# **CERTIFICATE PROGRAM IN**

# **PRACTICE-BASED RESEARCH METHODS**

# **SYLLABUS**

## **Steering Committee**

#### Co-Directors

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### <u>Members</u>

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**Miriam Dickinson, PhD**, Professor, Department of Family Medicine, University of Colorado, PRIME Net Center in Practice-based Research and Learning

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**Nancy Elder, MD, MPH**, Professor, Department of Family and Community Medicine, University of Cincinnati College of Medicine, Collaborative Ohio Inquiry Network (COIN)

Alex Fiks, MD, Assistant Professor, Department of Pediatrics, University of Pennsylvania, National Center for Pediatric Practice Based Research & Learning

**Chet Fox, MD**, Professor, Department of Family Medicine, University at Buffalo, The State University of New York, MOSAIC: Meaningful Outcomes and Science to Advance Innovations Center of Excellence **Kim Kimminau, PhD**, Associate Professor, Department of Family Medicine, University of Kansas, MOSAIC: Meaningful Outcomes and Science to Advance Innovations Center of Excellence

**Lyndee Knox, PhD**, Assistant Professor, Department of Family Medicine, University of Southern California, Coordinated Consortium of Networks (CoCoNet2), PRIME Net Center in Practice-based Research and Learning

**Cara Litvin, MD,** Assistant Professor, Department of Family Medicine, Medical University of South Carolina, PPRNet: Primary (Care) Practice Research Network

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**Mort Wasserman, MD**, Professor, Department of Pediatrics, University of Vermont, National Center for Pediatric Practice-Based Research & Learning

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#### Learning Objectives

After completion of the program, learners will be able to:

- 1) Apply methods of practice-based research network development to initiate new PBRNs and strengthen existing networks.
- 2) Describe the range of research questions that fit within PBRN settings, and provide examples of studies that play to the strengths of PBRNs.
- 3) Describe how PBRN research topics and questions can be elicited from PBRN members, patients, and other community stakeholders.
- 4) Conceptualize the changing landscape of PBRN research and describe approaches for expanding research from practices to patients and communities.
- 5) Engage PBRN members, network leaders, and patients in a collaborative process to develop a study concept.
- 6) Apply one or more research designs in the development of a PBRN study concept paper and Specific Aims.
- 7) Explain how electronic health record data and large administrative data sets can be effectively used to answer questions in PBRNs.
- 8) Describe sampling methods used in PBRN research, explain common threats to validity in PBRN studies, and discuss the rationale for nested analyses and outline the steps involved.
- 9) Apply principles, methods, and tools for quality improvement research within primary care PBRNs.
- 10) Explain human subject protection issues that are relevant to PBRN research and describe effective methods for addressing IRB and HIPAA issues. Explain the typical processes and timelines in IRB review for practice-based research protocols.
- 11) Understand PBRN research in the contexts of implementation science and the translational science continuum.
- 12) Describe the range of strategies that can be used to disseminate PBRN research findings, and cite examples of PBRN dissemination strategies.

#### **Program Summary**

A practice-based research network (PBRN) is a group of ambulatory practices devoted principally to the primary care of patients and affiliated in their mission to investigate questions related to community-based practice and to improve the quality of primary care. PBRNs draw on the experience and insight of practicing clinicians to identify and frame research questions whose answers can improve the practice of primary care. By linking these questions with rigorous methods, PBRNs produce research and quality improvement findings that are relevant to clinicians and readily translated into everyday practice.

The Certificate Program in Practice-Based Research Methods seeks to develop a new generation of independent investigators within the PBRN community. The program will provide training in concepts, skills, and methods for conducting practice-based research and building PBRNs. It will use three primary learning modalities: 1) Participation in training seminars taught by PBRN experts; 2) Development and

presentation of a research concept paper for a PBRN study; and 3) Development and presentation of a refined Specific Aims section.

Training Seminars will take place approximately monthly and will be held via internet-based webinars. PBRN content experts will lead each Training Seminar. The presentation portion of the Training Seminars may be open to the larger PBRN community, including individuals who are not seeking to earn the program's certificate. `

Each fellow will have one or more experienced local mentors. Fellows may have additional mentors who are not local, if desired.

Fellows will consult with PBRN members, leaders, patients and other stakeholders in the development of a research concept paper, under the guidance of their mentor(s).

In order to build skills in developing grant proposals for PBRN research, each fellow will build upon his or her concept paper by writing and refining a Specific Aims section for a research proposal designed to be implemented in a PBRN.

The Certificate Program will be approximately ten months in duration and will culminate with a Convocation of fellows and mentors that will precede the NAPCRG PBRN Conference in Bethesda, MD in June 2016. Fellows will present their concept papers and Specific Aims at the Convocation, where they will receive constructive input from members of the Steering Committee, program mentors, and other fellows.

#### **Program Structure**

#### <u>Oversight</u>

The Steering Committee will oversee and guide the program. Members of the committee will hold an orientation webinar with fellows and mentors at the start of the program to explain the program's structure, objectives, and the responsibilities of fellows and mentors. Thereafter, conference calls will be held with individual fellows and their mentors during months 3, 6, and 9 to assess the fellow's progress towards achieving learning objectives. Members of the Steering Committee will review each fellow's Learning Plan; each plan must be approved by the committee. Members of the committee will determine at the end of the program whether individual fellows have met the qualification standards required to be awarded the program's certificate.

#### **Fellows**

The Certificate program seeks to recruit individuals who aspire to become independent PBRN research investigators. Ideal candidates include individuals with research career development awards (K-awardees, T- awardees, etc.) who want to gain exposure and skills in PBRN methods. Others may not have a career development award but are seeking to develop into an independent investigator. Finally, others may be established research investigators who want to gain exposure to PBRNs.

Applicants should meet the following criteria to be eligible to participate in the Certificate Program in Practice-Based Research Methods:

- 1) Aspire to become an independent PBRN research investigator, or be an independent investigator who wants to obtain training and experience in PBRNs.
- 2) Hold a doctoral degree (MD, PhD, EdD, PharmD, PsyD, DNP, etc).
- 3) Hold a faculty position with a university or non-profit research institution.

#### Anticipated Time Commitment

It is expected that fellows will devote approximately 4-6 hours/month to fellowship activities during the ten-month long program.

#### Application Process

Applicants should complete the steps below to apply to the program:

- 1) Provide your current CV.
- 2) Provide a brief statement describing your interest in the program (one page maximum).
- 3) A letter of recommendation on the fellow's behalf should be submitted by the PI of an AHRQ-supported P30 PBRN Center of Excellence in Practice-based Research and Learning. The letter should also be signed by one or more experienced PBRN investigators who have agreed to mentor the fellow during the tenmonth long program.

Application materials should be sent to the program's coordinator, Amanda Ross, at <u>air67@case.edu</u>. The deadline for applications is September 20, 2015.

#### **Mentors**

One or more local mentors will guide and support each fellow through the course of the program. Mentors should be experienced PBRN investigators who have served as principal investigator on one or more research grants from NIH or AHRQ. Additional mentors can be located at other sites. Mentors will guide the fellow in developing the concept paper, Specific Aims, and the Learning Plan.

Mentors should attend the first training seminar (orientation) and are welcome to attend all of the remaining training seminars. One or more mentors for each fellow are required to participate in scheduled calls with the Steering Committee (during months 3, 6, and 9) and attend the program Convocation that will precede the NAPCRG PBRN Conference in June 2016.

#### Anticipated Time Commitment

It is anticipated that mentors will devote approximately 1-2 hours/month to mentoring their fellow during the ten month fellowship period.

#### Training Seminars

The program will hold thirteen 90-minute webinar-based Training Seminars over the ten month program period. An orientation webinar for fellows and mentors will be held a few days before the initial webinar on PBRN content. Each PBRN seminar will be led by a topic expert (see schedule below) who will present during the first 40 minutes of each seminar. A discussion will take place with the presenter during the subsequent 30 minutes, during which a designated fellow will pose discussion questions prepared in advance. Fellows will provide brief updates on their concept papers and Specific Aims during the final 20 minutes.

Training Seminars will be held from 12:00-1:30pm Eastern time on the 3<sup>rd</sup> Thursday of each month except during the months of February and April when they will be held on both the 1<sup>st</sup> and 3<sup>rd</sup> Thursdays of the month.

#### Individual Video Profile

Fellows may not have the opportunity to meet one another until they attend the Convocation at the end of the program. During the first few weeks of the program, fellows should post informal 3-5 minute videos introducing themselves, describing their professional backgrounds, and discussing their research interests. Fellows should view all of the videos in order to become familiar with others in the training cohort.

#### Concept Paper

Each fellow will develop and write a concept paper for a PBRN research study on a topic of significant professional interest. The fellow will develop the concept paper in close consultation with key stakeholders that may include PBRN leaders, network members, and patients. Mentors should guide fellows through this process. The concept paper should be widely distributed within the PBRN or P30 Center in order to obtain feedback about the study concept and its implementation. The fellow will use this input to refine

the concept paper and inform the development of the Specific Aims. Guidelines for writing the concept paper will be provided. Fellows will present their concept papers at the program's Convocation in June, 2016.

#### Specific Aims

Building upon the concept paper, each fellow will write a Specific Aims section for an NIH/AHRQ research proposal for a study designed to be implemented within a PBRN. Mentors will be instrumental in providing guidance, and the aims should be iteratively refined. Guidelines will be provided. Fellows will present their Specific Aims at the program's Convocation in June, 2016.

#### Learning Plans

Each fellow will develop and maintain a Learning Plan in collaboration with his or her mentor that specifies his or her individual learning goals, objectives, and timelines for task completion. Review and approval of Learning Plans by the Steering Committee members from the fellow's sponsoring P30. The Learning Plan template is provided in the Appendix.

#### Program Culmination and Convocation

Fellows will present their concept papers and Specific Aims at the Convocation of fellows, mentors, and Steering Committee members held in conjunction with the NAPCRG PBRN Conference in Bethesda, MD in June 2016. Program certificates will be awarded at the Convocation.

#### **Qualification for the Certificate**

Fellows must meet the following criteria in order to earn the *Certificate of Practice-Based Research Methods*:

- 1. Actively participating in the entirety of at least 80% of webinar-based Training Seminars.
- 2. Posting a descriptive video profile during the first 2 weeks of the program.
- 3. Preparing and asking effective discussion questions during training seminars, as assigned.
- 4. Completing and presenting a concept paper at the Convocation, per guidelines provided.
- 5. Completing and presenting a Specific Aims section at the Convocation, per guidelines provided.
- 6. Developing and achieving an approved Learning Plan.

#### **Program Administration**

The program's coordinator will be Amanda Ross of COIN (ajr67@case.edu). Learning management software will be used to distribute materials and facilitate learning. CourseSites by BlackBoard is the online system that will be used by the program. Instructions for using CourseSites will be provided.

#### Readings

The program has one required text that can be downloaded at no cost (see the link below). Additional readings will be available on CourseSites whenever permitted by copyright; otherwise, articles should be obtained through a library system. The reading list is provided at the end of this syllabus.

Required: Neale, AV, et al. *PBRN Research Good Practices (PRGP)*. September 2014. Free download available at: <u>http://www.napcrg.org/PBRNResearchGoodPractice</u>

#### Lecturers

(list all lecturers when confirmed)

# CERTIFICATE PROGRAM IN PRACTICE-BASED RESEARCH METHODS

## SCHEDULE OF WEBINAR-BASED TRAINING SEMINARS 12:00-1:30PM EASTERN TIME

Week Date	Title	Leaders/ Lecturers	Topics	Readings
	Program orientation for fellows & mentors	Members of Steering Committee	Program goals, structure, timeline, deliverables, Q & A	Syllabus
	Introduction and theory of Practice-Based Research Networks (PBRNs)	Kurt Stange	Reflective, inquiring practice Types of networks & examples Success & failure in practice-based research	2, 5,6,7,8,9,11,13 23,25,27 2,5,13,27,31 2,6,27,31
	PBRN development and maintenance Use of practice facilitators	Zsolt Nagykaldi Lyndee Knox	Enrollment methods; Network infrastructure; Representativeness; Changing PBRN landscape	3,26, 36 3,17,26 1,3,4,14,24,28,30
4 11/19/15	Recruitment and engagement of clinicians, practices, patients, & healthcare systems The Card Study Method	LJ Fagnan Melinda Davis Jack Westfall	Recruitment & engagement methods; Bottom-up research	
5 12/17/15	Participatory research in	Lyndee Knox Don Nease	Participatory approaches; Patient engagement & PCOR	31, 32, 41, 42
6 1/21/16	Research using electronic health records & big data	Wilson Pace Alex Krist	DARTNet Institute	

7	Sampling and nested	Miriam	Biostatistical methods	22 21 25 20
2/4/16	analyses in PBRNs	Dickinson	Diostatistical methous	55,54,55,59
2/4/10		or		
		Steve Zyzanski		
8	Qualitative methods	Sue Flocke	Qualitative & mixed	1 22 22 24 25
	and multimethod	Sue FIOCKE	methods PBRN	1, 22, 23, 34,35
2/10/10	research methods in		research	
	PBRN research			
0				40
9	Quality improvement research	Chet Fox	Linking quality	40
3/17/16	research	Zsolt Nagykaldi	improvement & clinical research	
	Alliances and methods	Mike Parchman		
	for practice	WIKE Parchinan		
	improvement			
10	Translational research in	Steve Woolf		
4/7/16	PBRNs			
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	Linking research to			
	policy			
11	Human subjects	Leslie Wolf	IRB, HIPAA;	1,25,38, 39, 43
4/21/16	protection and data	Debbie Graham	Ethical and practical	
	privacy in PBRN		issues	
	research			
12	Writing PBRN research	Victoria Neale	Writing, review, and	Handout
5/19/16	for publication		publication process	
	Methods of research			
	dissemination			
13	Obtaining funding for	Rowena Dolor	NIH, AHRQ, other	46
6/16/16	PBRN research		federal agencies,	
			foundations,	
			professional	
			organizations	

#### **READING LIST**

- 1. Task Force to Enhance Family Practice Research. *Methods for Practice-Based Research Networks: Challenges and Opportunities*. Leawood, Kansas: American Academy of Family Physicians; 2003.
- 2. Task Force to Enhance Family Practice Research. *Practice-Based Research Networks in the 21st Century: The Pearls of Research*. Leawood, Kansas: American Academy of Family Physicians; 1999.
- 3. Nutting PA. *Methods and Procedures for Practice-Based Research*. (in preparation). Washington, DC: Agency for Healthcare Research and Quality; 2004.
- Nutting PA, Baier M, Werner JJ, Cutter G, Reed FM, Orzano AJ. Practice patterns of family physicians in practice-based research networks: a report from ASPN. Ambulatory Sentinel Practice Network. J Am Board Fam Pract. 1999;12:278-284.
- Nutting PA, Stange KC. Practice-based research: The opportunity to create a learning discipline. In: Rakel RE, ed. *The Textbook of Family Practice*; 2002.
- Nutting PA. Practice-based research: laboratories for outcomes and effectiveness research. Paper presented at: AHCPR Conference Proceedings. Primary Care Research: Theory and Methods, 1991; Washington, D.C.
- 7. Nutting P, Green L. Practice-based research networks: reuniting practice and research around the problems most of the people have most of the time. *J Fam Pract.* 1994;38:335-336.
- Nutting P. Practice-based research networks: building the infrastructure of primary care research. J Fam Pract. 1996;42:199-203.
- Nutting P. Community-Oriented Primary Care: From Principals to Practice. Washington, DC: U.S. Government Printing Office; 1987. DHHS Publication No. HRS-A-PE 86-1 (Available from the University of New Mexico Press).
- 10. Thomas P, Griffiths F, Kai J, O'Dwyer A. Networks for research in primary health care. *BMJ*. 2001;322:588-590.
- Thomas P, While A. Increasing research capacity and changing the culture of primary care towards reflective inquiring practice: the experience of the West London Research Network (WeLReN). *J Interprofessional Care.* 2001;15:133-139.
- 12. Green LA, Fryer GE, Yawn BP, Lanier D, Dovey SM. The ecology of medical care revisited. *N Engl J Med*. 2001;344(2021-2025).

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- Green LA, Miller RS, Reed FM, Iverson DC, Barley GE. How representative of typical practice are practice-based research networks? A report from the Ambulatory Sentinel Practice Network (ASPN). *Arch Fam Med.* 1993;2:939-949.
- 15. Green L, LJ L. Notions about networks: Primary care practices in pursuit of improved primary care. In: Mayfield J, ML G, eds. *Primary Care Research: An Agenda for the 90s*. U.S. Department of Health and Human Services, Public Health Service: Agency for Health Care Policy and Research; 1990:125-132.
- 16. Green L. The weekly return as a practical instrument for data collection in office-based research: a report from ASPN. *Fam Med.* 1988;20:185-188.
- 17. Green L, Niebauer L, Miller R, Lutz L. An analysis of reasons for discontinuing participation in a practicebased research network. *Fam Med.* 1991;23:447-449.
- 18. Green L, Nutting P. Family physicians as researchers in their own practices. *J Am Board Fam Pract.* 1994;7:261-263.
- 19. Green LA, Reed FM, Miller RS, Iverson DC. Verification of data reported by practices for a study of spontaneous abortion. *Fam Med.* 1988;20:189-191.
- 20. Talia AF, Stange KC, McDaniel RR, Aita VA, Crabtree BF. Understanding organizational designs of primary care practices. *J Healthcare Manage*. 2003;48:45-59.
- Stange KC, Zyzanski SJ, Smith TF, et al. How valid are medical records and patient questionnaires for physician profiling and health services research? A comparison with direct observation of patient visits. *Med Care.* 1998;36:851-867.
- 22. Stange KC, Miller WL, Crabtree BF, O'Connor PJ, Zyzanski SJ. Multimethod research: approaches for integrating qualitative and quantitative methods. *J Gen Intern Med.* 1994;9:278-282.
- Stange KC, Miller WL, McWhinney IR. Developing the knowledge base of family practice. *Fam Med.* 2001;33(4):286-297.
- 24. Stange KC. Practice-based research networks: Their current level of validity, generalizability, and potential for wider application. *Arch Fam Med.* 1993;2:921-923.
- 25. Wolf LE, Croughan M, Lo B. The challenges of IRB review and human subjects protections in practicebased research. *Med Care.* 2002;40:521-529.

- 26. Niebauer L, Nutting P. Practice-based research networks: the view from the office. *J Fam Pract.* 1994;38:409-414.
- Hickner J. Practice-based network research. In: Bass M, Dunn E, Norton P, Stewart M, Tudiver F, eds. *Conducting Research in the Practice Setting*. Vol 5. Newbury Park, California: Sage Publications, Inc; 1993:126-139.
- 28. Gilchrist V, Miller R, Gillanders W, et al. Does family practice at residency teaching sites reflect community practice? *J Fam Pract.* 1993;37(6):555-563.
- 29. Gilchrist VJ, Stange KC, McCord G, Bourget CC, Flocke SA. A comparison of the National Ambulatory Medical Care Survey (NAMCS) measurement approach with direct observation of outpatient visits. *Med Care.* 2004;(in press).
- Christoffel K, Binns H, Stockman J, et al. Practice-based research: opportunities and obstacles. *Pediatrics*. 1988;82:399-406.
- 31. Macaulay AC, Commanda LE, Freeman WL, et al. Participatory research maximises community and lay involvement. *BMJ.* 1999;319:774-778.
- 32. Crabtree BF, Miller WL, eds. Doing Qualitative Research. Thousand Oaks: Sage; 1999.
- Bass MJ, Dunn EV, Norton PG, Stewart M, Tudiver F, eds. Conducting Research in the Practice Setting. Newbury Park, California: Sage Publications; 1993.
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- 35. Donner A, Klar N. *Design and Analysis of Cluster Randomization Trials in Health Research*. New York: Oxford University Press; 2000.
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- Primary Care Practice-Based Research Networks. Fact Sheet, June 2001. AHRQ Publication No. 01-P020. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/research/pbrnfact.htm
- 40. Mold JW, Peterson KA. Primary Care Practice-Based Research Networks: Working at the Interface Between Research and Quality Improvement. *Ann Fam Med.* May 1, 2005 2005;3(suppl\_1):S12-20.
- 41. Westfall J, Stevenson J; North American Primary Care Research Group. A guided tour of communitybased participatory research: an annotated bibliography. *Ann Fam Med.* 2007 Mar-Apr;5(2):185-6.
- 42. Macaulay AC, Nutting PA. Moving the Frontiers Forward: Incorporating Community-Based Participatory Research Into Practice-Based Research Networks. *Ann. Fam. Med,* Jan 2006; 4: 4 - 7.
- 43. Pace WD, Staton EW, Holcomb S. Practice-Based Research Network Studies in the Age of HIPAA. *Ann. Fam. Med*, May 2005; 3: S38 S45.
- 44. Nagykaldi Z, Mold JW, Robinson A, Niebauer L, Ford A. Practice facilitators and practice-based research networks. *J Am Board Fam Med*. 2006 Sep-Oct;19(5):506-10. Review.
- 45. Nagykaldi Z, Mold JW, Aspy CB. Practice facilitators: a review of the literature. *Fam Med.* 2005 Sep;37(8):581-8. Review.
- 46. Westfall JM, Mold J, Fagnan L. Practice-based research--"Blue Highways" on the NIH roadmap. *JAMA*. 2007 Jan 24;297(4):403-6.
- 47. Green LA, Hickner J. A short history of primary care practice-based research networks: From concept to essential research laboratories. Journal of American Board of Family Medicine 2006; 19: 1-10.
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# Learning Plan

# Fellow's Name: Title of Concept Paper: Title of proposal for Specific Aims:

Career Goals/	Concept Paper	Products/Dates	Specific Aims	Products/Dates
Objectives	Activities		Activities	
Goal One:	<u>Objective 1</u> :	Objective 1:	Objective 1:	Objective 1:
	<u>Objective 2</u> :	<u>Objective 2</u> :	Objective 2:	<u>Objective 2</u> :
	Objective 3:	<u>Objective 3</u> :	Objective 3:	Objective 3:
Goal Two:				
	Objective 1:	Objective 1:	<u>Objective 1</u> :	Objective 1:
	<u>Objective 2</u> :	<u>Objective 2</u> :	Objective 2:	<u>Objective 2</u> :
	Objective 3:	<u>Objective 3</u> :	Objective 3:	Objective 3:
Goal Three:				
	Objective 1:	Objective 1:	Objective 1:	Objective 1:
	<u>Objective 2</u> :	Objective 2:	<u>Objective 2</u> :	<u>Objective 2</u> :
	Objective 3:	Objective 3:	<u>Objective 3</u> :	Objective 3: