

IMPLEMENTATION, POLICY AND COMMUNITY ENGAGEMENT
SPECIAL COMMUNICATION

The Northwest Participant and Clinical Interactions Network: Increasing opportunities for patients to participate in research across the Northwestern United States

Laura-Mae Baldwin^{1,2*}, Laurie Hassell¹, Cindi Laukes³, Michelle Doyle¹, Anne Reedy⁴, Brenda Mollis¹, Sandra Albritton⁵, Elizabeth Ciemins⁶, Robert Coker⁷, Jeannine Brant⁶, Katherine R. Tuttle^{1,8}, Laura Baker¹ and Bonnie Ramsey^{1,9,10}

¹ Institute of Translational Health Sciences, Seattle, WA, USA

² Department of Family Medicine, University of Washington, Seattle, WA, USA

³ Neural Injury Center, University of Montana, Missoula, MT, USA

⁴ MultiCare Health System, Tacoma, WA, USA

⁵ Kootenai Health, Coeur d'Alene, ID, USA

⁶ Billings Clinic, Billings, MT, USA

⁷ Institute of Arctic Biology, University of Alaska, Fairbanks, AK, USA

⁸ Providence Health Care, Spokane, WA, USA

⁹ Department of Pediatrics, University of Washington, Seattle, WA, USA

¹⁰ Seattle Children's, Seattle, WA, USA

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Introduction. The Institute of Translational Health Sciences (ITHS) promotes and supports translational research collaboration between clinicians, communities, and investigators across the five-state Washington, Wyoming, Alaska, Montana, and Idaho (WWAMI) region. The ITHS has developed a collaborative regional clinical research network, the Northwest Participant & Clinical Interactions Network (NW PCI), involving 12 diverse clinical health systems and academic institutions.

Methods. This descriptive article details NW PCI's development, infrastructure and governance, tools, characteristics, and initial outcomes.

Results. Regional NW PCI sites are conducting largely industry-sponsored studies; they are interested in including more grant-funded research. Regional NW PCI sites had over 1,240 open studies involving over 6700 patients in 2016. NW PCI trials are largely industry-sponsored; NW PCI sites are interested in including more grant-funded research. In its first three years, the NW PCI Coordinating Center facilitated regional sites' participation in 34 new grant and contract applications across diverse topics.

Conclusion. The NW PCI model supports the goals of the developing CTSA Trial Innovation Network by increasing access to cutting-edge research across the Northwestern U.S., by supporting investigators seeking diverse populations, including those with rare diseases, for their research studies, and by providing settings to test implementation and dissemination of effective interventions.

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* Address for correspondence: L.-M. Baldwin, M.D., M.P.H., Department of Family Medicine, University of Washington School of Medicine, Box 354696, Seattle, WA 98195, USA. (Email: lmb@uw.edu)

Introduction

To complete the circle of scientific discovery and ensure its translation into practice, translational investigators must collaborate with clinicians and healthcare organizations in the community. These collaborations can inform the entire translational science spectrum, from identifying health and research priorities, to designing new

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interventions, to developing and testing best practices for implementing interventions in real-world settings [1].

The Clinical and Translational Science Award (CTSA) Program, funded by the National Center for Advancing Translational Science, recognizes the importance of these critical community-academic partnerships, and asks its awardees to demonstrate and support meaningful engagement with clinicians and healthcare organizations in translational research [2]. The Institute of Translational Health Sciences (ITHS) is a CTSA partnership between the University of Washington (UW), Fred Hutchinson Cancer Research Center, and Seattle Children's Hospital & Research Institute. Although the majority of ITHS services and infrastructure are based in Seattle, Washington, the ITHS has fostered research collaborations with clinical and academic institutions, healthcare providers, and community organizations across the 5-state, Washington, Wyoming, Alaska, Montana, and Idaho (WWAMI), region. These collaborations build on the decadeslong relationships that the University of Washington School of Medicine has established in medical education and clinical care across the WWAMI region [3–7].

The ITHS has established and grown a Regional Research Collaborations (RRC) Program to promote and support multidirectional translational research collaboration and exchange between clinicians, communities, and investigators across the WWAMI region. The RRC carries out the following:

- (1) identifies translational science resources, needs, and priorities of clinical and academic institutions, investigators, communities, and clinics;
- (2) develops trusting research partnerships with institutions, organizations, communities, clinicians, and investigators committed to collaborating on translational research;
- (3) increases the capacity of investigators, clinicians, and healthcare institutions to conduct research in community-based settings; and
- (4) provides research infrastructure, processes, tools, and guidance that support translational research in communities and community-based clinical settings.

The RRC has a regional research liaison, based in the WWAMI region outside of the Puget Sound metropolitan area, who conducts outreach to regional organizations and healthcare institutions as one strategy to meet its aims. Through this outreach, the liaison identified multiple centers for the conduct of research in health systems outside Seattle (referred to as regional clinical research centers (CRCs) in this article), similar to those available in the ITHS-funded, Seattle-based CRCs. Most of these regional CRCs are sited in large community-based healthcare systems that include hospitals, primary-care clinics, specialty clinics, and other health services. The liaison also identified regional CRCs in a rural-serving primary-care organization, at a regional university, and in a specialty clinic within a university setting. Some of these health systems are affiliated with a local university and provide training to medical professionals. Some serve as tertiary or quaternary referral centers in their geographical areas. Many conduct not only clinical trials but also health services research, observational studies, and discovery science. These regional CRCs are largely conducting industry-sponsored studies; thus, a great deal of grant-funded research is not benefitting from the diversity of patients receiving care in these settings.

Several regional CRCs expressed interest in including more investigator-initiated research in their portfolios, and believed that there would be potential benefit in forming a network of ITHS-based and regionally based CRCs committed to the following:

- (1) building successful new research collaborations between their CRCs and university-based investigators;
- (2) expanding their capacity for investigator-initiated research; and
- (3) ensuring availability of best practices, standard operating

procedures, and training in core competencies for conducting clinical and health services research in community hospital and regional research settings.

From these beginnings, the Northwest Participant & Clinical Interactions (NW PCI) Network was born. This article details the NW PCI Network development process, infrastructure and governance, tools and resources, and initial characteristics and outcomes, aiming to inform the developing CTSA Trial Innovation Network as well as academic medical centers that may want to create similar regional networks. Development of such networks will increase access for patients throughout the United States to research studies that can advance knowledge and improve health.

NW PCI Network Supporting Network Development

NW PCI was built on the principles of community engagement and stakeholder involvement. These principles state that stakeholders and communities must have compelling reasons to be involved in a particular project (eg, pressing patient or institutional need) and anticipate tangible benefits from their participation [8, 9]; partners should be equal collaborators and recognized and valued for their contributions to a project [10–12]; and the needs and priorities of community partners should align with project goals and activities [8, 13].

Faculty and staff from the ITHS's RRC Program and a leader from the ITHS's CRC core initiated this partnership by holding one-on-one conversations with research administrators and clinical investigators at CRCs across the region, exploring their successes, interests, needs, and priorities related to forming a collaborative network that would leverage existing research infrastructure. The regional CRCs identified their extensive research infrastructure (eg, Institutional Review Boards (IRBs), budgeting, contracting, and regulatory monitoring capabilities and diverse research staff) and efficiencies in conducting industry-sponsored trials as clear strengths that could support their goals of involvement in more grant-funded, investigator-initiated research. These meetings also illuminated variation in the institutional cultures across regional hospitals and healthcare systems, including areas such as comfort of clinical providers with involving patients in research, experience with studies involving special populations such as infants, children, and the elderly, how to integrate research with clinical care, and institutional support for conducting research.

The ITHS hosted a meeting of research leaders from these diverse CRCs across the WWAMI region so that they could share information about existing research and related services at their respective institutions, discuss research-related challenges, and collectively identify goals and outcomes for a CRC network. The planning group for the meeting included regional research leaders as well as ITHS faculty and staff to ensure that the meeting agenda was responsive to the needs and interests of the regional partners. Annual meetings sponsored by the ITHS have become a core mechanism for community-building and supporting inclusive governance (eg, policy development, research priorities) among the NW PCI sites and between the sites and the ITHS.

Through this planning and engagement process, the NW PCI Network was created with an understanding of the similarities and differences between diverse CRCs, ensuring that the Network's policies and procedures support the following aspects:

- (1) research studies that align with the priorities of the institutions and the health needs of their patients;
- (2) feasible research protocols that are designed collaboratively with the sites and minimally interrupt operations in the clinical setting; and
- (3) collaborations with regional CRCs as equal partners in the research.

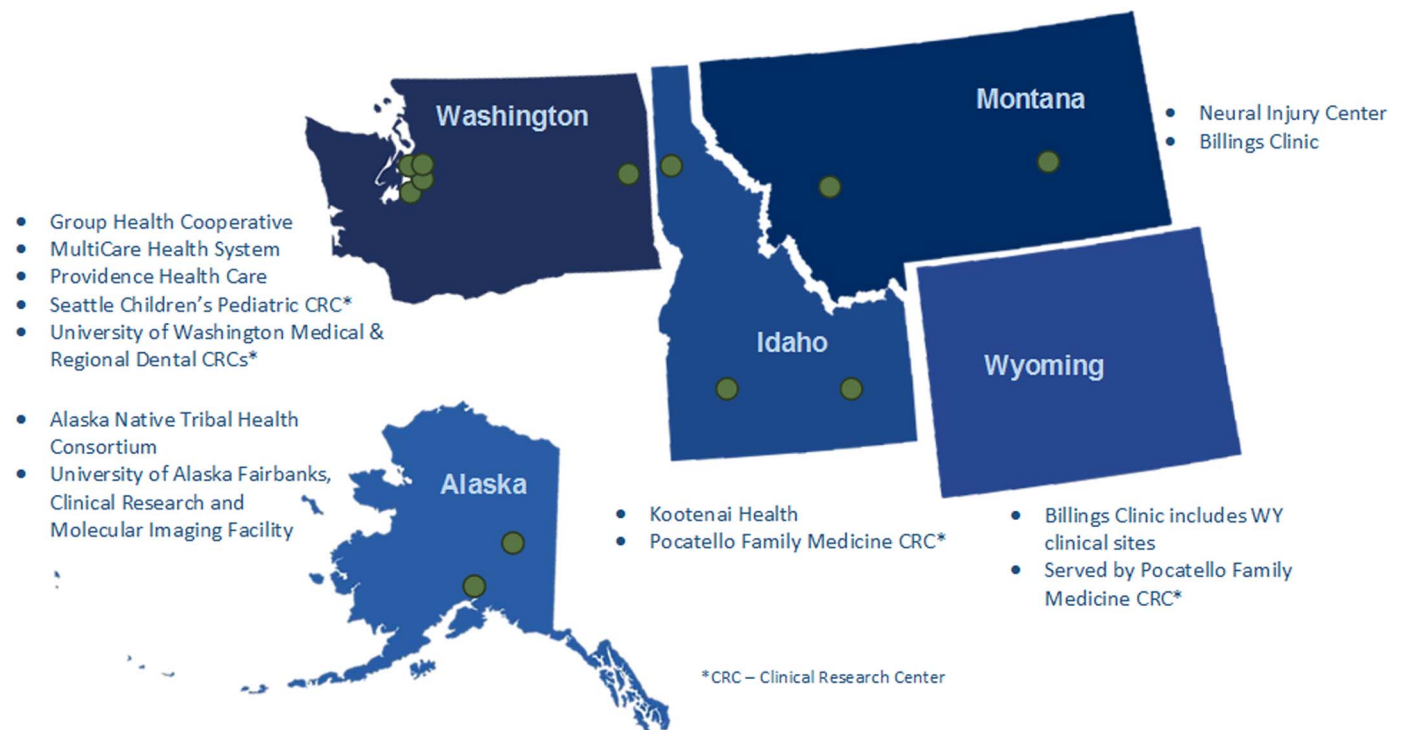


Fig. 1. Map of Northwest Participant and Clinical Interactions Network clinical research center sites.

The result has been a collaborative CRC network involving diverse clinical and academic institutions (Fig. 1) that increases access to cutting-edge research across the Northwestern United States, expands the research capacity of clinical and translational research centers, and serves as a natural testing environment for research innovations in real-world settings.

Infrastructure and Governance

The ITHS leadership includes individuals with strong experience in launching and maintaining clinical research networks (eg, the Cystic Fibrosis Therapeutics Development Network) and primary-care, practice-based research networks (ie, the ITHS's WWAMI region Practice and Research Network). We drew from these experiences in establishing the NW PCI's infrastructure and governance [14–16]. The NW PCI Network Coordinating Center, comprising 1 faculty member, a network liaison, and a research scientist from the ITHS RRC Program, is responsible for network administration, member engagement, and mentorship and coaching of investigators. The NW PCI Coordinating Center draws extensively from the expertise of the ITHS' clinical research resources and practice-based research units for guidance, tools, and resources [17].

The Coordinating Center is guided by a Steering Committee comprising 5 volunteer research leaders from regional NW PCI sites, 3 NW PCI Coordinating Center faculty and staff, 1 ITHS Co-Principal Investigator who has established and directed a specialty clinical research network, and the ITHS Operations Director of Clinical Resources. The Steering Committee meets monthly to vet new sites and study proposals, develop network policies and procedures, and discuss issues impacting the NW PCI Network.

Individual NW PCI site champions are vital to the success of the NW PCI Network. Site champions are administrative or clinical representatives from member sites who serve as liaisons between the NW PCI Coordinating Center and the potential research collaborators (eg, Site Principal Investigators) at their institution. They receive information about study opportunities that have been vetted by the Steering Committee, determine whether the study might be a good fit for their institution, and then disseminate the information to clinicians

or other personnel who might be interested in collaborating on the study. By working directly with the NW PCI Coordinating Center and representing their institutions at the annual meeting, the site champions communicate their institutions' research needs and priorities, develop and refine network governance, provide research-related information about their institution, and are active participants in strategic and operational initiatives.

Institutional support provided by the ITHS has been vital to the development and maintenance of the NW PCI Network. The ITHS has supported the NW PCI Coordinating Center and Steering Committee in developing a strong group of site champions, who identify as collaborative, community-based research leaders and colleagues, and in nurturing partnerships with investigators and their study teams. Ongoing maintenance of the relationships between these individuals and groups is key to the long-term success of the NW PCI Network in facilitating collaborative research, developing new pathways for academic-community partnerships, and mitigating barriers to conducting translational research in communities and community-based clinical settings.

Tools and Resources

One of the NW PCI's first projects was the development of tools to better understand the research infrastructure and experience at NW PCI regional sites (eg, site curriculum vitae or site "CVs"), as well as sites' relevant policies and procedures (eg, study vetting and approval processes), so that the resources and strengths of the regional CRCs could be communicated to investigators who might benefit from working with the NW PCI Network. In addition, we have developed tools and structures through which to vet and distribute research opportunities to our regional partners, and ensure quick turnaround times to identify collaborators on specific grant or contract applications. Together, the tools described in Table 1 help to ensure that high-quality research is conducted across the network.

Characteristics and Outcomes

The ITHS has created an innovative collaboration between its 3 CRCs (the UW Medical CRC, UW Regional Dental CRC, and Seattle

Table 1. Description of Northwest Participant and Clinical Interactions (NW PCI) network operational tools

Tool	Description
Mission, vision, and values	Forms the foundation for all NW PCI initiatives and studies, and guides the development of NW PCI Network study criteria and documents, such as the Principles of Collaboration
Principles of Collaboration	Outlines the NW PCI Network’s purpose, mission, values, and governance; describes the roles and responsibilities of the NW PCI Coordinating Center, clinical sites, and research affiliates. Not intended to be a legal document
Steering Committee Information Sheet	Defines roles and responsibilities, composition, and selection criteria and process
Site Curriculum Vitae (CVs)	Information about site geographical catchment area, patient demographics, types of clinical and health services research (eg, drug and device trials, diagnostics development and testing), electronic health record platform, availability of key research personnel and essential services, and IRB requirements
Site Information Distribution and Privacy Policy	Establishes guidelines for distributing identifiable and de-identified information (eg, research capabilities) about NW PCI sites
Standard Operating Procedures (SOP) matrix	Inventory of research-related SOPs by category (eg, investigational products, authorship guidelines, informed consent) at member sites. Intended to facilitate sharing and standardization of operational information and identify gaps
Core curriculum matrix for research personnel	Inventory of existing training and curriculum by category (eg, records management, research budgets, responsible conduct of research). Intended to identify gaps and facilitate prioritization of training and professional development efforts for network sites
Member and Site Champion Contact Form	Identifies clinical site champion and champion contact information
NW PCI Network Collaborative Research Study Development Criteria and Proposal Template	Criteria are used to assess alignment between a proposed study and NW PCI Network goals. Proposal template is used by investigators to create a 1-page description of the study. Steering Committee members use the proposal to vet the study, before the proposal is either returned to investigators for revisions or disseminated to NW PCI site champions
Study vetting and selection process	Defines the vetting and approval process used to determine alignment of study proposals with NW PCI Network goals, and ensures that site champions only receive collaboration opportunities that are relevant to and feasible within their institutions
Publication policy	Defines expectations for the development and authorship of reports and manuscripts

ITHS, Institute of Translational Health Sciences.

Children’s Pediatric CRC) and 10 diverse regional CRCs, and has demonstrated the capacity of the network for engaging in a full spectrum of translational research. The 10 regional CRCs serve a catchment area of over 5.5 million individuals across 9 states, and have experience with a wide range of clinical and translational research, including phase 1–4 drug and device trials, and health services research, with funding from multiple sources (Table 2). These sites conduct research studies in outpatient and inpatient settings and in primary and specialty care with patients of all ages. Eight of the 10 regional sites have searchable electronic health record systems. On average, in 2016, the 10 regional CRCs have roughly 1240 open studies (range 3–240), involving over 6700 individuals (range 25–2400+).

In its first three years, the NW PCI Coordinating Center facilitated regional sites’ participation in 34 new grant and contract applications (2 funded and completed, 7 funded and ongoing, 7 pending, 6 in development at the time of manuscript submission, 12 not funded), as well as an internally funded project to identify factors that influence clinicians’ likelihood of serving as investigators on research studies (Fig. 2). Completed and ongoing studies have recruited 791 individuals from NW PCI Network regional sites by the time of manuscript submission during the same 3 years (1 study involving a comparison of IRB professionals’ and patients’ views on consent for research on medical practice has been published [18] and 2 others with planned manuscripts).

Table 2. Characteristics of the 10 regional clinical research centers

Characteristics	Description
Affiliated hospitals	Thirty hospitals with more than 5800 beds
Geographic catchment areas	Washington, Wyoming, Alaska, Montana, Idaho, Oregon, North Dakota, South Dakota, and Utah
Research funding	All sites receive funding from industry and federal sponsors. Some sites receive funding from private foundations, as well as local, regional, and state government sponsors
Research capability	All sites can conduct outpatient studies. Eight can conduct inpatient studies, 5 can conduct pediatric studies, and 6 can conduct home-based studies
Electronic health records	Eight regional sites have searchable electronic health record systems
Research personnel	All network sites have research coordinators and research nurses. Eight have research pharmacists. All sites have personnel to support contracts, budgets, and general research administration
Institutional Review Boards (IRBs)	Eight regional sites have experience with or will consider using a centralized IRB process for multisite clinical trials. Nine regional sites have their own IRBs; 1 site contracts with an IRB at another institution
Types of research	All network sites have conducted two or more types of clinical research studies. Types include phase 1-4 clinical trials, investigational device studies, investigational procedures or methods studies, imaging and/or imaging agent development studies, social behavioral studies, and health outcomes and/or quality assessment studies



Fig. 2. Summary of the Northwest Participant and Clinical Interactions Network accomplishments.

Investigators working with the NW PCI Network's regional sites have come from the 3 core ITHS partner institutions (University of Washington, Seattle Children's and Fred Hutchinson Cancer Research Center), other academic institutions and CTSA programs (eg, University of Colorado, Stanford University, University of Wyoming, University of Alabama Birmingham, and Montana State University), and NW PCI member sites themselves (Fig. 1). These applications have addressed diverse topics such as laboratory medicine consultation methods for returning results of complex genomic tests to clinicians, management of low back pain, patient attitudes toward randomization to alternate standard-of-care treatments [18], advance care planning, and predicting care transitions for teens with cerebral palsy, and have involved different types of clinical and health services research (eg, care delivery improvement, provider training, drug trials, comparative effectiveness research). The NW PCI Network is currently a core resource to the Pacific Northwest Node of the National Institute on Drug Abuse Clinical Trials Network and a partner in a master Indefinite Delivery, Indefinite Quantity contract to the Agency for Healthcare Research and Quality—Accelerating Change and Transformation in Organizations and Networks (ACTION III), a model of field-based research designed to promote innovation in healthcare delivery by accelerating the diffusion of research into practice, with a focus on patient safety and quality.

Addressing Challenges to Conducting Clinical and Translational Research in a Distributed Research Network

Engaging Busy Clinicians in Research

Conducting research in collaboration with the NW PCI Network's regional CRCs involves many of the same challenges as research in university-based settings, such as engaging busy clinicians in research, recruiting patients, and leveraging electronic health record data for research [19]. Community-based hospitals and health systems use a production model to successfully engage clinicians in industry-sponsored research, supported by personnel who identify relevant clinical trials, negotiate and implement contracts and budgets, facilitate centralized human subjects research review, consent, and enroll patients, and collect data. However, few community-based clinicians have the protected time needed in investigator-initiated research to conceptualize and plan research projects, write proposals, lead research initiatives, direct data analysis, and disseminate findings. Few, if any, personnel with knowledge about and experience with federal grants administration may be available, and internal IRBs may have limited or no experience reviewing novel, investigator-initiated research protocols.

NW PCI's regional CRCs have highlighted engaging busy clinicians and their clinical organizations in research as one of their most

significant challenges. Clinicians are more likely to successfully engage in research if they have protected research time. Without protected time, the responsibilities of clinical care will take precedence. In most university-based settings, there is an expectation that clinicians will participate in research; this is not the case in most of the clinical institutions hosting NW PCI Network's regional CRCs. More often, extraordinary interest and personal commitment to advancing knowledge and improving patient care are key drivers of research by clinician investigators at NW PCI's regional CRCs.

The NW PCI's Coordinating Center and Steering Committee assess the potential for synergy between research projects and NW PCI regional settings as they vet investigators' proposals, drawing on the priority topic areas and clinical needs voiced by NW PCI site champions. The NW PCI Coordinating Center also has identified the subject areas in which NW PCI regional sites have active site Principal Investigators (Table 3 and online Supplementary Material), indicating some of the strengths of NW PCI regional sites to help link appropriate partners with potential projects.

Table 3. Top areas of research at Northwest Participant and Clinical Interactions (NW PCI) regional sites*

Research area	Number of NW PCI sites with active site PIs (n = 10)
Primary care	8
Cardiovascular	7
Nursing	
Oncology	
Pharmacy	
Healthcare access and disease management	6
Diabetes	5
Hyperlipidemia	
Hypertension	
Nutrition and metabolism	
Women's health	
Behavioral health	4
Endocrinology	
Internal medicine	
Neurology	
Physical/Occupational therapy	
Pulmonology	
Stroke	

PI, Principal Investigators.

*For a complete list of research areas at the NW PCI regional sites, see online Supplementary Material.

Primary care, oncology, cardiovascular disease, nursing practice, healthcare access, and many other specialties are highly active research areas across the NW PCI Network. Fewer sites are conducting research with special populations such as infants, children, and the elderly, and this is an area of planned growth for the Network.

NW PCI Network champions in 7 sites are collaborating on a project to better understand the interests of primary, specialty, behavioral, and allied healthcare clinicians in research and the barriers to their involvement in research at their institutions. Data from this study will inform individual institutional leaders about the specific barriers to be addressed to support clinician involvement in research at their sites, and will be compiled with data from other participating sites to inform the development of a testable intervention to increase clinician engagement in research.

Minimizing Regional Site Burden During the Pre-Award Process

The NW PCI Coordinating Center has developed systems that minimize effort by the regional sites in grant submissions to avoid burdening them with excessive paperwork. By using processes and tools outlined in [Table 1](#), the NW PCI Coordinating Center assists in developing standard budgets, budget justifications, scopes of work, and letters of support, which helps to ensure standardization of these documents for studies involving multiple collaborators, and in gaining economies of scale.

A related challenge is maintaining regional sites' enthusiasm for collaborative research efforts given a national success rate of less than 20% [20] for investigator-initiated research grant proposals to the NIH. Minimizing the clinical site burden may enable NW PCI regional sites to consider a higher volume of proposals than would be possible if each site had to develop its own grant application materials.

Program Sustainability

The NW PCI Coordinating Center has determined the costs of maintaining the NW PCI Network infrastructure so that it can recover some of these costs through a "Network User Fee" that is leveraged to investigators annually in grant applications. This fee helps offset infrastructure costs for activities such as NW PCI Network meetings (eg, annual, Steering Committee, and Coordinating Center meetings), time spent developing policies and procedures, general marketing and communications, recruiting new members, compiling site information, and conducting site visits.

Training and Mentoring Investigators and Regional Site Personnel

Preparing investigators new to community-based research involves training in the principles of community engagement, as well as dissemination and implementation science, and mentoring to be effective collaborators with NW PCI Network regional sites. The NW PCI Coordinating Center draws upon the expertise of experienced faculty to guide the alignment of investigators' research aims with the health and research priorities of their community-based collaborators, a network coordinator to assist with the development of the scope of work and operability of their studies, and a research scientist experienced in community-engaged research to consult with investigators, and ensure consistent communications and focus on milestones. Emphasizing the use of standard operational procedures, document templates, and other tools enables the faculty and staff in the NW PCI Coordinating Center to scale up efforts to train and mentor more investigators.

Regional site personnel such as clinicians, hospital administrators, and research personnel also require training specific to their research

roles, the type of funding sought, and the desired level of research independence. One NW PCI regional site organized available, online ITHS educational seminars and other materials into role-specific training modules for investigators, nurses, research associates, regulatory personnel, and business operations staff. Personnel in each category have lists of required, optional, and secondary topics. Information about the training modules has been made available to all NW PCI sites, and it is available to others upon request.

Some NW PCI regional sites seek to develop new, independent clinical investigators who can successfully compete for research funding, which requires training in grantsmanship, study design, federal grant administration, and other topics typical of early-career investigator training. The NW PCI Coordinating Center works with NW PCI regional sites collectively and individually to identify training needs and facilitate access to workforce development opportunities.

Conclusions

The ITHS' commitment to (1) learning about the translational research resources, strengths, and needs across the 5-state, WWAMI region and (2) collaborating with regional investigators and clinical institutions led us to the discovery of a diverse pool of healthcare organizations and their clinical research units eager to collaborate on research. The research-related experience, skills, and capacity of these ITHS partners that have been amassed through the conduct of largely sponsored clinical trials translate readily to investigator-initiated clinical, translational, and health services research.

Access to clinical trials is often limited for patients distant from university-based medical centers. For example, less than 1 in 1000 individuals, 800 of whom experience symptoms on a monthly basis, will be admitted to a university-based medical center [21]. The National Cancer Institute (NCI), National Clinical Trials Network [22] conducts large-scale clinical trials and enrolls patients via 30 "Lead Academic Participating Sites" and a newly developed NCI Community Oncology Research Program (NCORP) of community hospitals and medical centers. In its first year, the NCI Community Oncology Research Program reported enrolling 25% of all patients involved in NCI National Clinical Trials Network studies [23]. Four of the 5 states in the WWAMI region do not have their own university-based medical centers, and access to clinical trials is an issue of national concern. A network such as NW PCI provides more opportunities for patients, regardless of their residence location, to access clinical trials as well as other research studies. It could also provide access for investigators of rare diseases to tap into heretofore hard-to-reach populations to recruit adequately for their trials.

The ITHS and its NW PCI Network Coordinating Center and Steering Committee have developed tools, procedures, policies, structures, and materials to support CTSA programs and institutions nationally in implementing and maintaining similar networks (www.iths.org and available upon request). NW PCI's strong research capability in real-world settings, representative of where the majority of Americans receive their care, is a model that supports the goals of the developing CTSA Trial Innovation Network. The NW PCI Network is an important research resource for the CTSA Consortium and for investigators seeking diverse populations for their clinical and health services research, adequate numbers of individuals with rare diseases, and settings to test implementation and dissemination of effective interventions.

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Conflicts of Interest

None.

Supplementary Material

To view supplementary material for this article, please visit <https://doi.org/10.1017/cts.2016.18>

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