Guidance for Researchers Developing and Conducting Clinical Trials in Practice-based Research Networks (PBRNs)

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Background: **There is increased interest nationally in multicenter clinical trials to answer questions about clinical effectiveness, comparative effectiveness, and safety in real-world community settings. Primary care practice-based research networks (PBRNs), comprising community- and/or academically affiliated practices committed to improving medical care for a range of health problems, offer ideal settings for these trials, especially pragmatic clinical trials. However, many researchers are not familiar with working with PBRNs.**

Methods: **Experts in practice-based research identified solutions to challenges that researchers and PBRN personnel experience when collaborating on clinical trials in PBRNs. These were organized as frequently asked questions in a draft document presented at a 2013 Agency for Health care Research and Quality PBRN conference workshop, revised based on participant feedback, then shared with additional experts from the DARTNet Institute, Clinical Translational Science Award PBRN, and North American Primary Care Research Group PBRN workgroups for further input and modification.**

Results: **The "Toolkit for Developing and Conducting Multi-site Clinical Trials in Practice-Based Research Networks" offers guidance in the areas of recruiting and engaging practices, budgeting, project management, and communication, as well as templates and examples of tools important in developing and conducting clinical trials.**

Conclusion: **Ensuring the successful development and conduct of clinical trials in PBRNs requires a highly collaborative approach between academic research and PBRN teams. (J Am Board Fam Med 2014; 27:750–758.)**

Keywords: **Clinical Trials as Topic, Practice-based Research**

There is increased interest nationally in multicenter clinical trials, especially pragmatic clinical trials (PCTs), to answer questions about clinical effectiveness, comparative effectiveness, and safety in real-world community settings. PCTs measure the effectiveness that a community-, clinical-, or system-level intervention produces in routine clinical settings.[1] Primary care practice-based research networks (PBRNs) are an ideal setting for these PCTs.

PBRNs are composed of community- and/or academically affiliated practices that are committed to improving medical care for a range of health problems by conducting primary care research, engaging understudied populations, and accelerating

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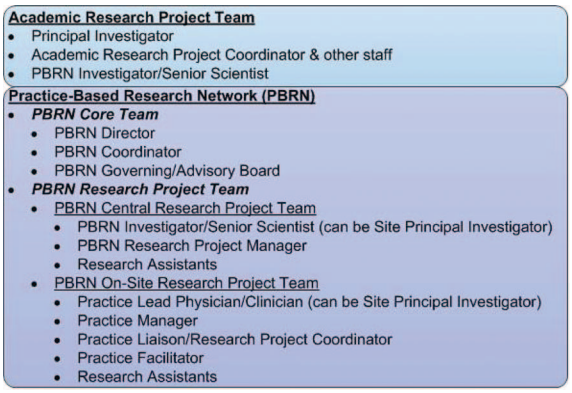
Figure 1. Academic and practice-based research network (PBRN) teams and personnel.



the adoption of new knowledge and best practices. More than 100 PBRNs are registered with the Agency for Health care Research and Quality.[2] A number of PBRNs have conducted PCTs in community-based primary care practices to evaluate treatment effectiveness and behavioral interventions for chronic conditions.[3–5]However, many investigators have not had experience working with PBRNs.

Through extensive involvement with clinical trials, PBRN leaders have found that the projects are most successful when the PBRN team (Figure 1) is engaged to assist with trial design, procedures, and budgeting (during the proposal submission phase); practice recruitment, participant recruitment, and communications (during the enrollment phase); management of the trial (during the trial conduct phase); and interpretation and dissemination of trial results, manuscripts, and presentations (during the close-out and dissemination phase). We created a toolkit consisting of a set of frequently asked questions (FAQs), templates, and examples of tools to guide researchers who are interested in conducting a clinical trial in a PBRN setting. In addition, these FAQs will assist PBRN directors and their teams in communicating with researchers about the project-specific needs of their PBRN.

Methods

Experts in practice-based research who are members of 2 workgroups—the DARTNet Institute (DI) Research Steering Committee and the Clinical Translational Science Award (CTSA) Community Engagement PBRN workgroup—identified the need to better communicate solutions to the challenges that researchers and PBRN personnel experience when collaborating while developing and conducting clinical trials in PBRNs. Five topic areas for development were originally proposed by these workgroups: (1) practice recruitment and engagement, (2) budgeting, (3) project management, (4) engaging and maintaining study teams, and (5) communication.

Each section was written in an FAQ format with advice relevant to different phases of a clinical trial: trial development, conduct, close out, and dissemination. A draft of the 5 sets of FAQs was presented at the 2013 North American Primary Care Research Group PBRN conference in Bethesda, Maryland, in a workshop format with small-group breakouts to discuss and refine each section. Based on feedback from the workshop participants, 2 sections (project management and engaging and maintaining study teams) were merged into 1 section entitled project management, and the resulting 4 FAQ documents were revised based on participant feedback. A revised draft of the FAQs and an introduction to these documents were sent to the DI Research Steering Committee, the CTSA Community Engagement PBRN, and North American Primary Care Research Group Committee for the Advancement of Science in Family Medicine PBRN workgroups for further input and modification.

The FAQ documents have been combined with templates and examples of tools important to clinical trial development and conduct, as well as with a glossary of terms (see Table 1 and Appendix 1) to create a web-based toolkit entitled "Toolkit for Developing and Conducting Multi-site Clinical Trials in Practice Based Research Networks." This toolkit is available on the DARTNet Institute website at www.dartnet.info/clinicaltrialsPBRNtoolkit.htm.

Results

Summaries of the key recommendations from the FAQs are presented in the following sections.

Recruiting and Engaging Practices

Including a PBRN core team member (eg, PBRN director, PBRN investigator, PBRN coordinator) on the clinical trial research team is critical to facilitate practice recruitment. PBRNs have established relationships and garnered the trust of the practices and know or can determine the research capacities and suitability of the practices specific to a clinical trial. A short, 1-page information sheet

Table 1. Glossary of Terms for Practice-based Research Network (PBRN) Research Project Teams

Title	Definition/Role/Responsibilities
Academic research project team	This is the team of investigators and staff at an academic institution who develop, procure funding for, and take responsibility for a research project. Academic leaders of this team may approach a PBRN to participate in a clinical trial or other research project. If a research project's principal investigator is a member of a PBRN core team, the PBRN core team may function as the academic research project team.
PI	The PI is the individual who is responsible for oversight and direction of the research project. This is often a faculty member at an academic institution or a physician who is in a leadership role at a PBRN. This individual is responsible for communicating research project updates, changes, or problems to research project team members and funders (as appropriate) and for communicating with research project consultants.
PBRN	A group of community- and/or academically affiliated practices that are committed to improving medical care for a range of health problems by conducting primary care research, engaging understudied populations, and accelerating the adoption of new knowledge and best practices. PBRNs may also be referred to as "networks" in the FAQs.
PBRN core team	The core team comprises staff and investigators who are part of a PBRN's core operations and administrative unit, often at a university but sometimes in an independent nonprofit entity. The core team almost always includes the PBRN director and the PBRN coordinator. The PBRN core team functions like a coordinating center for the PBRN practices participating in a multicenter clinical trial.
PBRN director	The PBRN director is usually a clinician or researcher who is responsible for PBRN operations and overall PBRN management and sets the direction for the PBRN mission, goals, oversight, opportunities, and collaborations. The director identifies research investigators to work with the PBRN, provides direction, and reports to a governing board and to any other entities to which the PBRN is responsible (eg, a university). The PBRN director frequently serves as a research project PI or co-PI. The director communicates regularly with the PBRN coordinator and other PBRN staff.
PBRN coordinator	The PBRN coordinator, sometimes known as the network coordinator, is a member of the PBRN core team and is responsible for managing the daily operations of the PBRN. This includes primary hiring, training, and oversight of staff and assignment of staff to research projects. This individual is responsible for communicating with other PBRN core team members about the status of research projects in the PBRN. The PBRN coordinator communicates regularly with the PBRN director. The PBRN coordinator often serves the role of PBRN research project manager.
PBRN governing/advisory board	The governing board of a PBRN usually comprises representatives from the PBRN core team and member practices. The governing board may also include community representatives.
PBRN research project team	The research team comprises all staff and investigators affiliated with the PBRN who are working on a particular research project. This team includes individuals from the PBRN central research project team and the PBRN on-site research project team.
PBRN central research project team	The central research project team comprises all staff and investigators from the PBRN's core operations and administrative unit who are working on a particular research project. This team includes individuals such as academic investigators and a PBRN coordinator.
PBRN investigator/senior scientist	The PBRN investigator is a member of the PBRN central research project team who can serve as a research project PI, co-PI, co-investigator, or, occasionally, the site PI. This individual is either a member of the PBRN core team or has experience working with the PBRN core team and the PBRN's practices. The PBRN investigator is a member of the academic research project team who represents and advocates for the PBRN and its practices throughout the research project.
Site PI	In a PBRN, this role in a multicenter clinical trial is generally held by the practice lead physician/clinician and sometimes by a PBRN investigator/senior scientist, depending on the organizational structure of the PBRN.
PBRN research project manager	The PBRN research project manager is a member of the PBRN core team and the PBRN central research project team who manages and organizes the PBRN-based activities of an individual research project. This may include the following types of activities, all specific to the research project: hiring, training, and supervising PBRN research project team staff; maintaining communications across the PBRN research project team; assigning tasks to research project staff; coordinating roles to complete the PBRN-based research project; ensuring adherence to research project procedures and timelines; and overseeing research project recruitment and follow-up activities. The PBRN research project manager serves as the PBRN central research project team contact for both participating practices and the academic research project team and/or PI. If the PBRN is the prime organization for a research project, then the PBRN research project manager may manage and organize the research project overall.

Table 1. Continued

Title	Definition/Role/Responsibilities
Research assistants	Research assistants can be members of the PBRN on-site research project team and/or the PBRN central research project team. They are responsible for conducting research project activities. Depending on their research project activities, they stay in close communication with and are supervised by the Practice liaison/research project coordinator and/or the PBRN research project manager.
PBRN on-site research project team	The on-site research project team includes staff organized by the PBRN who are conducting work at the practice site. These individuals are most commonly practice liaisons/research project coordinators, practice facilitators, and research assistants. They can be practice staff members who take on these roles or individuals outside the practice who are hired by the PBRN for this work.
Practice lead physician/clinician	These are physicians or clinicians practicing at PBRN sites who are responsible for communicating information regarding all phases of the research project with other practice providers and staff. They work closely with the PBRN central research project team (eg, PBRN research project manager) and on-site staff involved in the research (eg, practice liaison/research project coordinator, research assistants, practice facilitators). The practice lead physician/clinician serves as a leader for the research project at the practice. Some multicenter trials designate this person as the site PI.
Practice manager	This is the individual who manages clinical operations at a practice. This individual is often involved in communications with the PBRN central research project team and the PBRN on-site research project team (eg, practice liaison/research project coordinator, practice facilitator) to ensure the research project runs smoothly without adversely affecting the work of the practice.
Practice liaison/research project coordinator	This individual is a member of the PBRN practice on-site research project team who serves as the key practice contact for the PBRN central research project team and maintains timely and ongoing communication with individuals at the site. This individual organizes and conducts research project procedures at one or more practice sites. This person may be a member of the practice's nursing or administrative staff or hired by the PBRN for this work. This role can also be filled by a research assistant or a practice facilitator. Practice liaisons/research project coordinators are generally supervised by the PBRN research project manager. This person works closely with the practice lead physician/clinician and may champion the research project in the practice.
PF	Practice facilitators are members of the PBRN on-site research project team. The role of the PF in conducting practice-based research and the relationship that the PF maintains with the PBRN sites make PBRN studies unique. Within the PBRN, the PF can function as a research project coordinator, a research assistant, and as a practice enhancement resource to member practices. PFs also function in a manner similar to an agricultural extension agent, sharing ideas and successes across practice teams within the region served by the PF. Practice facilitators are generally supervised by the PBRN research project manager. Not all research project teams include practice facilitators.

PF, practice facilitator; PI, principal investigator.

that emphasizes the value of the trial to the practices and outlines the work required is ideal for recruiting purposes. There are a variety of different venues (eg, PBRN meetings, regular practice meetings) and communication tools (eg, newsletters, E-mails) that may be used to attract practices to participate in a trial. The PBRN team can help to determine the most effective venues and tools for a particular clinical trial and/or practice.

Strategies to keep practices engaged include minimizing the amount of work required by the practices, working with practices to implement the intervention(s) into their existing workflow, adequately compensating practices for their participation, providing additional training as needed throughout the trial, and frequently soliciting feedback from the practices. Keeping practices engaged can also be facilitated by identifying a practice lead physician/clinician who can provide leadership for the trial at the practice. Good communication is critical to keeping practices engaged and excited about a project. Table 2 summarizes the key points regarding recruiting and engaging practices.

Budgeting

As with other areas of a clinical trial, engagement of PBRN core team members as early as possible in the development of the budget is crucial. Ideally, a clearly designated scientific lead and administrative lead, including representation from the PBRN, should be involved in the budget process from the beginning. The PBRN core team will be able to advise on the overall structure of the budget as well as particular costs unique to a PBRN-based clinical

Table 2. Key Points Regarding Recruiting and Engaging Practices

- Including a PBRN core team member on the academic research project team to facilitate recruitment of practices to a trial is important.
- A simple 1-page information sheet about the trial is extremely helpful for the recruitment process and for informing participating practices about the trial details, how it will impact the practice, and what value it provides to the practice.
- Using different forums (eg, PBRN meetings, E-mail, newsletters) to advertise the trial is best.
- To improve chances of successful recruitment, target practices in which there is already an interest in the trial's topic and provide incentives (eg, continuing medical education, financial incentives, quality improvement).
- Considering practical factors such as size of practice, scope of practice, and resources available is necessary when determining appropriate practices to approach.
- Involving primary care practices in the design of the trial and engaging them in an ongoing advisory or participatory role will improve buy-in.
- For each trial, try to minimize the work required by the practice and design the intervention to cause as little disruption as possible to clinical care.
- Providing adequate funding to the practices and reducing their burden of regulatory requirements is crucial.
- For a successful trial, key practice clinicians and staff need adequate training at the start of and as needed throughout the trial.
- To maintain trusting relationships, keep PBRN personnel involved in all steps that involve the practices.
- Maintaining ongoing communication between the PBRN research project manager and a key contact at each participating practice is helpful.
- At the completion of the trial, make sure to recognize the accomplishments and contributions of the participating practices.
- Keep the trial fun and interesting.

PBRN, practice-based research network.

trial (eg, PBRN infrastructure costs, practice honoraria, dissemination of findings to practices). Because of the multiple collaborators, following a strict timeline for completion of a grant proposal's budget, including a draft budget completed at least 6 weeks before the grant proposal due date and a final budget at least 3 weeks before the due date, is important. Discussion of any changes to the budget by all research team leaders and clear communication of these changes to participating entities is critical. Table 3 summarizes the key points related to the budgeting process.

Project Management

Practice-based research is distinctive because PBRN and practice representatives (eg, PBRN investigators, practice lead physicians/clinicians) are essential members of the research project team. Their roles are critical in all stages of a clinical trial. Early engagement of these team members is essential for the appropriate design and implementation of the trial protocol.[6] With their knowledge of the capacity of the participating practices, the PBRN director and PBRN coordinator are able to offer critical feedback on the effort required by the

Table 3. Key Points Regarding Budgeting

- Although the budget process may vary among PBRNs, the most important aspect of budget development is to include the PBRN core team in the process to ensure that the budget is appropriate and realistic.
- Deciding who will hold the primary budget and who will serve as subcontractors may depend on whether the PBRN and/or the principal investigator are affiliated with an academic institution or a nonprofit organization.
- Ideal timing for a rough draft of the budget is no later than 6 weeks before a grant due date and a final budget, including subcontracts, no later than 3 weeks before the due date.
- Nonprofit PBRNs may provide budgeting advantages to a grant, such as lower indirect cost rates or efficient strategies for paying incentives and honoraria to patients and practices.
- It is important that a trial budget includes costs that are particular to working in a PBRN (eg, practice honoraria, PBRN infrastructure costs, site visits).
- Linking practice payments to milestones is a good way to structure a budget.
- When budget cuts or changes are required, it is important that both the academic research project team and the PBRN core team make these decisions together.
- It is critical that the academic research project team meets its obligations to both the PBRN and the practices participating in the trial to maintain willing practice partners for future trials.

PBRN, practice-based research network.

Table 4. Key Points Regarding Project Management

- PBRN and practice representatives are essential members of the research project team, and involving them in all aspects of a clinical trial is important.
- The PBRN central research project team members offer critical feedback and advice on how best to work with the member practices.
- PBRN research project personnel vary depending on the particular PBRN and the specific clinical trial.
- Responsibilities for PBRN research project personnel also differ for each trial, so clarifying who is responsible for which activities before the trial starts is important.
- For most studies, a PBRN research project manager works closely with the academic research project team during all phases of trial implementation.
- In some studies an on-site practice liaison/research project coordinator helps to facilitate implementation of the trial within a practice.
- For a trial to run smoothly, creating a manual of protocol procedures that clearly outlines all trial procedures and provides simple, clear presentations of the work and workflow in the practice setting is imperative. Storing this manual in a secure manner that is accessible to all research team members is critical (see Table 5).
- Developing a data-sharing agreement that addresses issues such as data ownership before the commencement of a trial is important. The data-sharing agreement should address how patient confidentiality will be maintained, including what information will be de-identified and how this will be accomplished.
- Each trial should also use a regulatory binder to manage important documents. This binder contains the most recent version of the protocol, informed consent document, IRB approval letters, training documents of study personnel, a site personnel delegation log, and other study correspondence.
- Ensuring quality requires detailed documentation of trial progress and maintenance of organized trial files.
- A clinical trial quality management plan can help to make sure that all issues that affect trial quality are being appropriately addressed. Regular review of this plan is important.
- Regular communication between the academic research project team, the PBRN on-site research project team, and the participating practices is key to keeping all team members engaged in the trial.
- Offering opportunities for training and professional development is another strategy for keeping PBRN on-site research project team members engaged.
- Understanding all the steps necessary for closing out a trial and clarifying who will be responsible for which steps is important.

IRB, institutional review board; PBRN, practice-based research network.

PBRN central research project team and the participating practices to implement the clinical trial. Given its established research relationships with the practices, the PBRN central research project team also plays a key role in the ongoing conduct of the clinical trial.

Because responsibilities differ for each clinical trial, determining before the start of the trial which tasks will be performed by the academic research project team, the PBRN central research project team, and the PBRN on-site research project team is imperative. For most studies, a PBRN research project manager will be assigned to coordinate clinical trial implementation with the academic research project team. The PBRN research project manager and PBRN central research project team may manage the trial directly or they may work closely with an on-site practice liaison/research project coordinator who manages on-site trial implementation.

Given the different personnel and organizations involved, a PBRN-based clinical trial will run more smoothly with a formal manual of protocol procedures that outlines all trial procedures and is accessible to all project personnel; the manual should include flow charts or summaries that address any workflow questions. This helps to ensure fidelity to the intervention and the collection of high-quality data. In addition the PBRN should maintain a regulatory binder, which contains the study protocol, consent form, institutional review board (IRB) approval/correspondence, regulatory documents (such as the US Food and Drug Administration Statement of Investigator 1572 form, drug accountability form, if applicable), curriculum vitae and training documents of the principal investigator and key personnel, and other site-related documents. Managing the quality of the trial also requires documenting trial progress in detail and maintaining organized trial files. Communication is key to keeping all members of the PBRN on-site research project team engaged. Finally, keeping the participating practices and patients informed by providing updates on trial results and publications through letters, E-mail, or newsletters is important. Table 4 summarizes the key points regarding project management.

Table 5. Key Points Regarding Communication

- Given the number of collaborators involved with most studies involving PBRNs, establishing clear lines of communication to ensure that a trial runs smoothly is important.
- Engaging the PBRN core team and/or PBRN central research project team in communications with the practices at all phases of the trial is crucial.
- All research project team members should promote good communication, but the PBRN coordinator often oversees this task with the help of the practice liaison/research project coordinator.
- Communication should be ongoing and updates should occur frequently.
- Effective communication should be multidirectional, recognizing and respecting the expertise that all collaborators bring to a trial.
- There are several different methods of communication (eg, in person, E-mail, phone conferences), and they should be tailored to the preferences of the collaborators.
- In-person meetings are ideal for the initial presentation of the trial, practice training, and periodic trial updates. Video or web-based conferences can be used in place of in-person meetings if there are distance and/or financial limitations.
- Websites associated with the trial or the PBRN provide good venues for trial information and for providing continual trial updates. Secure, password-protected web pages on these sites or proprietary software programs can provide centralized project document and communications storage and retrieval.
- E-mail, newsletters, and social media are useful methods for providing periodic trial updates, answering questions, or providing tips to participating providers/staff.
- Engaging PBRNs in publication and presentation opportunities when appropriate and acknowledging the contribution of the PBRN and the PBRN research project team members who are not authors in publications and presentations are important.

PBRN, practice-based research network.

Communication

Good communication ensures that the clinical trial runs smoothly and that patient care is enhanced and not compromised. Clinical trials conducted in collaboration with a PBRN often have a number of diverse collaborators. Given these many diverse collaborators, establishing clear lines of communication is especially important. To be effective, communication should be multidirectional, allowing all the collaborators the ability to share ideas, ask questions, or voice concerns. Good communication depends on the recognition that each collaborator brings particular skills and expertise that are important to the success of the trial. Good communication is designed to keep all collaborators updated on issues such as trial progress, issues or concerns that have arisen, and changes in the clinical trial protocol. Toward the end of the trial, ensuring that the participating practices receive trial results and have a chance to help interpret research findings is particularly important. These "observations from the field" help to explain research results and inform the discussion of the findings. Table 5 summarizes the key points regarding communication.

Discussion

PBRNs provide an ideal setting in which to conduct clinical trials, especially PCTs. However, many academic researchers have not worked with PBRNs and may not be aware of the many elements specific to designing and implementing an effective clinical trial with PBRN partners. We have developed the "Toolkit for Developing and Conducting Multi-site Clinical Trials in Practice Based Research Networks" to offer guidance to investigators interested in conducting clinical trials with PBRNs with the hope of facilitating collaborations between investigators and PBRN teams and promoting the success of clinical trials. To reach as broad an audience as possible, this toolkit will be hosted on the DARTNet Institute website with links to the CTSA/National Center for Advancing Translational Sciences, Community Campus Partnerships for Health, and research toolkit web sites, among others.

As an example, the Translating Research into Primary Care Practice for Postpartum Depression (TRIPPD) study funded by the Agency for Health care Research and Quality assessed the effectiveness of postpartum depression screening and management in 28 practices in a single PBRN, the American Academy of Family Physicians National Research Network. During the grant submission phase, the project principal investigator, co-investigators, and PBRN director were involved in writing the proposal and developing the budget. Together they modified the research plan (eg, recruitment and study procedures) to fit a busy clinical environment and calculated the personnel

time and practice reimbursement required during the course of a project. The PBRN director served as the principal investigator for the PBRN subcontract. When the grant was awarded, the PBRN central research team was instrumental in recruiting practices using established communication venues (practice meetings, teleconferencing) and materials (research summary with copies of recruitment materials and consent) that were collaboratively developed by the academic research project team and the PBRN core team. The practice personnel received study-specific training, IRB training, regulatory document support, and a manual of protocol procedures was created to ensure implementation fidelity. After IRB approval, recruitment commenced and the academic research project and PBRN core teams collaboratively monitored enrollment metrics and retention rates. Regular communication between the academic research project team, the PBRN central research and core teams, and the participating practices was established through weekly team (academic project research team and PBRN core team) conference calls, weekly project calls between PBRN central research team members and practice staff, weekly study E-newsletters called "FAQs," and monthly calls between academic study investigators, the PBRN principal investigator, and practice lead clinicians. The academic research project team and the PBRN core team met face to face at least once a year to discuss data analysis, interim results, dissemination of results, and publications. The budget included personnel effort for the PBRN director, PBRN associate director, PBRN research assistant, and PBRN system analyst. Practice lead clinicians and practice research project coordinators were compensated for time spent on training. Participating practices were provided an annual stipend based on completing milestones. A 2-day face-to-face study kickoff meeting with 2 attendees from each practice site, as well as annual meetings for the academic research project team and PBRN central research project team during the life of the grant, were budgeted. All practice staff were invited to periodic events funded by the academic research project team, such as pizza parties, to encourage practice-wide involvement in the trial. Indirect costs for the PBRN were included.[5,7]

A listing of documents such as those used for practice recruitment, participant recruitment, and site communication is included in Appendix 1. The full resources are available as links or downloads on the DARTNet website (www.dartnet.info/clinicaltrialsPBRNToolkit.htm). Many were developed for projects we conducted and were determined to be good examples to list as resources.

Conclusion

Ensuring the successful development and conduct of clinical trials in PBRNs requires a highly collaborative approach between academic research and PBRN teams—collaboration that we hope is facilitated by our "Toolkit for Developing and Conducting Multi-site Clinical Trials in Practice Based Research Networks."

The DARTNet Institute Research Steering Committee, CTSA Community Engagement PBRN workgroup members, the North American Primary Care Research Group (NAPCRG) Committee on Advancing the Science of Family Medicine PBRN workgroup, workshop participants at the NAPCRG PBRN 2013 conference, Kim Kimminau, PhD, and Wilson D. Pace, MD, FAAFP, all contributed to the development of the "Toolkit for Developing and Conducting Multi-site Clinical Trials in Practice Based Research Networks."

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Appendix 1

Toolkit Resources

Type of Resource	Example(s)	Applicable Toolkit Section			
		Project Management	Recruiting and Engaging Practices	Communication	Budgeting
Budget templates	ResearchToolkit.org budget template				✓
Certificate of trial completion	WPRN study completion certificate template		✓		
Dissemination tools	Beyond Scientific Publication: Strategies for Disseminating Research Findings (Community Alliance for Research Engagement, Yale Center for Clinical Investigation)			✓	
PBRN personnel training documentation form	Training log for study personnel (NIDCR toolkit for clinical researchers)	✓			
Interim trial results	Translate CKD performance report		✓		
Interim Update to PBRN Central research project team	PROMISE		✓		
Manual of protocol procedures	National Institute on Aging's guidelines for developing a manual of operations and procedures	✓			
Newsletters for practices and patients	Cities for Life newsletters (n = 4) PROMISE newsletter Translate CKD newsletter		✓	✓	
Study introduction information sheet	WPRN research study question and answer one-pager		✓		
Press release at trial start for practices	AIM-Hi press releases (n = 2)		✓		
Quality management plan template	CDC quality management plan	✓			
Study results document for participants	Generic results letter to participants template			✓	
Study results document for practices	WPRN Patient Preferences for Weight Loss Programs study results one-pager			✓	
Clinical research toolkit	NIDCR General Toolkit for Clinical Researchers	✓			
Study communications to practices	Asthma Tools Study Word Search Asthma Tools Study FAQ: Case Review Asthma Tools Study FAQ: Inhaler Technique	✓	✓	✓	
Study poster	Cities for Life poster		✓	✓	
Practice research success story	PROMISE newsletter	✓	✓	✓	

CDC, Centers for Disease Control and Prevention; CKD, chronic kidney disease; FAQ, frequently asked questions; NIDCR, National Institute of Dental and Craniofacial Research; PBRN, practice-based research network; PROMISE, PROspective Multicenter Imaging Study for Evaluation of Chest Pain; WPRN, WWAMI Region Practice & Research Network.