study sites to review records, schedule time with outside practices)
  - o Schedule time with the site lead clinician for brief meeting with monitor at completion of the visit

2.10   STUDY CLOSE-OUT

- Conduct study close-out, if the following are completed:
  - Enrollment is completed
  - Research-related intervention is completed
  - Subject follow-up is completed
  - Data are de-identified
  - Biological specimens are de-identified
  - Study sponsor agrees to close study
- Submit an IRB project closure form to terminate the project
- Determine how long documents need to be kept
- Label and store paper copies of materials (i.e., informed consents, questionnaires) in locked storage according to agency and local IRB policy
- Shred paper files of subject identifiers linked with data
- Delete electronic files containing subject identifiers
- Delete emails containing subject identifiers
- Destroy investigational products and maintain documentation of the destruction
- Notify PBRN member's practice of study closure
- Provide preliminary study findings to PBRN member's practice
- Provide final reports to regulatory authorities and funding agency
- Financial close out with accounting office

Info Links for Chapter 2 start on next page.

2.1   PRE-PROJECT DEVELOPMENT

Example of Collaboration Guidelines (2.1.1.1)
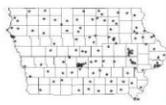
Iowa Research Network (IRENE)
Department of Family Medicine, University of Iowa
Collaboration Guidelines

IRENE's MISSION:
To create new knowledge that is relevant to rural primary care clinicians and their patients with the outcome of improving patient care.

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Examples of IRENE Projects

Randomized Trial to Improve Colorectal Cancer Screening: Barcey T. Levy, PhD, MD, Jeanette Daly, PhD, RN, Yinghui Xu, MS, John W. Ely, MD, MSPH: This was a randomized trial conducted in 16 practices to improve colorectal cancer screening among patients due for screening. We found that mailed educational materials plus a fecal immunochemical test (FIT) improved screening compared with usual care and compared with a physician chart reminder. A telephone call did not improve screening compared with the mailed education and FIT. (*American Cancer Society*)

Management by Clinicians of Patients Suspected of Having Community- Acquired MRSA : Barcey Levy, PhD, MD & Jeanette Daly, RN, PhD
The purpose of this study is to identify and evaluate the best methods and procedures for primary care practices to follow in managing patients suspected of having community-acquired methicillin-resistant staphylococcus aureus infections. (*Agency for Healthcare Research and Quality*)

The Iowa Research Network (IRENE) is a practice-based research network (PBRN) affiliated with the Iowa Academy of Family Physicians (IAFP), the University of Iowa Department of Family Medicine and the IAFP's Family Health Foundation of Iowa. IRENE is governed by its membership and supported by professional staff from the University of Iowa, Department of Family Medicine. Begun in 2001, IRENE is an established PBRN consisting of 191 family physician practices. One hundred eighty-seven practices have participated in a study and 113 physicians have completed Humans Subjects Training.

Many investigators have indicated an interest in collaborating with IRENE and are invited to determine what is appropriate. To be of interest to IRENE, your study must be relevant to primary care. If you are interested in writing a grant proposal that includes IRENE, please follow these steps well ahead of the grant deadline:

- Contact Barcey Levy or Jeanette Daly to discuss your research idea.

- At their direction, prepare eight copies of a 2–3 page description of your proposal that includes: names of the principal investigator(s), co-investigators and their affiliation; proposed funding agency; submission due date; dates of the grant period; research purpose or questions; and a description of how the IRENE network would participate.

- Specify any needs you foresee for time commitments by IRENE support staff (recruitment, data collection, programming, analysis). IRENE practice recruitment will be handled through the IRENE Research Office and will cost up to $2,000 per practice recruited, depending on the type of study. (We have spent over 10 years developing and nurturing our network.)

- Designate an appropriate portion of your budget to support IRENE offices and office coordinators.

- Work with the Department of Family Medicine to identify a co-investigator on the proposed study.

- The IRENE Research Development Committee will review the proposal. You may be asked to meet with the committee.

- Authorship should be shared with appropriate IRENE investigators and IRENE should be acknowledged on all publications resulting from your research.

2.5   STUDY PERSONNEL EVALUATION AND SITE FEEDBACK FORM

Example of Site Feedback Form (2.5.1)

Site Performance Feedback Form

Site Liaison Name: _____

Site Name: _____

Site Location: _____

Date: _____

Please review feedback provided in each category, as applicable, with constructive comments and practical and creative suggestions.

WORK PERFORMANCE	Poor	Satisfactory	Good	Superior	COMMENTS
Hosted education session for research	☐	☐	☐	☐	
Enrolled subjects	☐	☐	☐	☐	
Proper storage of subject privacy information	☐	☐	☐	☐	
Attended research meetings	☐	☐	☐	☐	
Adherence to protocol as required for research activities	☐	☐	☐	☐	
Staff expertise and proficiency as related to research activities	☐	☐	☐	☐	

COMMUNICATION WITH RESEARCH TEAM

	Poor	Satisfactory	Good	Superior	
Responsive in a timely manner	☐	☐	☐	☐	
Collaborative as appropriate	☐	☐	☐	☐	
Clarity of communication/response	☐	☐	☐	☐	
Interactions with research team	☐	☐	☐	☐	

members

2.6   PROCEDURE MANUAL

PBRN Recruitment Plan Examples (2.6.1.1)

EXAMPLE #1

- Recruiting PBRN members announcing an upcoming proposal submission could be conducted via fax, email, letter or telephone
- Outline key components in the announcement that a practice setting would have to provide to participate in a study, such as
  - PBRN member site liaison
  - Nurse manager or health coach
  - Consent subjects
  - Provide subject contact information
  - Review medical records and complete data collection forms
  - Take surveys
  - Implement an intervention
- Provide participation payment information for practice and subjects
- Provide timeframe for responding to request
- Provide sample letter of support
- Ask for contact PBRN member site liaison's name and contact information

EXAMPLE #2

Recruitment and Enrollment of Clinicians. Clinician selection criteria will include:

- See at least 15 Medicare beneficiaries per week who have three or more chronic medical conditions;
- PBRN member's practices must be stable, not involved in or anticipating a major transition or reorganization;
- Clinician and PBRN member practice are willing/able to use standing orders and reminder systems; and
- Clinician and PBRN member practice must be able to complete 60 Medicare annual wellness visits (AWVs) within a six-month period.

Eligible clinicians will provide informed consent to a Research Assistant (RA) by signing an IRB – approved informed consent document indicating an interest and willingness to participate. In PBRN member's practices with an administrative decision maker, board of directors, and/or the tribal council,

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the administrator or Chairman of the Board or Council will also provide informed consent. For example, participating clinicians will receive $1500 in remuneration for generation of patient lists (with 3+ chronic conditions), completion of baseline surveys, and participation in academic detailing on the implementation. They will receive another $1500 for participating in performance feedback, facilitation, and completion of the post-intervention surveys and interviews. Clinicians, nurses and practice managers will receive instruction on how to obtain proper reimbursement for Medicare AWVs. Apply for Maintenance of Certification Part IV through the American Board of Family Medicine and Internal Medicine and continuing education credits through the American Academy of Family Physicians.

EXAMPLE #3
Recruitment and Enrollment of Subjects. Sixty (60) patients from each clinician's practice (10 practices; N=600) will be selected from a list of patients generated from patient management or health records. Patient selection criteria will include:

- Medicare beneficiary with three or more chronic health conditions;
- Seen at least twice by the clinician in the last 12 months;
- Not living in an institution (nursing home, prison, etc.); and
- Able to understand and provide informed consent.

After practices have been randomized, patients will be notified via letters, flyers, handouts, and electronic communication (e.g., social media messages from clinicians), followed by phone calls from the research team. All recruitment approaches will be reviewed by participating clinicians. Appointments will be made for interested patients to be enrolled in their clinician's practice by an RA until 60 patients from each practice have been enrolled (N=600). At the baseline visit with the RA, provide an informed consent process, and ask patients to fill in a baseline set of questionnaires using a wireless touch-screen computer. The RA will then help patients schedule a wellness visit with their clinician within two months. Alternatively, interested patients may receive a study packet via regular mail or in the practice that will include a cover letter, the consent form, and instructions for completing baseline surveys online. Participation will not start until the research team receives the signed consent form. Subjects will receive a $50 gift certificate after baseline data collection and another $50 gift certificate after completing the study.

[BACK TO 2.6.1 CREATE A "MANUAL OF PROCEDURES"]

Example of Memorandum of Understanding for a Research Project (2.6.1.2)

IOWA RESEARCH NETWORK

Memorandum of Understanding

John Doe, MD (Principle Investigator); Jane Smith, PhD, MD (Co-Investigator)

Implementing Network's Self-management Tools Through Engaging patients and Practices

This document serves as a Memorandum of Understanding for _____ to participate in the above named PBRNE study for approximately 10 months. The practice agrees to participate in the roles and responsibilities listed below.

This project will promote and study the use of AHRQ's Self-management Support (SMS) Toolkit across 16 primary care practices in 4 PBRNs. We will utilize Boot Camp Translation (BCT) as an intervention to encourage and support SMS among staff and patients, assess the impact of the Toolkit on practice staff and patients, and identify factors related to successful implementation. Outcomes of the study could provide a basis for improving patient SMS in primary care.

Who	Practice responsibilities	PBRN responsibilities	Dates
All clinic staff involved in patient care, care management or care coordination	• Complete online survey every two months for 10 months = 5 surveys total per staff participant. Care management surveys take less than 10 minutes to complete. • Provide staff names and email addresses. • *A few staff/clinicians will be interviewed by the* **PBRN Coordinator** *two times for approximately 20 minutes each.*	• Enroll/inform staff • Collect, track and enter staff surveys • Conduct interviews	January 2014 through October 2014
Care manager	• Identify patients aged 18-80 with chronic illness that are receiving or targeted to receive care management support for recruitment into one of two arms: • **Arm 1: Boot Camp.** Recruit 2 to 3 "experienced" candidates from the above list who would be motivated and interested in Boot Camp intervention – able to share in group what patients want or need to manage their chronic illness. *(Criteria will be provided and PBRN will assist.)* • **Arm 2: Surveys.** Identify a new set of 4 patients every 2 months for 10 months = 20 total to complete online surveys 3 times during their 2 months of participation.	• Assist care management with patient recruitment into both arms per selection criteria • Enroll/inform patients • Collect, track and enter patient surveys	January 2014 through October 2014

	• Encourage staff participation.		
Care manager Clinician 2 to 3 Patients	• 2 to 3 experienced/interested patients travel to campus to attend Boot Camp. • 4 new patients every 2 months = 20 patients/practice will complete online survey 3 times during their 2 months of participation. *Survey takes less than 10 minutes to complete.*	• Provide Boot Camp materials • Track and pay subjects	Jan/Feb Mar/Apr May/June July/Aug Sept/Oct
	• Attend Boot Camp intervention (6 hours) (*July 18, 2014 at UIHC.*) • Participate in follow up 30-minute conference calls meetings over an 8-week period	• Arrange for and attend Boot Camp intervention. • Schedule, coordinate and participate in conference calls • Assist with, take minutes, and attend conference calls • Conduct site visits for follow-up support	June or July 2014 interven-tion

Site incentives: As acknowledgment of your clinic's work on this research study, PBRN will provide your practices with a payment of $750. In addition, the following compensation for is provided:

Boot Camp attendance (patients): $150/patient

Boot Camp attendance (patients or staff): mileage, per diem and lodging for four attendees (please car pool if possible).

Patients who complete 3 surveys in their 2-month participation period: $30 for three surveys.

Signatures

For the practice: _____ Date _____

For the PBRN: _____ Date _____

[BACK TO CREATE A "MANUAL OF PROCEDURES"]

Example of Site Confirmation Form (2.6.1.3)

Office Name: Date Sent:
Physician Name   Fax number:
Street Address
City, State Zip

                        Research Study
                       Title of Study:

Please complete and return this form page to indicate your interest in participating in the study.

_____   I am interested in participating in this study

_____   I am not interested in participating in this study.

_____   I may be interested in this study. Please call me and provide additional information.

My Name:

My email address:

Best telephone number to reach me:

Title:

Office assistant name:

Office assistant telephone number:

Contact email:

Feel free to call Principal Investigator at (319) 765-4321 if you have questions.

Please return your completed form by Date:_____

Return by fax to (319) 123-4567.

Thank you!

[BACK TO 2.6.1 "MANUAL OF PROCEDURES']

IRB Authorization Agreement (AA for an Individual Protocol
(For projects without federal funding)

Name of Research Project:

Principal Investigator(s):

IRB ID Number:

Sponsor of Funding Agency, if any:

Name of Institution Providing IRB Review:

IRB Registration Number:

The Officials signing below agree that _____may rely on the _____IRB review approval, and continuing oversight provided by the _____ for the above-named project only.

The review, approval, and continuing oversight performed by the _____ IRB satisfy the requirements of the U.S. DHHS regulations for the protection of human subjects at 45 CRF 46.

Relevant minutes of _____ IRB meetings shall be made available to _____ upon request. _____ remains responsible for ensuring compliance with the University of Iowa's IRB's determinations.

This document should be kept on file at both institutions and must be provided to OHRP upon request.

IRB Chair: Date:

Authorized Official: Date:

Authorized Official: Date:

Timeline, Milestones and Measurable Outcomes (2.6.2.1)

	Year 1				Year 2				Year 3			
Quarters **Activity**	1	2	3	4	1	2	3	4	1	2	3	4
For all aims: quarterly meetings of the Advisory Team and any regional Community Assistants able to attend: • Review updated maps and other materials for dissemination • Brainstorm about "problem" issues • Plan for agendas in meetings with IRENE physicians and with the regional groups	x	x	x	x	x	x	x	x	x	x	x	x
Aim 1. Enhance data analysis capabilities.												
Review SEER, BRFSS, and IRENE cancer data	x	x										
Obtain IRB approval for aim 1	x	x										
Compare SEER, BRFSS and IRENE CRC screening/ incidence/mortality data			x	x								
Provide results of analyses to the community (see aims 2 and 3 below)	Ongoing for all three grant years											
Measurable outcome: Write up and submit results for publication					x	x						
Measurable outcome: Prepare updated geocoded maps for various cancers	Ongoing for all three grant years											

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Aim 2. Facilitate participation in cancer control research.												
Measurable outcome: Identify and hire CAs in 5 regions of Iowa	x	x										
Measurable outcome: Hold 6 meetings per year in each of 5 regions	Each region to hold six meetings each grant year organized by the Community Assistants with facilitation from Tina Devery and Sara Comstock											
Measurable outcome: Members of Advisory Team to present information regarding cancer control and hold a dialog during two annual state-wide meetings each grant year (State Cancer Summit and either the IAFP meeting or the Annual Family Physician Refresher course)		x		x		x		x		x		x
Measurable outcome: Present cancer maps and comparative effectiveness reviews to regional meetings and receive community input	Members from Advisory Board will present information at a total of 15 regional meetings each year of the grant (10 in person and 5 via teleconference)											
Aim 3. Increase the number of family physician offices actively involved in cancer control research.												
Provide educational session on IRB requirements & cancer control research for CAs & physicians twice each year at state-wide meetings (at Cancer Summit, IAFP meeting, or Family Physician Refresher Course)		x		x		x		x		x		x
Each participating IRENE office will receive a visit from two Advisory Team members for the purpose of: • In service training on IRB & FWA requirements (for offices unable to attend the state-wide meetings) • Set up desktop computers in IRENE offices for use by the office research coordinators • Present cancer maps and/or comparative effectiveness reviews to IRENE offices via teleconferences and in person and encourage dialogue on further plans for research	Ongoing throughout the three-year grant period – each of 50 offices to receive one visit from two Advisory Team members, at least one of whom is affiliated with IRENE											

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Measurable Outcomes:				x				x					x
• The number of IRENE offices who have "signed on" for the project • The number of IRENE offices who have individuals who have completed IRB and FWA training • The number of offices who have received and installed computers and printers • The number of offices who have received in-service from Advisory Team members on cancer control issues/effectiveness reviews													

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2.7   COMMUNICATION PLAN EXAMPLES

Ground Rules for Conducting Meetings (2.7.2.1)

- Start and finish meeting on time
- Decide on length of meeting
- Turn off cell phones
- Use Robert's Rules of Order [url: http://www.robertsrules.com/] or Consensus Methods, such as Technology of Participation [url: http://ica-usa.org/pdf/ToP%20Brochure%208-4-09.pdf]
  - Allow everyone to be heard, e.g., "there are no stupid questions; the best solution comes from everyone's perspective"
  - Use the conflict resolution method, i.e., committee members attempt to resolve group conflicts by actively communicating information about the conflict and engage in collective negotiation
  - Treat other research team members with respect, even in the face of disagreement
  - Send a substitute if you cannot attend
  - Bring a handout when you are making a proposal for action
  - Cancel the meeting if there are no pertinent issues on the agenda

Communication Modes Available in Most PBRNs (2.7.2.2)

Example methods of communication:
- E-mail
- Phone
- Conference call
- Group meeting
- Paper
- Web (e.g. webinar, wiki, list serve, AHRQ PBRN portal)
- Fax Blast (computerized mass fax software)

[BACK TO 2.7.2 DEVELOP COMMUNICATION STRATEGY FOR EACH GROUP INVOLVED IN PBRN STUDY]

Example of Meeting Minutes (2.7.2.3)

Research Team Meeting #20
February 14, 2014; 8:45 am–10:15 am
Small Conference Room, Department of Family Medicine
Study {title} Minutes

Attendees: SX, BX, JX, MX, JXX, CX

Agenda Item	Action Taken	Responsible Party	Next Steps	Completion Due Date
1. **Review of minutes**	Minutes of {date} were reviewed and accepted.			
2. **Newspaper ad**	JX suggested that we advertise the study in a smaller community newspaper {names}	JX	PX will obtain information in regard to University policy as well as advertising.	26 Feb 2014
3. **Study supplies**	We need to inventory supplies and order in advance of running out (e.g. den lights, mirrors, napkins, gauze).	CX	CX will inventory supplies.	1 Mar 2014
4. **Recruitment**	Five subjects were recruited on {date} at the {location}.	MX	MX will send a thank you card to the {location} Executive Director.	28 Feb 2014
5. **Dental Visit {location}**	A dental visit has been scheduled at Dr. BY's practice, in {location} on {date}; {time}. JY will be the dental examiner. Spanish translators need to be study educated and human subject education certified. Scheduling subjects for the event will be planned next meeting.	BX	BX will conduct the education for the Spanish translators and instruct them to take the online human subject education course.	15 Mar 2014
6. **Next meeting**	4 Mar 2014			

Respectfully submitted, JXX

[BACK TO 2.7.2 DEVELOP COMMUNICATION STRATEGY FOR EACH GROUP INVOLVED IN PBRN STUDY]

2.8   QUALITY MANAGEMENT PLAN

Example of Regulatory Binder Index (Clinical Trial) (2.8.1)

1.	**Protocol**	**Study Protocol/Protocol Summaries** **Study Protocol Amendments** **Protocol or Amendment Signature Pages** **Non-Disclosure Agreement** **Investigator Drug Brochure** **Annual Reports to Sponsor and/or IRB**
2.	**1572/1571/Regulatory Forms/CV**	- Form FDA 1572 (Statement of Investigator) (if applicable) - Form FDA 1571 (Investigational New Drug Application) (if applicable) - Investigational/New Devices Exemption Letters - Curricula Vitae (CVs) - Medical Licenses (US only, if applicable) - Financial Disclosure Agreement - Conflict of Interest Management Plan (if applicable)
3.	**Approved Consent Form(s) or Waiver(s)**	- Informed Consent(s) or Waiver(s) - Note: If original signed/dated ICFs are kept elsewhere, note the location.
4.	**IRB Approvals and Correspondence**	- IRB/IBC/RAC Approvals for Protocol - Amendments, Advertisements, Renewals - Protocol and/or Consent Modification Approvals - IRB Correspondence (progress reports, letters of submission for approval, IRB notification, responses to Serious Adverse Events reports, Investigational New Drug Safety Reports, Data Safety Monitoring Board Reports, etc.)
5.	**Laboratory**	- Laboratory Certifications (CAP & CLIA) - Laboratory Normal Ranges - CV Pathologist (if applicable) - Specimen Handling Instructions
6.	**Study Logs**	- Investigator Personnel Team Protocol Signature Page - Signatures and Delegation of Authority Logs - Site Visit Logs - Site Signature Logs - Master Subject Logs - Screening/Enrollment Logs - Education Logs (site initiation visit attendance log& education certificates)
7.	**Correspondence**	Study Related Correspondence Between the Site, Sponsor, Contract Research Organization, etc.
8.	**Adverse Events(AE)**	- Master Adverse Event Reporting Form and Instructions - Completed Prompt Reporting Forms and Associated - Documentation (or note where they are located) - Safety Letters
9.	**Drug/Device Accountability**	- Study Drug/Device Receipt/Packing Invoices - Study Drug/Device Accountability Form - Study Drug/Device Supply Forms - Temperature Logs

10.	Miscellaneous	• Miscellaneous (CRF transmittal logs), etc.
		• Subject Payment Logs
		• Certificate of Confidentiality
		• SOPs

[BACK TO 2.8 QUALITY MANAGEMENT PLAN]

Example of Regulatory Binder Index (Retrospective Chart Review) (2.8.2)

1. Protocol (including all amended versions) and/or summary
2. All IRB submissions and approvals
3. Signed delegation of authority log with copies of key personnel CVs and medical licenses (if applicable)
4. Enrollment log (list of charts included; if de-identified, then include the key)
5. Case Report Form (CRF) template (document used to collect the data)
6. Paper copy of all completed CRFs, if applicable (images, etc.)
7. Electronic copy of all CRF/other documents maintained for study analysis
8. Correspondence, if applicable; may include Notes/Memos to File
9. Data Transfer Agreement (if applicable)
10. A copy of publications generated from the project.

[BACK TO 2.8 QUALITY MANAGEMENT PLAN]

CHAPTER 3: DATA MANAGEMENT

Data management is the foundation for scientific reliability and validity. The purpose of this chapter is 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.

3.1 DATABASE DEVELOPMENT

3.1.1 Determine Data Sources

The method of data collection and data source is driven by the research question(s). Specify the type of data collection needed for each variable:

- Qualitative data are often collected via focus group or stakeholder interviews. Consider a qualitative approach for studies where you are developing hypotheses and/or where study attributes are not readily known.
  [See: Qualitative Studies: Sampling] (3.1.1.1)
- Quantitative data is usually analyzed with standard statistics (e.g., laboratory values or demographic characteristics).
- Consider collecting both types of data (a mixed-methods study design): Qualitative data may help define which quantitative data (especially as a precursor to developing surveys.

3.1.2 Format Data

1. Determine original data format (e.g., paper, electronic, audio/video recording, laboratory measurements, tissue/blood samples).
2. Determine how original data will be converted into a format that can be entered into a database.
3. Outline variable types, such as categorical or continuous for quantitative variables.
4. Review each data element and variable.
5. Determine ideal output wanted from each element/variable.
6. Use standard terminology for coding data elements.

3.1.3 Develop a Data Dictionary and Codebook

1. Write a study-specific introductory paragraph that includes the following project elements:
   - Title
   - Purpose
   - Month and year of data collection
   - Process and data source(s) (e.g., questionnaire instrument, database abstraction or interview)
2. Determine the data components (recruitment, data gathered) at the provider level and the patient level.
3. Create a table with the following headings:
   - Data Source, if more than one instrument used
   - Variable Name – many statistical programs allow for up to 32 characters, but often it is easier to work with shorter variables names that have some meaning
   - Variable Alias (8 alphanumeric characters or less)
   - Variable Definition (explains the nature and form of the variable)
   - Data Type (e.g. numeric, alphanumeric,)
   - Data Length
   - Allowed Data Range (e.g. 1-5)
   - Response Options (i.e., coding conventions)
   - Required Field (Yes or No); this data field be must completed for all participants
   - Data Relationship:
     - Identify or state relationships to other data elements (if this is a key field that links to another database)

4. Enter each variable in the table and define each field.

See Example Database Planning Table (3.1.3.1)
See Example of Codebook Content (3.1.2.2)
See Example of Clinic Identification Scheme (3.1.3.3)
See Example of Patient Identification Scheme (3.1.3.4)
See Example of Record Retention Scheme (3.1.3.5)

Note: Store your table, data dictionary, and codebook with the final data set in the Data Analysis project folder (section 3.2.2 below)

3.1.4 Develop Study Database

1. Determine who will be responsible for database development.
   - The PI and statistician should be readily involved throughout all phases of development.
2. Select the database for data capture.
   a. Determine the type of database required (e.g., longitudinal, document-oriented database, etc.).
   b. Examine what tools are available in various software packages.
   c. Select a software for the database
      - Survey software includes REDCap, Survey Monkey, Qualtrics, etc., and other online resources.
      - Study capture software includes REDCap, Microsoft Excel, Microsoft Access, etc.
      - Qualitative software examples include NVivo, Atlas.ti, etc.

3. Use your table from 3.1.3, above Steps 3 & 4 to define content and create a data dictionary.
   [See example of Sample database planning table (3.1.3.1)]

4. Create the database.
   a. Define the data fields within the selected software.
   b. Implement logic/range checks consistent with those indicated in the table (See Example 3.1.3, Steps 3 & 4.).
   c. Create appropriate ranges for data entry.
      - Identify the range of data values from the minimum to the maximum that you are sampling or the smallest interval that contains all the data.
         o Example for age: Study sample is adult 18 years and older up to 80 years. Range should be set at 18 to 80. If an adult age of 150 years is entered, it is out of range.
         o Example for satisfaction on a Likert scale: Range is: 1 = very dissatisfied, 2 = dissatisfied, 3 = neutral, 4 = satisfied, 5 = very satisfied. The range is 1 to 5. If any other number, such as 0, 6, or 20 was entered, it would be out of range.
         o Example for true/false question: 0 = false and 1 = true. The range is 0 to 1. If any other number, such as 5, 6 or 100 was entered, it would be out of range.
         o For yes/no questions, using a "1" to indicate the "yes" responses and "0" to indicate "no" will facilitate calculating the percentage who responded

"yes". Examine the average of the responses to determine the percentage of the individuals who responded "yes".

   d. Link primary and secondary data sets if warranted for study.
- o Determine linking variable in each data set, such as ID number that is associated with both data sets based on participant's name and date of birth or other identifies.
- o Create a data dictionary for the secondary data set.
- o Randomly select 5-10% of dataset that is linked and determine if appropriate linkage occurred.

5. Test the data entry plan with the pilot database.
- Use "dummy data" to test entry and output of the database.
  - o Check each variable in the database to determine if it will accept data.
  - o Enter out-of-range data to ensure that out-of-limit data beyond these ranges are not accepted.
  - o Export data to determine the structure of data output.
- Make changes to database as determined from the test entries of dummy data.

Note: See Section 3.4 below Data Entry for entering study data into this database.

3.2   DATA STORAGE AND SECURITY

3.2.1 Develop a Data File-Naming Protocol
1. Name files
- Use project name, content, "pre" or "post", site, and date.
- Separate descriptive components using an underscore
- Examples:
  - CKD_Demographics_pre_clinic0200_06_13_11_RW
  - CKD_CPCI_pre_clinic0700_06_14_10

2. Generate participant identifiers (IDs) (3.2.1.1)
- Use a clear, detailed and appropriate algorithm that is easy to follow in a reliable manner.
- Ensure no IDs are repeated through duplicate checks. Excel can aid in assessing duplicates by using the Advanced Filter dialogue box or using conditional formatting.

3. Create key to participant identifiers
   - Use strong passwords and at least 128-bit encryption. These can be achieved easily via free software (e.g., "ZIP" programs).
   - Restrict access to key data files to blinded individuals during, and potentially even after, the study.

4. Manage participant identifier codes
   - Consider the needs of the study. Consider that some studies might require a procedure to "break the code" and associate participant IDs with demographics before or after the end of the study.
   - Craft a clear, provisional plan about who has access, when and how the key file can be opened, and reporting requirements (i.e., Data Safety Monitoring Board or Study Oversight Committee).
   - Accomplish permanent destruction of participant IDs via multiple wiping of the files and backups using professional software.
     - Permanent erasing (or wiping) of electronic data can be achieved with specialized software. Some products are available for free (e.g., OpenPGP); others are proprietary. These can be installed typically as desktop applications and invoked from the context menu (by right-clicking on the file or folder) and confirming the "shredding" or "wiping" operation. Alternatively, files or folders to be destroyed can be dragged and dropped on an icon. The software then physically overwrites the data bits on the medium with random bits using multiple passes which, if done correctly, renders the content virtually unrecoverable even by digital forensic methods.

5. Update data file after editing
   - Include the initials of the person making the modification at the end of the file name.
     - For example, when files are modified to add a new, calculated variable. The new file name would be:
       Demographics_pre_clinic0200_rev_06_14_11RW
   - Consider using version control, such as Perl.

3.2.2 Develop a Plan for Data Storage

1. Store electronic data on firewalled and password protected hardware.
   - Create a series of folders on a secure shared drive using a standard naming system [See 3.2.1 above Develop a data file naming protocol]

- Example folders:
  - Proposal
  - IRB Protocols, Amendments and Approvals
  - Planning & Implementation
  - Data
  - Data Analysis
  - Funding Agency Reports
  - Presentations, & Manuscripts/Publications
  - References
- Follow IRB-approved process for handling Protected Health Information (PHI) in raw and entered data. For example,
  - Place password protection on data containing unique patient identifiers.
  - Maintain study keys providing link between patient unique identifiers and assigned study number on separate password-protected file, which only key study personnel can access (e.g. study coordinator(s), PI, data manager).
  - Maintain paper copies in a locked filing cabinet.
- Group patient-level and clinic-level data into subfolders by collection type, by participant/clinic identification number (e.g., baseline survey, focus group or clinic characteristics, etc.).
- Create text file(s) describing location of all study data and date for data destruction.
- Ensure that the shared drive is regularly backed up by the Institution's information technology (IT) Group.
- Store all electronic study data on this drive when possible.

2. Keep records in a locked file cabinet within a locked room.
   - Limit room access to study personnel.
   - File and secure study data daily (do not leave PHI or study data on desktop).

3. Maintain research data for timeframe specified by study sponsor and Institution Review Board (IRB) regulations
   a. Identify date after which the data may be destroyed as part of study closure activities.
      - Consider IRB and HIPAA requirements.
      - Follow local or sponsor guidelines.
   b. Consider shredding all paper data and deleting electronic data after that time period.

    c. Select a safe method of erasure/destruction.

o Examples of safe erasure: wiping, scrubbing (exceeds deletion), shredding

o Electronic data should be removed from hard or shared drives using a program that can erase the entire disk or selected files.

- The utility should also erase free space that can include temporary files.
- Local information technology staff can recommend products.
  [See http://www.oit.umn.edu/security/tools/destroying-data/index.htm)

3.2.3 Develop a Plan for Data Sharing – Data Use Agreements

Research partners agree about data access and use early in the research process. Formal data sharing agreements, (e.g., Memorandums of Understanding or Data Use Agreements) address ownership, transfer, or restricted use of data and conform to regulatory requirements of the funder and IRB ethics boards. Project-specific procedures for data access and use are particularly important in "community-engaged" research where data control and dissemination is shared equitably among partners. All agreements are coordinated to ensure conformity with requirements of the granting agency.

Data from PBRN studies may come from sources other than the PBRN setting. Collaborators may include investigators, co-investigators, other PBRNs, community partners (e.g., tribal communities), state/policy partners, non-PBRN members, health systems, contract research organizations, industry sponsors, and others. An effective plan for data sharing enhances trust, communication, collaborative relationships, and future research possibilities.

Determine type of agreement. See example type of agreement (3.2.3.1)

1) Establish criteria for data sharing

    See Sample Criteria for Data Access Agreements (3.2.3.2)

    - Identifiable data
    - Release of study information
    - Responsibility for data analysis
    See Sample "Project-Specific" Data Sharing form (3.2.3.3)

2) Write the agreement

    Guidance for development of formal data sharing agreements is available on the NIH website: Data Sharing Policy and Implementation Guidance: http://grants2.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#ex (date accessed 09/26/2014)

3.3 DATA COLLECTION

3.3.1 Identify All Data Collection Components

1. Outline the goals of data collection.
2. Create or revise the protocol for data collection, including data sources, guidelines, definitions, timeline, and supporting material.
Qualitative Data Collection Process (3.3.1.1)
3. Complete required training for data collection staff (i.e., protocol and study methods, such as survey instruments, observations, interviews, and chart audits)
4. Archive files.

3.3.2 Establish Data and Task Tracking Systems

1. Identify elements needed to complete data management.

2. Create a checklist that covers all steps of data management and store with administrative information to facilitate tracking of overall data management.
   - Identify tasks and monitor process, keeping "Who, What, When, and Where" in mind when identifying tasks.

3. Establish participant payment tracking procedure
   - Determine university, funding agency and IRB rules for participant payment.
   - Decide upon the nature and level of incentive or payment.
   - Decide what portion of participants will receive the payment.
   - Decide on method of payment allocation (e.g., drawing, first 10 people, all respondents).
   - Decide on the form of payment (e.g., cash vs. gift card).
   - Identify campus collaborators (e.g., who will authorize the payments).
   - Develop accounting process (e.g., keep identifiable information in a separate location).
   - Develop cash handling procedure in compliance with your organization's policies.
   - Develop tracking system to ensure proper tracking of:
     a. Funds used to acquire payments
     b. Payment converted to appropriate payment form
     c. Payment has been delivered
     d. Payment has been received
     e. Collect any missing signatures and/or forms

4. Develop plan and materials for participant communication
   - Participant approach
   - Participant eligibility
   - Informed consent
   - Participant follow-up and communication
   - Study visit schedule
   - Participant withdrawal
   - Thank you letter

3.3.3 Determine and Develop Data Collection Methodology

1. Consider collecting data from more than one source.
   - Other considerations:
     - Available resources
     - Potential for generalization increased by variety in the sources of data
     - Analysis and reporting resources
     - Skill/training of data collector
   - Example methods:
     - Interview
     - Self-administered survey
     - Focus group
     - Paper or EHR chart review
     - EHR or other database extraction

2. Develop data collection instruments
   - Use pre-existing validated instruments.
     - Consult the literature to evaluate what others have successfully used in a similar setting.
     - Adapt pre-existing instruments to fit your setting.
     - Obtain author permission to use instrument, as needed.
   - Design your own instrument.

3. Test data collection instruments.
   - Consider content validation review from panel of experts.
   - Pilot test your instrument before starting data collection.
   - Consider validation study for new instruments.

4. Determine participant eligibility, defining inclusion and exclusion criteria.
   - After data collection format has been determined, specify participant eligibility (practice patient or provider, general public, etc.).
   - Formulate plan to gain access to participants.
   - Provide appropriate training (based on target group) for each data collection tool.
   - Distribute data collection tools.
   - Retrieve completed data collection tools.

5. Identify physical location and strategy for data collection.
   - Examples:
     - Clinic or community locations
     - E-mail, Telephone, Web/online
   - Considerations:
     - Consider access to EMRs, or paper medical records: plan enough time to gain the authorization needed for a hospital's or clinics EMR, or authorization to gain access to paper charts
     - Other logistical concerns:
       - Ask about internet access to site (if needed), area/room to interview participants, participant consent, or data entry
       - Anticipate equipment needed: laptops, software, supplies, such as gloves, needles, collection tubes
       - Sample size requirements or limitations (i.e., large sample size may lend itself best to a web based survey)
       - Characteristics of respondents (e.g., literacy, internet access; may consider providing paper copy ahead of time)
       - Need for complete anonymity and/or confidentiality
       - Knowledge of potential answer categories (i.e., responding to extensive or complex options may be difficult over the phone)
   - Pilot test your method before starting data collection.

3.4   DATA ENTRY

3.4.1 Determine the Data Acquisition Process

- Determine data needed for study completions that is not collected within the study, such as U.S. Census data or Nursing Home Online Survey, Certification and Reporting data.

- Locate agency/office responsible for dispersing data.
- Review process for acquisitioning data, such as complete a Freedom of Information Act request.
- Determine if there is a cost associated with acquiring the data.
- Process a request for data.

3.4.2 Review Data Entry Plan

- Determine that fields for all collected data are found in database.
  a. Test database using a sample of real study data, if available.
     1) Check each variable in the database to determine if it will accept data.
     2) Enter data out of range to ensure that out of limit data is not accepted.
     3) Export data to determine the structure of data output.
  b. Make changes to the database as determined from test entries of real data.
- Enter sample of data from each source to check that entry sequence correlates with source sequence.
- Generate data output for sample data to verify output accurately reflects desired format (e.g., does date of birth produce an "age" or 'yes' response produce a "1"?).
- Conduct logic checks after entering a few participants' data.
  o Review data to ensure structure matches what is expected, such as matching with number fields, date fields, etc.
  o Seek to understand data patterns.
  o Compare unexpected or missing values with the data source and resolve problem.
  o Review non-standard responses (outliers, unexpected values) and develop specific method of resolution for each.
  o Run range checks to determine minimum and maximum numbers.
  o Run frequency checks to determine distribution of answers.
- Develop override method for true data that is out of range, as necessary.
- Develop missing value plan (e.g., missing = 999 or -99).

3.4.3 Develop Plan for Data Entry Occurring in De-centralized Locations

1. Identify who will enter data at de-centralized locations.

2. Develop documentation plan for completing data entry procedures

   - For studies that require more than one person collecting data, create a data entry identifier (for example: Mary =1; Tom =2). This aids in record keeping, merging

databases, pinpointing discrepancies in the data, and identification of personnel who may need retraining with data entry.

3. Train data entry staff to insure data accuracy.

4. Conduct regular quality control checks at random intervals throughout the study.

5. Communicate regularly with data entry staff to review progress and identify concerns.

6. If working with paper surveys, plan to begin to enter the data electronically once a certain threshold is met (i.e., after 10 surveys are collected).

3.4.4   Manage the Documentation of the Informed Consent Process

1. Unless a waiver of documentation of informed consent has been granted, develop a tracking system for documenting participant informed consent (e.g., is it complete, signed, filed, and current).
2. Track receipt of informed consent documents by updating tracking system.
3. Store hard copy version of informed consent documents in a locked storage cabinet and/or file room.
4. Determine how long consent forms need to be stored and dispose of appropriately.

3.4.5.   Develop a consistent data management and tracking process for hard copy information

1. If data are coming in or entered on hard copy case report forms (CRF), it needs to be clear who is entering them and what to do with them once entered.

2. Once entered, document when and by whom the data form was entered.

3. Data entry personnel need clear procedures to follow for illegible or uninterpretable responses.

4. Data entry personnel need to understand the work flow for the hard copy forms, once the data are entered. For example, should they give it to the Study Coordinator for filing or do they file themselves (e.g. in a locked cabinet)?

   - The goal is for the PI or Study Coordinator to easily find any hard copy data that are needed for verification or site monitoring visits.

3.5 DATA DE-IDENTIFICATION

Data that identifies study participants can be removed from datasets entirely, coded, or encrypted.

3.5.1 Generate a Study Participant Identification (ID) Management Process

1. Maintain a reliable link (key) between various records that belong to the same study participant in order to ensure integrity of the data.
2. Incorporate participant ID as a required field for each data entry (e.g., each form, spreadsheet row, database record, etc.).
3. Inspect data acquisition tools and repositories regularly (i.e., especially paper-based or manually entered) to ensure that participant IDs are implemented consistently.
4. Use validation scripts, in completely electronic data capture, at the front-end (user interface) and at the back-end (database) to ensure that each record has a participant ID and that it is consistent with ID protocol.

3.5.2 Develop and Maintain a Key (Master List) for De-identified Data.

1. Generate a password-secured key connecting participant IDs to identifiers.
   - Keep participant keys linking IDs to demographic information or informed consent documents in password-protected and encrypted files on file servers with access limited to authorized study personnel.
   - Create backup of file containing keys to secure space, separate from other study materials, accessible only to those identified by the study protocol.

2. Create a plan for handling participant code upon need.
   - Develop plan for breaking the participant code including who, when, how, etc.
   - Establish plan for destroying keys after a prescribed period of time.

3.6 DATA CLEANING

3.6.1 Establish Plan for Ongoing Data Cleaning

1. Identify missing or incomplete data.
   - Seek to understand missing data patterns.
   - Decide if missing values will be imputed.
2. Conduct data verification for accuracy and inconsistencies.
3. Conduct manual data verification, which involves a person checking what is entered.
4. Conduct data verification by software program.

- Two persons enter data in two different duplicate files, and then a program (usually written by the statistician) compares the entry and notes any differences.
- Examples to ensure data quality also include completeness of each record, type and range of information, data elements are linked correctly across multiple sources or forms, authorized identifying information or redacting of same (e.g., from Qualtrics), from medical chart, from qualitative transcript, etc).
5. Correct any differences found in duplicate files with source.
   - Recheck database periodically during data entry for problems and accuracy.
6. Make any needed mid-course corrections, e.g. modifications of data dictionary & data entry systems and/or data collection methods.
7. Remove data from the final data set, if appropriate, but maintain the original data file in study folder or shared drive. For example, a participant may have not completed sufficient items in a specific scale to allow scoring and therefore inclusion in the final data for analysis.
8. Save the final data file in an established location, along with any intermediate data files used for published analyses.
9. Maintain a log documenting all changes made to the data, the date the changes were made, and the reasons for the change.

3.7   DATA TRANSFER

Data transfer implies how paper data are entered into an electronic format, or moved, or archived. It can include considerations such as duplicate data entry.

3.7.1 Create and Implement Data Transfer protocol
1. Adhere to IRB-approved process for handling of data prior to transfer for both sender and receiver [See 3.5 above De-identification].
2. Prepare data for transfer by reviewing data in general to add any relevant notes or make updates.
3. Transfer data
   - Transfer of data files can occur through various mechanisms, depending on the format in which the data resides. For example, many protocols could apply to the transfer of data from one structured electronic database to another, or between two electronic devices. This protocol will assume data occurs in a static electronic format, such as an Excel spreadsheet, Access database, or other data file.

- Confirm method for data transfer (e.g., through REDCap, e-mail, post to secure website, post to networked drive). Back up file to networked drive, media, secure website or other secure source.
- Place security on data file per data security protocol (e.g., encryption, password protection, creation of zip file, etc.) [See 3.2 above Data Storage & Security]
- Copy or upload file to mechanism for data transfer and deliver to recipient. Data files should be accompanied by copies of any data collection instruments used in the study and a data dictionary identifying the coding used for all variables.
- Contact recipient, under separate cover, to provide password or other information to access data.

4. Confirm receipt of data with intended recipient.
5. Remove file from transfer location.

Info Links for Chapter 3 start on next page.

INFO LINKS FOR CHAPTER 3: DATA MANAGEMENT

3.1   DATABASE DEVELOPMENT

Qualitative Studies: Sampling (3.1.1.1.)

- Maximize sampling through a diverse range of representation with regard to the topic of interest.
- Generate sampling frame based on attributes anticipated *a priori* to influence views about topic of interest.
- Select a sufficient number of participants to represent each attribute to assure data saturation.
- Structure data collection to maximize participant comfort with sharing information.

[BACK TO 3.1.1 DETERMINE DATA SOURCES]

Sample Database Planning Table (3.1.3.1)

Data Source	Variable Name	Variable Alias	Variable Definition	Data Type	Data Length	Data Allowed Range	Response Options	Required (Yes/No)	Data Relationship

Considerations:

- When naming repeated measures (instruments): add an extension to the variable name _0 for baseline; _1 for second, etc. (e.g. QWB_0, QWB_1, etc.)
- In coding categorical variables: if there is a "none" or "zero" category, begin with 0, otherwise begin with 1.
- Date stamp new variables to the data dictionary
- Assign a designation to missing data that does not correspond to any of the other responses (e.g., 990 or -99 or ".").

[BACK TO 3.1.3 DEVELOP A DATA DICTIONARY AND CODEBOOK]

Establish Codebook Content (3.1.3.2)

Research study codebooks can be created many different ways. Below are some examples of codes included in codebooks. Key points to include in a code book for a research project are the name of the variable name, the variable label, variable label values.

****

ethnic (name of variable)
ethnic origin (variable label)
variable label values:
      1 = White not Hispanic
      2 = Black not Hispanic
      3 = Hispanic
      4 = Asian or Pacific Islander
      5 = Filipino
      6 = American Indian or Alaskan Native
      7 = Mixed ethnicity
      8 = Other

marital (name of variable)
Marital status (variable label)
Variable label values:
      1 = married or domestic partner
      2 = single
      3 = separated
      4 = divorced
      5 = widowed

Diab (name of variable)
Type 2 Diabetes (variable label)
variable label values:
      0 = no, does not have the diagnosis
      1 = yes, does have the diagnosis

arnp_code (name of variable)
advanced registered nurse practitioner (variable label)
variable label values:
      1 = FAMILY NURSE PRACTITIONERS
      2 = NURSE MIDWIVES

3 = PEDIATRIC NURSE PRACTITIONERS

4 = CERTIFIED REGISTERED NURSE ANESTHETISTS

5 = SCHOOL NURSE PRACTITIONERS

6 = OBSTETRIC/GYNECOLOGY NURSE PRACTITIONERS

7 = PSYCHIATRIC NURSE PRACTITIONERS

8 = ADULT NURSE PRACTITIONERS

9 = CLINICAL NURSE SPECIALIST

10 = GERONTOLOGICAL NURSE PRACTITIONER

11 = NEONATAL NURSE PRACTITIONERS

12= ACUTE CARE NURSE PRACTITIONERS

13= PERINATAL NURSE PRACTITIONERS

[BACK TO 3.1.3 DEVELOP A DATA DICTIONARY AND CODEBOOK]

Clinic Identification (3.1.3.3)

- Below is an example of codes for practice-based research network offices and respective physicians. Note the office ID is built in the physician ID. In the physician ID number 7 was randomly selected to start the numbering system following by the office ID. The number 6 after the office ID was also randomly selected in case an office had more than 100 physicians the numbering system for physicians per office could go to 999.

Office ID	Clinic Name/City	Physician Study ID
01	Spencer Family Care Avera Health/Spencer	701601-7016xx
02	Medical Associates/Le Mars	702601-7026xx
03	Kossuth Regional Health Center/Algona	703601-7016xx
04	Unity Healthcare/Muscatine	704601-7046xx
05	Burlington Area Family Practice Center/West Burlington	705601-7056xx
06	Siouxland Foundation/Sioux City	706601-7066xx

[BACK TO 3.1.3 DEVELOP A DATA DICTIONARY AND CODEBOOK]

Patient Identification (3.1.3.4)

- Below is an example of codes for practice-based research network offices and respective patients. Note the office ID is built into the patient study ID. The example shown below depicts patient study IDs for 16 offices.

RECRID	Office ID	Clinic Name	Patient Study ID
701xxxxx	01	**Spencer Family Care Avera Health Spencer**	701001-701530
702xxxxx	02	**Medical Associates LeMars**	702001-702530
703xxxxx	03	**Kossuth Regional Health Center Algona**	703001-703530
704xxxxx	04	**Unity Healthcare Muscatine**	704001-704530
705xxxxx	05	**Burlington Area Family Practice Center, West Burlington**	705001-705530
706xxxxx	06	**Siouxland Medical Education Foundation Sioux City**	706001-706530
707xxxxx	07	**Sioux Center Medical Clinic Sioux Center**	707001-707530
708xxxxx	08	**Rebelsky Family Practice LLC Grinnell**	708001-708530
709xxxxx	09	**Manchester Family Medical Assc., P.C. Manchester**	709001-709530
710xxxxx	10	**Union County Health Foundation Elk Point**	710001-710530
711xxxxx	11	**Ellsworth Family Medicine Iowa Falls**	711001-711530
712xxxxx	12	**Alegent Health Center Corning**	712001-712530

[BACK TO 3.1.3 DEVELOP A DATA DICTIONARY AND CODEBOOK]

Record Retention (3.1.3.5)

Multiple guidelines to consider

- NIH Sponsored Research: "Financial records, supporting documents, statistical records, and all other records pertinent to an award shall be retained for a period of three years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report." (45CFR74.53.b)
- FDA regulated drug research (all sites in the US): "An investigator shall retain records … for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified." (21CFR312.62.c)

- Protected Health Information (PHI) Included in Research Data: "A covered entity must retain…for six years from the date of its creation…" (45CFR164.530 (j)(2))

[BACK TO 3.1.3 DEVELOP A DATA DICTIONARY AND CODEBOOK]

3.2   DATA STORAGE AND SECURITY

Determine Participant Identifiers (3.2.1.1)

Sequential identifiers could include sequential numbers of alphanumeric strings.

Random identifiers are generated by a random number algorithm.

- Non-Complete Blinding - generate sequence by assigning the initials of the clinician or practice, followed by a sequential number, left-padded by zeros to the maximum number of digits based on the cluster sample size (e.g. AB001, AB002, etc.)
- Complete Blinding - replace clinician/practice identifier with an undiscoverable alphanumeric code that becomes part of the primary key.

Fully electronic data capture into a relational database- use the automatically generated primary key (e.g. a bigint number) as participant ID or the root of the ID. Ensure that sequences follow relational database design best practices and map IDs automatically to other data tables as foreign keys.

[BACK TO 3.2.1 DEVELOP A DATA FILE-NAMING PROTOCOL]

Data Sharing Agreement (3.2.3.1)

Expectations for handling study data should be made explicit. Agreements may be legally or non-legally binding depending on organizational requirements. Formal legal agreements may be created including data use agreements or business associate agreements when sharing data that contains any protected health information (PHI). Creation of non-binding agreements, such as a data sharing agreement or a modified memorandum of understanding, can establish expectations for handling study data. Samples of data sharing agreements are available online and can be modified for each PBRN. These agreements can define the terms, conditions and obligations related to sharing of data between parties.

Requests for data sharing will be reviewed and approved by the principal investigator, and the PBRN Director will provide approval in the PI's absence.

Sample Criteria for Data Access Agreements (3.2.3.2)

- Include study information, such as study name, dates, names of parties entering into agreement
- Define what level of identifiable information is contained within the dataset, define how data will be handled to ensure confidentiality, where data must be stored (secure server, media), and outline process for encryption, if necessary.
- Record Institutional Review Board, federal, or other protections related to confidentiality and disclosure of information; handling of identifiable data.
- Sharing of data dictionaries and variable definitions, specification of analysis plan and variables under review, requirement for approval from PI or others while interpreting study results.
- Include authorship, acknowledgment of study support, review by PI and other parties.

Furthermore, an entity may request access to data collected within a PBRN for dissemination purposes. In addition to the fields described above, the following are considerations to explore when a PBRN study has received a request to access study data.

- "Request for use of data"
    1. Proposed use of data and audience
    2. Detailed description of data being used
        o Request to see a data analysis plan or protocol
    3. How will data be used
    4. Whether data can be shared with others

"Project-Specific" Data Sharing form (3.2.3.3)

REQUEST FOR DATA FORM

NAME:	DATE:
ADDRESS:	PHONE:
CITY/STATE:	EMAIL:
INSTITUTION/ORGANIZATION:	ROLE/TITLE:
DEGREE PROGRAM: MD/MPH MPH MD OTHER (Underline one, if applicable)	

A. Title of Proposal:

B. Please describe the focus area of your research and the target population.

C. Please describe the proposal or attach an abstract that explains the purpose of the proposed research/scholarly project and the data that you would like to use. This needs to be written in a language understandable to someone not familiar with the specific academic discipline.

D. Please identify the publication/conference to which you intend to submit your proposal. Include relevant deadlines. Please notify us of acceptance/rejection of your proposal.

E. Please state how this proposed research/scholarly project would follow the Bridges to Equity program principles and dissemination guidelines; particularly: Please state how this research will benefit the community.

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F. Please state how you will work with members of the Bridges to Equity Core Team in this process.

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G. Please describe how and when the results of this research/scholarly project will be reported back to the Bridges to Equity Core Team in a way that is meaningful and useful. There is an expectation that you will report back within 6 months following the completion of the project. The Core Team holds monthly meetings. Advisory Board Meetings are held quarterly. Presentations can include reporting your findings to a B2E Community Partner, another organization, or local community group with invitations extended to the Core and Advisory groups.

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H. If there is a deadline for approval of this research, state it here:

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I. Does this research require IRB approval? If so, please state the date of submission to the IRB committee:

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All documents developed for dissemination must include the following statement in the Acknowledgements section: "*This project* (*Grant number: T85HP24473) was funded by The Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services.*"

Your signature on this document indicates your agreement and understanding that the data will only be used for the stated purposes and will be destroyed upon completion of the project.

_____   _____   _____

Name (Printed)   Signature   Date

Please return this completed form to: xxx. If there are any questions please feel free to contact yyy.

[BACK TO 3.2.3 DATA USE AGREEMENTS]

Qualitative Data Collection (3.3.1.1)

- Identify specific project components and required areas of expertise.
- Ensure appropriate and diverse qualitative research design experts are part of diverse and multi-disciplinary team.
- Select the qualitative research approach (e.g., grounded theory, different ethnographic approaches).
- Establish research design and sampling strategy.
- Develop rigorous data collection methods, data collection and analysis protocol.
- Train team members who will be collecting or analyzing data.
- Standardize qualitative entries.
- Pilot test the data collection processes/guides.
- Develop standard procedures for group moderation, including:
  - Ground rules
  - Dual moderation, such as facilitator and observer, with note taking
  - Dual audio recording
  - Immediate post-group reflections and note-taking review by moderators
  - Consider audio recording the immediate post-group reflections (debriefings) so that important summary points will not be missed
  - Verbatim transcriptions of the audiotapes
  - Review and coding of data by two or more skilled qualitative analysts
- Resolve thematic coding differences by meetings of the analysts.
- Review of preliminary findings by entire investigative team and by representatives of the participant groups/communities involved.
- Complete member checking through anonymous review of preliminary findings by participants.
  - Member checking is a standard step of several qualitative research methods. It ensures that the researchers understanding of the participants response is indeed what the participants wanted to convey; this is done by showing respondents their collected data and the researcher's conclusions.
- Use multiple and varied sources of data to support validity of findings.
- Follow-up and monitor to ensure appropriate levels of compliance among members of the data collection team.
- Complete concurrent data collection and analysis to engage in iterative processes of revising data collection instruments based both preliminary and advanced research findings.

CHAPTER 4: DISSEMINATION POLICIES

Dissemination of findings or outcomes from PBRN work is important to: 1) influence policy, 2) build and sustain relationships, 3) inform local/regional practice settings about emerging trends, 4) acknowledge stakeholder roles/support, 5) increase PBRN visibility and relevance, and 6) improve science and knowledge transfer. Peer-reviewed manuscripts are one of numerous approaches to dissemination.   This chapter takes a broad perspective to the challenge of effectively communicating specific messages to a range of PBRN audiences.

4.1   PRIORITIES AND ALIGNMENT

Dissemination products that align with the PBRN mission are important to advance the PBRN mission and reputation. Priorities should align with overall mission, purpose, aims, and stakeholder's interests.

4.1.1 Activate a Dissemination Process (4.1.1)

The dissemination process should advance the PBRN mission.

- Engage PBRN advisory committee representative during study execution and data analysis to interpret results.

- Provide authors the PBRN mission statement to orient manuscript to the mission while writing.

- Insert step in dissemination product review process where advisory committee representative **and** a member of the PBRN leadership review to ensure alignment with mission.

- PBRN clinician and staff who participated in the PBRN study are often the best ones to present the study results at meetings, increasing the validity of the PBRN with outside audiences

- Consider using the PBRN name in the title of the manuscript and other dissemination products

Example: Dissemination Process (4.1.1)

4.1.2 Create a Forum to Discuss Dissemination Assignments

4.1.3 Create or Review the **Publication/Dissemination Policy (4.1.3)**

- Engage the PBRN and collaborators in reviewing PBRN mission and purposes for publication/dissemination
- Establish definitions of key terms used in the publication/dissemination policy
- Outline responsibilities and appropriate use of data
- Describe common language, wording, keywords, and attributions for consistency and visibility of your PBRN
- Provide acknowledgment guidelines especially to recognize contributions of participating member practices
- Establish a process for resolving conflicts
- Refer to authorship guidelines for specific authorship requirements

4.2   DISSEMINATION TEAM

4.2.1 Identify the Dissemination Team
- Team composition: team members should include the investigative team, those who need to know about the findings, a dissemination concept expert, and one or more disseminators. For peer-reviewed manuscripts, potential team members include: Principal Investigator (PI), co-investigators, study coordinator/team members, clinicians, patients, caregivers (if applicable) and community members

- Purpose: the dissemination team should meet early to review the overall dissemination conceptual model and plan as originally outlined.

4.2.2 Convene Smaller Sub-Teams to Plan Audience Specific Message Planning

4.3   DISSEMINATION PLAN/PROCESS

Project or study-level planning should ensure that the plan aligns with the aims, expected results, target audiences, timeline, and capacity.

4.3.1 Determine Number and Type of Dissemination Products
Dissemination products (4.3.1.1) include such things as publications, presentations, or technical reports, or briefing papers. For each, there is a need to consider the following:
- Outcomes to report

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- How data will be displayed
- Leads or authors (including graphic and technical) needed for specific sections
- The audience and appropriate outlet or format
- Specific formatting guidelines
- Use of professional and public communication networks

Inclusion of community (clinician; community organizations, etc) review and input and encourage community partner authorship

Materials placed on public websites may require modification to make them compliant with Section 508 Amendment to the Rehabilitation Act of 1973 (e.g. no animation, alternate text describing findings in figures or graphs)

4.3.2 Develop Timeline for Delivering Each Product

1) Lead or first author develops timeline

- Include milestones and meeting schedules in timeline

- The timing of the strategy may depend on copyright issues (for example, a journal may stipulate that the results have not been published or presented elsewhere prior to publication).

- Communicate expectations regarding contributions with the team

2) Team members accept assignments and create a review process for identifying problems and delays

- See Sample timeline with milestones (4.3.2.1)

- See Publication timeline example (4.3.2.2)

3) Monitor timelines to ensure accountability

4) Provide deadlines for each review/revision

5) Ensure collaborators adhere to timelines, agree to consequences for non-compliance to the timeline

6) Leads or first authors should approve changes to timeline

4.3.3 Specify Audience for Each Dissemination Product

In general, consider: Who stands to benefit? Who needs to know? Who would be interested? Who has to be informed in order to move forward? Consider tailored

products for funder, community, research, and public audiences. See Example of a Template for Dissemination Planning (4.3.3.1)

- The appropriate strategy will depend on the purpose and audience. The local, nonprofessional, and professional audiences may have preferred strategies for dissemination and the presentation of the results or key messages may need to be tailored for those audiences.
- Resources:
  - The Yale Center for Clinical Investigation CARE: Community Alliance for Research and Engagement reviews the preparation of a variety of dissemination products in the following online publication: *Beyond Scientific Publication: Strategies for Disseminating Research Findings*. Can be accessed at http://medicine.yale.edu/ycci/nethaven/memberresources/464_85777_CARE_Dissemination_Strategies_FINAL_eversion.pdf. Date Accessed: 09/29/2014)
  - CDC Social Media Tools website: http://www.cdc.gov/socialmedia/
  - CDC National 2011 Conference on Health Communication, Marketing, and Media (multiple videos): http://www.cdc.gov/nchcmm/2011/video.html

4.3.4 Map a Range of Topics or Messages Planned for Dissemination

- The "message" will differ according to audience and product.

- Topics can address methods/process, main results, secondary analyses, clinical practice reports, etc.

4.3.5 Consider Resources for Monitoring Dissemination Outcomes

- AHRQ website for Tools and Resources: Dissemination Planning Tool: Exhibit A: Volume 4. Programs, Tools, and Products. December 2006. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/advances-in-patient-safety/vol4/planningtool.html (Date Accessed 9/26/2014)

- For CBPR studies, guidance for community dissemination can be obtained from the Community-Campus Partnerships for Health website. *Developing and Sustaining Community-Based Participatory Research Partnerships: A skill-building Curriculum. Unit 6. Disseminating the Results of CBPR*, can be accessed at the following website: http://depts.washington.edu/ccph/cbpr/u6/u61.php (Date Accessed 9/26/2014)

- The UNC Translational & Clinical Sciences Institute, *Dissemination & Implementation Portal,* offers information, sample grants, methods, measures, theories, and publication sources. http://tracs.unc.edu/index.php/d-iportal/d-i-portal (Date Accessed 9/26/14)

4.4   PUBLICATION STANDARDS AND AUTHORSHIP GUIDELINES

4.4.1 Align with Communication Guidelines or Standards

The following are links to communication standards and guidelines

- AHRQ Publishing & Communication Guidelines
  http://www.ahrq.gov/research/publications/pubcomguide/index.html
- CDC Gateway to Health communication & Social Marketing Practice
  http://www.cdc.gov/healthcommunication/
- HHS Policies & Standards: Websites:
  http://www.hhs.gov/web/policies/index.html
- HHS Testing Documents for Section 508 Compliance:
  http://www.hhs.gov/web/508/training/testdocuments.html
- International Committee of Medical Journal Editors, Defining the Role of Authors and Contributors: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html/

4.4.2   Consider Authorship Guidelines for Publications

1) Set criteria, order and responsibility of all authors

2) Determine range and priority of manuscripts to be developed from the research study.

3) Define Authorship for the publication:

   a. The list of authors should reflect their actual involvement in planning, conducting or evaluating the study.

   b. Identify the lead author based upon the following considerations:

      - Specific interest/expertise of the team member

- Person who did most work on topic or area of the research study (ex. Qualitative researcher heads up descriptive, ethnographic pieces whereas biostatistician might choose to do a paper on the quantitative analysis.)

- The lead author (4.4.2.1) assumes responsibility for the integrity of the work as a whole.

c. Each author should contribute significantly to the conception, design, execution, and/or analysis and interpretation of data.

- The last author is often a senior faculty, mentor or the PI, but other arrangements are also possible upon agreement.

- All co-authors of a publication are responsible for authorship, approval, and the integrity of the scientific presentation.

- The order of authors is a collective decision of the authors or study group.

- A process for replacing or changing the order of authors may be necessary

d. Engage community partners as authors

- Establish personal relationships between academic center and champion community clinicians via academic professionals who are respected in the community (establish community–academia linkage).

- Promote interest in scholarly activity in community clinicians by aligning the benefits of publishing with locally relevant studies that can improve community practices (establish clinician buy-in).

- Instruct interested community clinicians in research methods that are relevant to primary care and assist them in writing publications without interfering with patient care (didactic mini-courses).

- Promote the work and accomplishments of community clinicians within and beyond the PBRN to set an example for clinical and academic excellence (dissemination). Example: Strategy to Develop Pipeline of Clinician Researcher/Authors (4.4.2.2)

- Ascertain if a PBRN member would like to participate in the writing of a manuscript. Community partner involvement may involve:

- o Discussion of concepts or interpretation of findings

- o Review and comment of at least one draft

- o Review and approve final version

    e. Advocate for change in a journal's "Authorship Guidelines" if guidelines interfere with inclusion of clinicians/staff or other community partners as authors.

4) Individuals who may have made some contribution to a publication, but who do not meet the criteria for authorship, such as staff, editorial assistants, medical writers, or other individuals, should be listed in an acknowledgement section of the work (and obtain permission to acknowledge when possible).

5) Participate in drafting, reviewing, and/or revising the manuscript for intellectual content.

6) Approve the manuscript to be published.

See [Authorship Attribution Table (4.4.2.3)](#)

4.5   PROCESS MANAGEMENT

1) The PI and project manager should create a process for managing the timeline and deliverables for all dissemination products, which include monitoring the individual product timelines & deadlines, and keeping abreast of changes to authorship or the timeline.

2) A master listing of all completed/published dissemination products should be kept for the project final report and posting on the PBRN website and/or newsletters.

3) Authors and contributors should be sent a congratulatory letter or e-mail of appreciation with information on how to reference the dissemination project on their CV or resume.

Info Links for Chapter 4 start on next page.

4.1   PRIORITIES AND ALIGNMENT

Dissemination Process Example (4.1.1)

PBRN leadership to vet projects based on set of guidelines that includes PBRN mission.

Vetted projects reviewed by advisory committee (e.g. Steering Committee, Clinician Advisory Board, Community Advisory Board or other made up of targeted membership, such as family medicine, pediatric or internal medicine clinicians) and must be approved by at least a majority.

If there is significant interest and participation by a PBRN clinician who participated in the study, he/she should be considered for inclusion as an author.

[BACK TO 4.1.1 ACTIVATION A DISSEMINATION PROCESS]

Publication Policies: CaReNet PBRN (4.1.3)

 Publication Policy 2001

We expect that CaReNet studies will produce results that we want to publish or present at meetings. This document describes CaReNet's official publication policy, which applied to all publication and presentation of results related to CaReNet studies or data. This policy is organized into the following sections.

Definitions

How Do CaReNet Investigators Prepare a Manuscript for Publication?

How Do CaReNet Investigators Prepare a Presentation?

Dispute Resolution

Definitions

CaReNet members expect to conduct many studies, and we want to make preparing publications as efficient and conflict-free as possible. With this in mind, we begin by specifying several definitions.

Principal Investigator: The principal investigator is the person responsible for the conception and design of the study and the analysis and interpretation of the data. The principal investigator is identified early in the study design process.

CaReNet Board of Directors: The Board of Directors oversees CaReNet, sets the research agenda, and establishes operational procedures. The Board is comprised of representatives from member institutions or practices and a representative from the Department of Family Medicine. See the CaReNet bylaws for details.

CaReNet Board Executive Committee: The Board appoints a three person executive committee from its membership to represent the Board between meetings. The Executive Committee is a source of advice and guidance for the Director.

CaReNet Director: The CaReNet Board of Directors appoints a Director who is not a member of the Board, but who is fully authorized to represent and commit the Network internally and externally. All research is under the jurisdiction of the Director.

CaReNet Director of Research: This person is responsible for overseeing the validity of the research methods used for CaReNet studies. This person is also responsible for reviewing the validity of data analysis and communication (either written or presented) for all CaReNet publications and presentations.

Primary Publication: A primary publication is one that details the design, methods, or primary results of a CaReNet study.

Secondary Publication: A secondary publication is one that details a secondary aim of a CaReNet study or a question developed and pursued by an investigator using CaReNet resources; for example, data from a CaReNet study. The principal investigator, or Director in the event the principal investigator is no longer involved with CaReNet, must agree to the preparation of manuscripts that do not directly relate to the stated purposes or hypotheses of a study.

Presentation: A presentation is any abstract, poster, or presentation that describes either a CaReNet study or describes a study that uses CaReNet resources or is presented to an audience that is outside the investigator's institution; for example, a national meeting.

How Do CaReNet Investigators Prepare a Manuscript for Publication?

The results of all CaReNet studies should be reported in a timely fashion through a publication in a peer reviewed scientific journal. Ideally, such publication will occur within one year of the completion of the study.

The manuscript should be well written, following the style required by the journal to which the author wishes to submit. The *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals* (formerly named the *Uniform Requirements*) is a good guide for preparing a manuscript. It is brief, thorough, and readily available online at icmje.org (accessed 9/26/2014). Another guide that is helpful, but considerably more comprehensive, is the *American Medical Association Manual of Style*, available in most libraries.

Manuscript Preparation for Primary Publications

The principal investigator is responsible for ensuring that the results of a CaReNet study are reported in the appropriate scientific journal. The steps involved in getting a manuscript published include:

- analyzing data generated from the CaReNet study;
- writing a manuscript that presents the results;
- obtaining the CaReNet Director's approval of the manuscript;
- submitting the manuscript to the journal;
- making the required editorial changes to the manuscript (if such changes are significant
- submitting the final manuscript to the journal.

The principal investigator may delegate any of these tasks to others; however, the principal investigator is ultimately responsible for publishing the results.

Once the principal investigator has completed the above sequence, she or he will allow release the data gathered in the CaReNet study for others to use with appropriate approval from the CaReNet Director of Research and relevant Institutional Review Boards. In general, de-identified, raw data will be released to qualified investigators for secondary analysis. With approval of the Director, secondary analysis may be carried out by CaReNet personnel for outside investigators.

What is the Title of Primary Publications?

A primary publication's title must include the suffix: "A Report from CaReNet". Any deviations from this policy must be approved by the Director. In the case of joint projects where CaReNet is

not the primary data collection site, the Director will negotiate and approve of how "CaReNet" will appear in titles of potential publications before the study begins.

Who is the Author of Primary Publications?

We follow the authorship guidelines defined in the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals:*

All persons designated as authors should qualify for authorship, and all those who qualify should be listed. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. One or more authors should take responsibility for the integrity of the work as a whole, from inception to published article.

Authorship credit should be based only on:

1) Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
2) Drafting the article or revising it critically for important intellectual content; and
3) Final approval of the version to be published.

Conditions 1, 2, and 3 must all be met. Acquisition of funding, the collection of data, or general supervision of the research group, by themselves, do not justify authorship.

Authors should provide a description of what each contributed, and editors should publish that information. All others who contributed to the work who are not authors should be named in the Acknowledgments, and what they did should be described.

Increasingly, authorship of multi-center trials is attributed to a group. All members of the group who are named as authors should fully meet the above criteria for authorship. Group members who do not meet these criteria should be listed, with their permission, in the Acknowledgments or in an appendix

The order of authorship on the byline should be a joint decision of the co-authors. Authors should be prepared to explain the order in which authors are listed.

Primary publications should acknowledge the contribution of CaReNet members to the study. This contribution should be acknowledged by listing the names of CaReNet practices in the Acknowledgement section. Again, we follow the *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals* (formerly named the *Uniform Requirements*); available at: icmje.org (accessed 9/26/2014)

- List all contributors who do not meet the criteria for authorship, such as a person who provided purely technical help, writing assistance, or a department chair who provided only general support. Financial and material support should also be acknowledged.
- Groups of persons who have contributed materially to the paper but whose contributions do not justify authorship may be listed under a heading such as "clinical investigators" or "participating investigators," and their function or contribution should be described – for example, "served as scientific advisers," "critically reviewed the study proposal," "collected data," or "provided and cared for study patients."
- Because readers may infer their endorsement of the data and conclusions, all persons must have given written permission to be acknowledged.

Manuscript Preparation for Secondary Publications

Once the principal investigator releases CaReNet data for others to use, other CaReNet investigators or outside individuals may prepare secondary publications. All secondary data analysis is the responsibility of the secondary publication author. He or she may contact the CaReNet Director to request assistance. The CaReNet Director or the CaReNet Director of Research will determine what assistance CaReNet staff may provide.

The sequence of the manuscript publication described above in the "Manuscript Preparation for Primary Publications" section also applies to secondary publications. The only additional step is for the author to obtain the principal investigator's approval of the manuscript before submitting it to a journal.

What are Appropriate Keywords for a CaReNet Publication?

Most journals ask authors to submit keywords that relate to the content of the article. Authors should include keywords that describe the topic of the study. All articles related to CaReNet studies or data must list "**PBRN**" as a keyword.

The following **bolded** MeSH keywords may also be useful for describing CaReNet studies, depending on the content of the article and focus of the research:

PBRN (required for all articles)

Insurance Coverage

Medically Underserved

Physician's Practice Patterns (diagnosis and treatment as influenced by cost of service requested and provided)

Professional Practice (The use of one's knowledge in a particular profession. It includes professional activities related to health care and the actual performance of the duties related to the provision of health care. *The emphasis is on individual physicians and their practices*.)

Cultural Diversity (Coexistence of numerous distinct ethnic, racial, religious, or cultural groups within one social unit, organization, or population)

Primary Health Care

How Do CaReNet Investigators Prepare Presentations?

Like publications, presentations should be prepared in a professional style according to the guidelines required by the meeting. Presentations also require review by the principal investigator (if she or he is not the presenter) and the CaReNet Director. The presenter is responsible for analyzing the data, ensuring that all data are correct and correctly interpreted, and ensuring that the data support all conclusions.

Dispute Resolution

Any disputes that arise as a result of this policy will initially be directed to the CaReNet Director or the CaReNet Director of Research. If either or both of these individuals are party to the dispute, then that individual will not arbitrate the dispute. If both of these individuals are involved in the dispute or if they are unable to arbitrate the dispute successfully, the issue will be referred to the Executive Committee who will have final authority.

{*End of CareNet policy*}

[BACK TO 4.1.3 CREATE OR REVIEW THE PUBLICATION/DISSEMINATION POLICY]

4.3   DISSEMINATION PLAN/PROCESS

Dissemination products/methods (4.3.1.1)

Overview of Dissemination Methods

Method	Purpose	Hints and Tips
Newsletter awareness	Inform	Project or institution newsletter can be used to announce the project, give regular updates, develop a profile, and get buy-in. Be creative. For example, include an interview with your project 'champion',

		some quotes from end users, or praise from an external evaluator. Make sure they know the project is a success.
Project website	Awareness Inform Engage Promote	A project website is one of the most versatile dissemination tools. It can contain information for different audiences. Add to it regularly so people keep coming back. Sell the project and engage the community.
Press releases	Awareness	A press release is a formal announcement to the national press. Projects can issue one to announce important achievements. It takes skill to write a press release and get it to the right media.
Flyers/brochures	Awareness	Flyers in printed form can be handed out at conferences or to colleagues at your institution. An electronic version (e.g. PDF file) can also be circulated electronically. Glossy brochures are rarely worth the time and expense.
Program meetings	Engage	Program meetings are excellent opportunities for projects to learn from each other, discuss common issues, and get feedback on their work.
Conference presentations	Engage Promote	National and international conferences are an important opportunity to share your achievements with experts in the field. Make sure you have something to say, select conferences where it will have an impact, and ones that will attract the experts you want to impress.
Conference posters	Engage Promote	A poster session at a conference may be more appropriate when you have work in progress. You write up your work in poster format, and present it to delegates who attend the session. It may not be as glamorous as doing a presentation in the auditorium, but it is an excellent way to engage people, gauge their reactions, and get one-to-one feedback.
Workshops engage		Workshops are small interactive events held to achieve a specific objective. A workshop can be used to get feedback from users on a demo or from experts on particular issues. Make sure to make it a *work* shop:

		the emphasis should be on discussion, not presentations.
Demonstrations engage		Demonstrations are useful early in the project to get feedback from stakeholders on functionality, usability, and look-and-feel. Consider a demo for stakeholders at your institution to keep them informed about what you're doing and to help with buy-in.
Online discussion lists	Awareness Inform Engage	E-mail lists are useful for discussing new developments, problems, and issues. They are an opportunity to be proactive and reactive, share your learning with the community, and develop a profile for your project.
Journal articles	Inform	Any and every opportunity should be taken to get articles published about the project. Consider peer reviewed journals in relevant disciplines near the end of the project when you have data and results to report. Make sure to post a copy of all publications on your website.
Case studies	Inform	Case studies explain what you did and what you learned so others can benefit from your experience.
Reports and other documents	Inform	Reports on specific topics can be posted on your website so they are accessible to a wide audience. Think of anything your project has developed that may be useful to others, e.g. guidelines, methods, evaluation criteria, toolkits, or questionnaires.

The above chart of dissemination methods is available as a pdf on the "EU Executive Agency for Health and Consumers" website: http://ec.europa.eu/eahc/management/Fact_sheet_2010_06.html

[BACK TO 4.3.1 DETERMINE NUMBER AND TYPE OF DISSEMINATION PRODUCTS]

Timeline sample with milestones (4.3.2.1)

- Time 0 – Author team meeting, consensus on data analysis
- Six weeks – Author team meeting, consensus on results
- Four weeks – First draft of manuscript circulated to secondary authors
- Two weeks – Revisions received from secondary authors
- Two weeks – Second draft of manuscript circulated to secondary authors
- Two weeks – Revisions received from secondary authors
- One week – First draft of abstract circulated to secondary authors
- One week - Revisions to abstract returned
- Two - four weeks (depending on outside agencies involved) - Final approval of manuscript and abstract (ex. Boards, funding agencies, internal network and external key stakeholders)

Publication timeline example (4.3.2.2)

Activity*	T	M1	M2	M3	M4	M5	M6
Weeks		1234	1234	1234	1234	1234	1234
Author team meeting, consensus on data analysis - time 0	**0**						
Author team meeting, consensus on results		XX XX	XX				
First draft of manuscript circulated to secondary authors			XX	XX			
Revisions received from secondary authors				XX			
Second draft of manuscript circulated to secondary authors					XX		
Revisions received from secondary authors					XX		
First draft of abstract circulated to secondary authors						X	
Revisions to abstract returned						X	
Final approval of manuscript and abstract (ex. Boards, funding agencies, internal network and external key stakeholders)						XX	XX
Submit to journal							X

Dissemination Plan Template (4.3.3.1)

TEMPLATE FOR DISSEMINATION PLANNING

Dissemination	1. Why	2. To whom	3. What	4. When	5. How	6. Who	7. Time resource	8. Cost	9. Evaluation

The planning chart above is available as a pdf on the "EU Executive Agency for Health and Consumers" website: http://ec.europa.eu/eahc/management/Fact_sheet_2010_06.html

[BACK TO 4.3.3 SPECIFY AUDIENCE FOR EACH DISSEMINATION PRODUCT]

4.4 PUBLICATION STANDARDS AND AUTHORSHIP GUIDELINES

Lead Author (4.4.2.1)

The lead author is usually the person who contributed significantly to a key component of the study, e.g. aims, recruitment, data collection, and/or analysis or has a priority for scholarly achievement by mutual agreement (assuming significant involvement). Students are often lead authors as part of their fellowship or graduate work.

Consideration for lead authorship should be given to any team member who was a strong study contributor. The lead author (most frequently the first author) is responsible for producing an outline or draft of the manuscript. This draft is then circulated to all authors for substantive input in multiple cycles of editing until all authors are satisfied with the manuscript. The level of input usually corresponds to the level of involvement in the study or the specific area of the study that is the particular author's expertise; however, considerations based on time constraints or scheduling issues of team members may be given.

[BACK TO 4.4.2 CONSIDER AUTHORSHIP GUIDELINES FOR PUBLICATIONS]

Strategy to Develop Pipeline of Clinician Researcher/Authors (4.4.2.2)

Using a bottom-up, participatory research approach, the OKPRN academic leadership elicited ideas for relevant research studies from the OKPRN membership on a regular basis. Beyond setting the agenda, members were also involved in setting priorities for projects. This created a certain level of buy-in and a sense of "ownership" of projects.

Dr. Mold, with the help of other research faculty at the academic center organized a set of mini-courses for interested clinicians at a convenient location that covered fundamentals of primary care research (research questions and hypotheses, study design, data collection, and data analyses) critical appraisal of literature, and techniques of writing publications. OKPRN clinicians then used these approaches to conduct a specific study in their practices with the help of PEAs. Academic researchers worked closely with community clinicians to analyze and publish their findings.

Finally, published papers were circulated in OKPRN and nationally and authors received acknowledgement for their participation among their peers.

[BACK TO 4.4.2 CONSIDER AUTHORSHIP GUIDELINES FOR PUBLICATIONS]

Authorship Attribution Table (4.4.2.3)

Project:
Title of Paper/Presentation:
Project:

Authors	CONDITION FOR AUTHORSHIP₁					OTHER CONTRIBUTIONS WORTHY OF ACKNOWLEDGEMENT	FOR OFFICE USE ONLY	
	Condition 1 (only 1 of 3 necessary to meet condition) **Substantial contribution required			Condition 2	Condition 3	Please Elaborate (i.e., Collected data, scientific advisor, etc.)	Offer of authorship/ acknowledgem ent made to team members Sign-off (authorship/ acknowledgem ent accepted)	
	Conception and Design	Acquisition of Data	Analysis and Interpretati on of Data	Drafting the Article/Critical Revision for Important Intellectual Content	Final Approval of the Version to be Published			