

## CERTIFICATE PROGRAM IN PRACTICE-BASED RESEARCH METHODS

### SYLLABUS

#### PROGRAM YEAR 2:

SEPTEMBER 2016 – JUNE 2017

#### Program Co-Directors

**Jim Werner, PhD**, Associate Professor, Department of Family Medicine & Community Health, Case Western Reserve University, Collaborative Ohio Inquiry Network (COIN);  
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**LJ Fagnan, MD**, Professor, Department of Family Medicine, Oregon Health & Science University, Meta-network Learning and Research Center (Meta-LARC); fagnanl@ohsu.edu

#### Steering Committee Members

**Laura-Mae Baldwin, MD**, Professor, Department of Family Medicine, University of Washington, Meta-network Learning and Research Center (Meta-LARC)

**Melinda Davis, PhD**, Research Assistant Professor, Department of Family Medicine, Oregon Health & Science University, Meta-network Learning and Research Center (Meta-LARC)

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

**Rowena Dolor, MD**, Associate Professor, Department of Medicine, Duke University, Meta-network Learning and Research Center (Meta-LARC)

**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

**Zsolt Nagykaladi, PhD**, Associate Professor, Department of Family & Preventive Medicine, University of Oklahoma, Coordinated Consortium of Networks (CoCoNet2)

**Victoria Neale, PhD, MPH**, Professor, Department of Family Medicine and Public Health Sciences, Wayne State University, PRIME Net Center in Practice-based Research and Learning

**Don Nease, MD**, Associate Clinical Professor, Department of Family Medicine, University of Colorado, PRIME Net Center in Practice-based Research and Learning, Meta-network Learning and Research Center (Meta-LARC)

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

**Carmen Portillo, RN, PhD**, Professor and Chair, Community Health Systems, School of Nursing, University of California San Francisco

**Valory Pavlik, PhD**, Associate Professor, Department of Family and Community Medicine, Baylor College of Medicine, PRIME Net Center in Practice-based Research and Learning

**Jonathan N. Tobin, PhD**, President/CEO, Clinical Directors Network (CDN) & N<sup>2</sup> Network of Safety Net PBRNs; Co-Director, Community Engaged Research Core, The Rockefeller University Center for Clinical and Translational Science; Professor, Department of Epidemiology & Population Health, Albert Einstein College of Medicine/Montefiore Medical Center

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

**Andrea Wessell, PharmD**, Research Associate Professor, Department of Family Medicine, Medical University of South Carolina, PPRNet: Primary (Care) Practice Research Network

**Randy Wexler, MD, MPH**, Associate Professor, Department of Family Medicine, Ohio State University, Collaborative Ohio Inquiry Network (COIN)

### **Program Website**

Program information and the online application form are available at:

<http://www.collaborativeohioinquirynetwork.com/pbrn-certificate-program.html>

### **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) Compare and contrast the U.S and Canadian healthcare systems, research funding systems, and research infrastructures.
- 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.

Seven learning modalities will be used:

- 1) Participation in monthly webinars taught by PBRN experts;

- 2) Ongoing mentoring by an experienced PBRN investigator;
- 3) Participation in Peer Learning Group calls facilitated by experienced mentors;
- 4) Development of a Learning Plan;
- 5) Development of a research concept paper for a PBRN study;
- 6) Development of a refined Specific Aims section
- 7) Presentation of the Concept Paper, Specific Aims, and a Career Development plan at the program's Convocation in Bethesda, MD on June 20-21, 2017.

Each fellow will have a 'Primary Mentor' who is an experienced PBRN investigator that is preferably in the same location as the fellow. Fellows may have additional mentors to provide content expertise, who are not necessarily local.

Webinars led by PBRN content experts will be held one or two times each month on either the 2<sup>nd</sup> or 4<sup>th</sup> Thursday from 12:00-1:30 Eastern time. Advance reading will be required for most of the webinars. The webinars will be recorded and made available to fellows and the larger PBRN community. Live participation in at least 75% of the webinars is required.

Each fellow will participate in a Peer Learning Group of 6-8 fellows that provides a venue to discuss progress towards assignments and to obtain helpful input and troubleshooting. Peer Learning Groups will be facilitated by experienced mentors and will be held four times over the 10-month program on either a 2<sup>nd</sup> or 4<sup>th</sup> Thursday from 12:00-1:30 Eastern time. Fellows are required to participate in at least 3 of the 4 Peer Learning Group sessions.

Fellows will develop a concept paper in consultation with PBRN members, leaders, patients and other stakeholders. Mentors will advise fellows in methods for accessing stakeholders.

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 culminate on June 20-21, 2017 with a Convocation of fellows and mentors that will precede the NAPCRG PBRN Conference in Bethesda, MD. Fellows will present their concept papers, Specific Aims, and a Career Development plan at the Convocation, where they will receive constructive input from members of the Steering Committee, program mentors, and other fellows. Fellows are strongly encouraged to attend the NAPCRG PBRN Conference (June 22-23, 2017), which will be an excellent professional development opportunity.

## **Program Components**

### Steering Committee

The Steering Committee will oversee and guide the program, and members of the Steering Committee will review each fellow's Learning Plan, Concept Paper, Specific Aims, and Career Development Plan. 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.

### Mentors

A Primary Mentor will guide and support each fellow through the program. Primary Mentors should be experienced local PBRN investigators who have served as principal investigator on one or more research grants from NIH or AHRQ. Primary Mentors will guide fellows in accessing local PBRN leaders and members, and in formulating their learning plan, concept paper, specific aims section, career development plan, and convocation presentation. Additional content mentors can be added based on the fellow's learning needs and they do not need to be local.

Primary mentors are encouraged to attend the orientation webinar and are welcome to attend all of the webinars. Mentors are invited to participate in the program's Convocation that will take place on June 20-21, which will immediately precede the NAPCRG PBRN Conference that will be held on June 22-23, 2017.

### *Anticipated Time Commitment*

It is anticipated that each Primary Mentor will devote approximately 1-2 hours/month to mentoring their fellow during the ten month fellowship period. Mentors will not be financially compensated by the Certificate Program.

### Fellows

The Certificate program trains individuals who aspire to become independent PBRN research investigators. 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 career development awards but are seeking to develop into independent investigators. Finally, others may be established research investigators who want to gain exposure to PBRN methods and experience working with PBRNs.

### *Anticipated Time Commitment*

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

### *No Cost to Participate*

There is no cost to participate in the program, which is made available by the AHRQ-funded P30 Centers for Primary Care Practice-based Research and Learning.

### *Qualifying for the Certificate*

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

- 1) Post a descriptive video profile by the due date.

- 2) Actively participate in the entirety of at least 75% of training webinars.
- 3) Read assigned articles prior to each webinar.
- 4) Submit online progress updates at the specified time points.
- 5) Participate in at least 3 of the 4 Peer Learning Groups sessions.
- 6) Develop and submit a Learning Plan by the due date.
- 7) Complete and submit concept paper assignments by the due dates.
- 8) Complete and submit a Specific Aims section by the due date.
- 9) Complete and submit a Career Development plan by the due date.
- 10) Present a satisfactory concept paper, Specific Aims section, and a brief plan for further career development at the Convocation in Bethesda, MD on June 20-21, 2017.

Due dates for fellows' assignments:

<b>Assignment</b>	<b>Due Date</b>
Individual Video Profile	September 30
Learning Plan	October 31
Progress Updates	November 15 February 15 May 15
Concept paper Assignment	
1-Page Study Plan	December 5
Final Concept Paper	March 6
Reflection Paper	March 13
Specific Aims Section	May 1
Career Development Plan	May 15
Presentation	At Convocation June 20-21

#### Individual Video Profile

During the first few weeks of the program, fellows should post 2-5 minute videos informally introducing themselves, describing their professional backgrounds, discussing their research interests, and sharing what they hope to gain from the program. Videos can be recorded using

equipment the fellow has available, eg., a cell phone, camcorder, etc. Instructions for uploading the videos will be provided. Fellows should view the videos in order to become familiar with others in the training cohort.

### Webinar-Based Training

The program will hold fourteen 90-minute webinar-based training seminars; the webinar schedule is provided in the table below. **Webinars will be held from 12:00-1:30pm Eastern time on either the 2<sup>nd</sup> or 4<sup>th</sup> Thursday of each month.** An orientation webinar for fellows and mentors will be held during the first few weeks of the program. Each webinar will be led by a topic expert (see schedule below) who will present for approximately 60 minutes, and a discussion between the fellows and the presenter will take place for approximately 30 minutes. Some presenters welcome questions and discussion as they present, and others prefer to hold questions until their presentation is finished. The webinar interface permits fellows to type in their questions as they come up.

\*\*\*Fellows are required to participate in at least 75% of the webinars. Fellows should navigate to the Participation link on CourseSites after every webinar they attend to provide a post webinar rating after each webinar. Participation will be tracked through submission of the post-webinar rating survey. A missing rating survey will constitute a missed webinar.

\*\*\*If a fellow will be unable to attend a webinar, he or she should notify the Program Coordinator (Amanda Ross) by [submitting a form here](#) at least 24 hours beforehand. The webinars will be available two weeks after their air date for review by fellows who were unable to attend the original airing.

### 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. The Learning Plan template and a Learning Plan example are provided in **Appendix A**. The complete Learning Plan will be submitted through the CourseSites Learning Hub by the posted due date.

### Fellows' Progress Update

Fellows [will be asked to submit a progress report online at this link](#) on November 15, February 15, and May 15 in which they report their progress towards meeting their Learning Plan objectives and assignment deadlines, and provide feedback about the program.

### Peer Learning Groups

Each fellow will participate in a Peer Learning Group that will meet via video conference call four times during the 10-month program. The objectives of the Peer Learning Groups are the following:

1. Provide a venue for fellows to discuss their progress in completing assignments (eg., learning plan, concept paper, specific aims, career development plan, final presentation);
2. Serve as a forum for discussing assigned readings and webinar content;
3. Provide a way for fellows to share challenges they may be facing and to both provide and obtain guidance in overcoming obstacles;
4. Foster cross-network learning about the diversity of research being conducted in PBRNs in the U.S. and Canada;
5. Provide a way for fellows to develop rapport with one another.

Seven Peer Learning Groups will be coordinated by the AHRQ P30 Centers of Practice-Based Research and Learning, and two additional groups will be coordinated by PBRN Centers in Canada. Fellows who are affiliated with a Center will become part that Center's Peer Learning Group, and fellows who are not affiliated with a Center will be assigned to one of the Peer Learning Groups.

Each of the four Peer Learning Group calls will be facilitated by one or more mentors who are affiliated with the Center that is coordinating that specific Peer Learning Group. These Mentor-Facilitators will be reminded of upcoming deadlines and provided with a suggested agenda for each call, which they can tailor to the needs of their group. After each call, Mentor-Facilitators will submit a brief summary of the call to the program's coordinating center using an online form.

Peer Learning Group calls will take place from 12:00-1:30 Eastern time on either the 2<sup>nd</sup> or 4<sup>th</sup> Thursday of the month, as shown on the schedule. An online video conferencing application will be used for the Peer Learning Group calls. Fellows should use a computer with a webcam to enable video conferencing. Before the first call, fellows should view the Individual Video Profiles posted by the other members of their Peer Learning Group.

#### 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 and investigators, network members, and patients. Mentors should guide their 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. Fellows will present their concept papers at the program's Convocation on June 20-21, 2017. Guidelines for writing the concept paper are provided in **Appendix B**. Concept papers will be submitted through the CourseSites Learning Hub by the posted due date.



### Specific Aims

Building upon the concept paper, each fellow will write a Specific Aims section for an NIH/AHRQ research proposal designed to be implemented within a PBRN. Mentors will be instrumental in providing guidance. Fellows will present their Specific Aims at the program's Convocation on June 20-21, 2017. Guidelines for writing Specific Aims are provided in **Appendix C**. Specific Aims will be submitted through the CourseSites Learning Hub by the posted due date.

### Career Development Plan

Near the end of the program, fellows will outline their prospective goals for development of their research careers over the next 1-3 years. Guidelines are provided in **Appendix D**. The Career Development Plan will be submitted through the CourseSites Learning Hub by the posted due date.

### Presentation at Convocation

Fellows will present their concept papers, specific aims sections, and a brief career development plan at the Convocation of fellows, mentors, and Steering Committee members that will be held prior to the NAPCRG PBRN Conference in Bethesda, MD on June 20-21, 2017. Program certificates will be awarded at the Convocation. Guidelines for the presentation are provided in **Appendix E**. Presentations will be submitted through the CourseSites Learning Hub by the posted due date.

### **Program Administration**

The program's coordinator is Amanda Ross of COIN ([air67@case.edu](mailto:air67@case.edu)).

The online learning management system, [CourseSites by BlackBoard](#), will be used to distribute materials and facilitate learning. All communication for the program will occur through this system. All assignments will also be uploaded to this system. Each fellow will receive an e-mail invitation to enroll in the PBRMCert Cohort 2 Program on *CourseSites*.

### **Readings**

Webinar readings are indicated on the webinar schedule provided below. Articles will be made available on *CourseSites* for downloading.

The program has one required text that can be freely downloaded (see the link below):

Neale, AV, et al. *PBRN Research Good Practices (PRGP)*. September 2014.

Free download available at: <http://www.napcrg.org/PBRNResearchGoodPractice>

### **Webinar Presenters**

**Laura-Mae Baldwin, MD**, Professor, Department of Family Medicine, University of Washington, MOSAIC: Meaningful Outcomes and Science to Advance Innovations Center of Excellence

**Melinda Davis, PhD, Research Assistant Professor**, Department of Family Medicine, Oregon Health & Science University, Meta-network Learning and Research Center (Meta-LARC)

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

**Mary Dolansky, PhD, RN**, Associate Professor School of Nursing, Case Western Reserve University, Cleveland, OH

**Rowena Dolor, MD**, Associate Professor, Department of Medicine, Duke University, Meta-network Learning and Research Center (Meta-LARC)

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

**LJ Fagnan, MD**, Professor, Department of Family Medicine, Oregon Health & Science University, Meta-network Learning and Research Center (Meta-LARC)

**Alex Fiks, MD, MSCE**, Associate Professor, Department of Pediatrics, Associate Director, Pediatric Research in Office Settings (PROS), Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA

**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

**Rodger Kessler, PhD, ABPP**, Research Associate Professor, Department of Family Medicine University of Vermont, Burlington, VT

**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

**Alex Krist, MD, MPH**, Associate Professor, Department of Family Medicine and Community Health, Virginia Commonwealth University, Co-director, Ambulatory Care Outcomes Research Network

**Zsolt Nagykaladi, PhD**, Associate Professor, Department of Family & Preventive Medicine, University of Oklahoma, Coordinated Consortium of Networks (CoCoNet2)

**Victoria Neale, PhD, MPH**, Professor, Department of Family Medicine and Public Health Sciences, Wayne State University, PRIME Net Center in Practice-based Research and Learning

**Don Nease, MD**, Associate Clinical Professor, Department of Family Medicine, University of Colorado, PRIME Net Center in Practice-based Research and Learning, Meta-network Learning and Research Center (Meta-LARC)

**Rebecca Roper, MS, MPH**, Director, Practice-Based Research Network Initiative, Project Officer, Health IT-enabled Quality Measures, Agency for Healthcare Research and Quality, Rockville, MD

**Kurt Stange, MD, PhD**, Professor of Family Medicine & Community Health, Epidemiology & Biostatistics, Oncology and Sociology, Case Western Reserve University, Collaborative Ohio Inquiry Network (COIN)

**Jonathan N. Tobin, PhD**, President/CEO, Clinical Directors Network (CDN) & N<sup>2</sup> Network of Safety Net PBRNs; Co-Director, Community Engaged Research Core, The Rockefeller University Center for Clinical and Translational Science; Professor, Department of Epidemiology & Population Health, Albert Einstein College of Medicine/Montefiore Medical Center

**Steven Woolf, MD, MPH**, Professor, Department of Family Medicine and Population Health, Director, VCU Center on Society and Health, Virginia Commonwealth University, Richmond, VA

## CERTIFICATE PROGRAM IN PRACTICE-BASED RESEARCH METHODS

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

	Title	Topics	Readings	Presenter
<b>Session 1: 9/8/16</b>	Introduction and Theory of Practice-Based Research Networks (PBRNs)	Reflective, inquiring practice Types of networks & examples; Success & failure in practice-based research	Required: 12, 16, 48, 51, 52 Supplemental 2, 5, 6, 7, 8, 9, 11, 13, 23, 25, 27, 31	Kurt Stange
<b>Session 2: 9/22/16</b>	Program orientation for Fellows & Primary Mentors	Program goals, structure, timeline, deliverables, Q & A	Program syllabus	Jim Werner
<b>Session 3: 10/13/16</b>	PBRN development and maintenance  Use of practice facilitators	Enrollment methods; Network infrastructure; Representativeness; Changing PBRN landscape	Required: 45, 47, 53, 54, 104 Supplemental 1, 3, 4, 14, 17, 24, 26, 28, 30, 36, 44, 102,	Zsolt Nagykalai  Bill Hogg

<b>Session 4: 10/27/16</b>	Recruitment and engagement of clinicians, practices, patients, & healthcare systems	Recruitment & engagement methods; Bottom-up research		LJ Fagnan Melinda Davis
<b>Session 5: 11/10/16</b>	Participatory research in PBRNs -- Patient Centered Outcomes Research	Participatory approaches; Patient engagement & PCOR	Required: 31, 32, 41, 42	Lyndee Knox Don Nease
<b>Peer Learning Group Session #1: 12/1/16</b>				
<b>Session 6: 12/8/16</b>	Research using electronic health records & big data	Electronic health records-based research, DARTNet Institute	Required: 49	Laura-Mae Baldwin Alex Fiks Alex Krist
<b>Session 7: 1/12/17</b>	Quality improvement research; Alliances and methods for practice improvement	Linking quality improvement & clinical research	Required: 40	Chet Fox Mary Dolansky
<b>Session 8: 1/26/17</b>	Research designs, sampling methods and nested analyses	Designs and techniques used in practice-based research	Required: 33, 34, 35, 39	Miriam Dickinson Don Nease
<b>Peer Learning Group Session #2: 2/9/17</b>				
<b>Session 9: 2/23/17</b>	Obtaining funding for PBRN research	Methods for seeking funding from NIH, AHRQ, other federal agencies, foundations, & professional	Required: 46	Rowena Dolor Rebecca Roper Sabrina Wong

<b>Session 10:</b> 3/9/17	Comparing and contrasting U.S. and Canadian healthcare systems and research infrastructures	Opportunities and challenges		LJ Fagnan
<b>Peer Learning Group Session#3: 3/23/17</b>				
<b>Session 11:</b> 4/13/17	Translational research in PBRNs -- Linking research to policy	Range of translational research studies in PBRNs; Implementation of translational research; How research influences policy	Required: 49	Jonathan Tobin  Steve Woolf
<b>Session 12:</b> 4/27/17	Qualitative methods and multimethod research methods in PBRN research	Qualitative & mixed methods PBRN research	Required: 1, 22, 23, 34,35	Nancy Elder
<b>Peer Learning Group Session #4: 5/11/17</b>				
<b>Session 13:</b> 5/25/17	Writing PBRN research for publication -- Methods of research dissemination	Writing, review, and publication process; Broad dissemination to through diverse avenues		Victoria Neale  Juliann Binienda
<b>Session 14:</b> 6/8/17	Methods for implementation of complex interventions in PBRNs	Implementation of complex interventions in real world practices	Required: 1, 25, 38, 39, 43	Rodger Kessler  Connie van Eeghen

## READING LIST

### [ACCESS THE READINGS IN A GOOGLE DOCS FOLDER HERE](#)

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.
4. 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.
5. Nutting PA, Stange KC. Practice-based research: The opportunity to create a learning discipline. In: Rakel RE, ed. *The Textbook of Family Practice*; 2002.
6. 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.
8. Nutting P. Practice-based research networks: building the infrastructure of primary care research. *J Fam Pract*. 1996;42:199-203.
9. 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.
11. 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).
13. Green LA, Dovey SM. Practice based primary care research networks. They work and are ready for full development and support. *BMJ*. 2001;322:567-568.
14. 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 practice-based 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.

21. 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.
23. 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 practice-based 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.
27. 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).
30. 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.



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**Appendices**

- A. Learning Plan Template and Example
  - B. Concept Paper
  - C. Specific Aims
  - D. Career Development Plan
  - E. Presentation at Convocation
- 

**Appendix A. Learning Plan Template and Example**

Develop your Learning Plan in consultation with your mentor(s). A template for the Learning Plan is provided below, followed by a partially completed Learning Plan that is provided as an example.

**Upload your Learning Plan to CourseSites by October 31.**

**Learning Plan Template**

**Fellow:** \_\_\_\_\_

**Primary Mentor:** \_\_\_\_\_

<b>Goals/Objectives</b>	<b>Activities</b>	<b>Products/Dates</b>
Goal One: (Concept paper)	<u>Objective 1:</u> 1.a. 1.b. 1.c.	<u>Objective 1:</u> 1.a. 1.b. 1.c.
Objectives: 1. 2. 3.	<u>Objective 2:</u> 2.a. 2.b. 2.c.	<u>Objective 2:</u> 2.a. 2.b. 2.c.
	<u>Objective 3:</u> 3.a. 3.b. 3.c.	<u>Objective 3:</u> 3.a. 3.b. 3.c.

<p>Goal Two: (Specific Aims)</p> <p>Objectives:</p> <ol style="list-style-type: none"> <li>1.</li> <li>2.</li> <li>3.</li> </ol>	<p><u>Objective 1:</u></p> <ol style="list-style-type: none"> <li>1.a.</li> <li>1.b.</li> <li>1.c.</li> </ol> <p><u>Objective 2:</u></p> <ol style="list-style-type: none"> <li>2.a.</li> <li>2.b.</li> <li>2.c.</li> </ol> <p><u>Objective 3:</u></p> <ol style="list-style-type: none"> <li>3.a.</li> <li>3.b.</li> <li>3.c.</li> </ol>	<p><u>Objective 1:</u></p> <ol style="list-style-type: none"> <li>1.a.</li> <li>1.b.</li> <li>1.c.</li> </ol> <p><u>Objective 2:</u></p> <ol style="list-style-type: none"> <li>2.a.</li> <li>2.b.</li> <li>2.c.</li> </ol> <p><u>Objective 3:</u></p> <ol style="list-style-type: none"> <li>3.a.</li> <li>3.b.</li> <li>3.c.</li> </ol>
<p>Goal Three: (Career Development Plan)</p> <p>Objectives:</p> <ol style="list-style-type: none"> <li>1.</li> <li>2.</li> <li>3.</li> </ol>	<p><u>Objective 1:</u></p> <ol style="list-style-type: none"> <li>1.a.</li> <li>1.b.</li> <li>1.c.</li> </ol> <p><u>Objective 2:</u></p> <ol style="list-style-type: none"> <li>2.a.</li> <li>2.b.</li> <li>2.c.</li> </ol> <p><u>Objective 3:</u></p> <ol style="list-style-type: none"> <li>3.a.</li> <li>3.b.</li> <li>3.c.</li> </ol>	<p><u>Objective 1:</u></p> <ol style="list-style-type: none"> <li>1.a.</li> <li>1.b.</li> <li>1.c.</li> </ol> <p><u>Objective 2:</u></p> <ol style="list-style-type: none"> <li>2.a.</li> <li>2.b.</li> <li>2.c.</li> </ol> <p><u>Objective 3:</u></p> <ol style="list-style-type: none"> <li>3.a.</li> <li>3.b.</li> <li>3.c.</li> </ol>

### Learning Plan Example

Fellow: \_\_\_\_\_

Primary Mentor: \_\_\_\_\_

Career Goals/ Objectives	Activities	Products/Dates
<p><u>Goal One:</u> Develop a concept paper in order to develop knowledge and skills in PBRN stakeholder engagement.</p>	<p><u>Objective 1:</u> 1.a. Meet with Mentor to discuss concept paper.</p> <p><u>Objective 2:</u> 2.a. Review literature 2.b. Write research questions.</p> <p><u>Objective 3:</u> 3.a. Write '7 questions to get started,' 3.b. Write 1-page 'study plan summary.'</p> <p><u>Objective 4:</u> 4.a. Through mentor, identify PBRN stakeholders &amp; request that they to provide input on 1-page study plan summary. 4.b. Engage stakeholders on research topic using 1-page study plan summary and gather their input &amp; perspectives.</p> <p><u>Objective 5:</u> 5.a. Write draft of concept paper using stakeholder input.</p> <p><u>Objective 6:</u> 6.a. Distribute draft concept paper to stakeholders 6.b. Obtain stakeholder input.</p> <p><u>Objective 7:</u> 7.a. Refine and finalize concept paper using stakeholder input. 7.b. Submit concept paper.</p> <p><u>Objective 8:</u> 8.a. Write brief reflection paper about knowledge and skills acquired towards achieving Goal One.</p>	<p><u>Objective 1:</u> 1.a. Meet with Mentor by (date).</p> <p><u>Objective 2:</u> 2.a. Review literature by (date); 2.b. Write research questions by (date).</p> <p><u>Objective 3:</u> 3.a. Write '7 questions to get started' by (date). 3.b. Write 1-page 'study plan summary' by (date).</p> <p><u>Objective 4:</u> 4.a. Connect with stakeholders by (date). 4.b. Gather input using 1-page study plan summary by (date).</p> <p><u>Objective 5:</u> 5.a. Write draft of concept paper by (date).</p> <p><u>Objective 6:</u> 6.a. Distribute concept paper by (date). 6.b. Obtain stakeholder input on concept paper by (date).</p> <p><u>Objective 7:</u> 7.a. Finalize concept paper by (date). 7.b. Submit on CourseSites by (date).</p> <p><u>Objective 8:</u> 8.a. Write reflection paper by (date). 8.b. Submit on CourseSites by (date).</p>

	8.b. Submit reflection paper.	
<u>Goal Two:</u> Develop a Specific Aims section in NIH format for a PBRN-based research grant application.	<u>Objective 1:</u> <u>Objective 2:</u> <u>Objective 3:</u>	<u>Objective 1:</u> <u>Objective 2:</u> <u>Objective 3:</u>
<u>Goal Three:</u> Write a 3-5 year Career Development Plan	<u>Objective 1:</u> <u>Objective 2:</u> <u>Objective 3:</u>	<u>Objective 1:</u> <u>Objective 2:</u> <u>Objective 3:</u>

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## **Appendix B. Concept Paper Assignment**

### **Developing a Research Concept Paper with Stakeholder Input**

#### **Learning Objectives**

After completion of this assignment, learners will be able to:

- 1) Develop and refine research questions.
- 2) Identify and engage key PBRN stakeholders who are relevant to their selected research topic.
- 3) Systematically gather stakeholder input and perspectives on the research topic and methods for studying it.
- 4) Develop and refine a research concept paper.

#### **Introduction**

In this key component of the program, you will develop a research concept paper. The concept paper is a means to develop your ideas into a research study using a flexible framework. Concept papers are useful for sharing research ideas with other investigators, PBRN members, community members, and funding agencies. You will capture input from key stakeholders about your topic and use it to develop and refine the study you will ultimately describe in the concept paper. Later in the program, you will write a Specific Aims section based on the final version of your concept paper. The recommended steps involved in developing the concept paper are provided below.

#### **Steps**

- 1) If you have not already done so, identify a research area of interest and narrow it to a specific topic. This is likely to involve consulting the research literature to determine what is known about the topic and identifying important gaps in existing knowledge. Keep track of the relevant literature as you will use it for the literature review section of the concept paper.
- 2) Draft a primary research question along with secondary research questions. The primary research question should ultimately be the focus of your study plan, while secondary research questions can address other predictors or outcomes. Useful resources are the readings by Cummings, Browner, and Hulley (2007)<sup>1</sup> and Kwiatkowski and Silverman (1998)<sup>2</sup>. Keep in mind that you are developing preliminary research questions that may change as you work through the steps outlined here. Allow your mentor to review these preliminary research questions before moving ahead.
- 3) Answer the “Seven Questions to Get Started” (provided below) and discuss your responses with your mentor. Refine your ideas with your mentor’s input and your continued reflection on the questions and the research literature. Consult the research literature again if your research questions or your methods change. Iteratively compare what is already established in the research literature, what is not established in the literature (gaps), and what you are seeking to learn through a research study. Refine your research questions and methods as needed.
- 4) The characteristics of a good research question is that it be Feasible, Interesting, Novel, Ethical, and Relevant (which form the mnemonic FINER). Using the reading by Cummings, Browner, and Hulley (2007)<sup>1</sup> as a resource, determine if your research questions meet the FINER criteria. If any of the criteria are not met, modify your research questions and methods in the “Seven Questions to Get Started” document.
- 5) Develop a study plan of no more than 1 single spaced page in length that contains the information from your “Seven Questions to Get Started.” Essentially, this will contain the contents of your ‘Seven Questions’ document with section headings in place of the 7 questions. For example, use the heading ‘Research Questions’ rather than ‘What is your research question (if it’s not finalized, what is it presently)?’ Write to a general audience and avoid using scientific jargon. Allow your mentor to review this document. Modify your 1-page study plan based on feedback from your mentor. Upload your 1-page study plan to CourseSites. **DUE DECEMBER 5.**
- 6) With input from your mentor and PBRN leaders, identify key stakeholders to consult about your chosen research topic. These are individuals who are knowledgeable about the topic of your research or affected by it, and whose perspectives on your one-page study plan would be helpful. Depending on the focus of your study, this may include PBRN member clinicians and leaders, research investigators, patients, community members, or others.
- 7) Develop a plan to engage and obtain input from the stakeholders at two points in time. The first time point will involve key individuals who read and provide input on your one-page study plan summary. The second time point will be after writing a draft of the concept paper. It may be useful to follow the Community Engagement studio<sup>3,4</sup> framework for obtaining stakeholder input, or methods such as individual and group

interviews. The PCORI Methodology Report<sup>5</sup> also provides guidelines for engaging stakeholders in research. Obtain feedback from your mentor on your plan to engage stakeholders and modify as needed.

- 8) Gather initial stakeholder input on your one-page study plan summary from Step 5 (this is the first time point). Capture their input in a systematic way (eg, audio recording, taking detailed notes, etc). Provide this information to your mentor and determine if it has the potential to change your study, and if so, refine the study plan accordingly. Upload your refined study plan to CourseSites.
- 9) Write an initial draft of the research concept paper. The structure of the concept paper is outlined below. Write in a style that is appropriate for your target audience and refrain from using scientific jargon if your key stakeholders include community members or others who may not have much training in research methods. Submit the draft to your mentor for his or her input and then modify the concept paper as needed.
- 10) Present or distribute the concept paper to relevant stakeholders for their critique (second time point) per Step 7. This may involve obtaining feedback from individuals and/or groups as described in step 7. Capture their feedback as described in step 8.
- 11) Incorporate stakeholders' input into the draft of your research concept paper, with guidance from your mentor.
- 12) Finalize the concept paper and submit it to your mentor(s), PBRN Director for their input. Upload your final concept paper to CourseSites. **DUE MARCH 6.**
- 13) Reflect on this process and write a brief reflection paper of 500-1000 words on what you learned. Address the following topics in your reflection paper:
  - a) Describe your experience of developing the "Seven Questions to Get Started" and working through the FINER criteria. Indicate where changes were needed based on the FINER criteria, the research literature, and input from your mentor.
  - b) Indicate how input from stakeholders affected your concept paper at each time point;
  - c) Assess the value of stakeholders' input to your concept paper;
  - d) Describe any challenges you encountered obtaining stakeholder input;
  - e) Based on your learning, indicate what you would do differently if you were to use this process to develop a concept paper in the future. Upload your reflection paper to CourseSites. **DUE MARCH 13.**

### **Structure of the Concept Paper<sup>6</sup>**

Please include the following sections in your concept paper. The concept paper may be as few as 1500 words in length (3 single spaced pages) to as many as 5,000 words (10 single spaced pages) plus references.

Statement of the Problem — provides the purpose for the research. This section of the concept paper introduces the problem under investigation, addresses why the researcher wants to investigate this problem, and how the research findings may help. Supporting documentation, including statistical data if available, should be used to emphasize the need for this research.

This section is one of the most important sections of the concept paper; its serves to gain the reader's attention and support. The first few sentences of the concept paper should intrigue the reader to spike his or her interest and encourage further reading.

As you begin to write the problem statement of your concept paper, consider why you believe that the problem is important. Consider how your study relates to previous work in the field. Finally, consider the theoretical and practical implications involved in your research project. A well-developed, concise, and clear problem statement will lay the foundation for a strong concept paper.

Preliminary Literature Review — provides identification of major literature that supports and validates the topic. The most successful research projects have been based on the research of predecessors, and this section of the concept paper should provide enough of a description of previous research to plant seeds in the mind of the reader suggesting more information is needed. A strong concept paper is based on a wide-range literature review that is condensed into a summary of key points.

Goal Statement -- provides a broad or abstract intention, including the research goals and objectives. This part of the concept paper should tell the reader “who, what and when” regarding the research goal.

Research Questions -- provides a preliminary view of the questions that you will investigate. Research questions are based on theory, past research, experience, and need. These questions will direct the research methodology; their inclusion in the concept paper links the research problem with the methodology. For some, composing the research questions may be the most difficult part of the research project, or possibly the most difficult aspect of writing the concept paper. The questions will direct everything that will be done; therefore, it is important that they are accurate and focused on the main research problem. The research questions will specifically direct the research and the type of analyses conducted.

Methods -- provides the methods for how to conduct the research and analyze the data. The goals and research questions identified in previous sections of the concept paper should directly relate to the research methods described in this section. Specify the study design and describe the methods that you plan to use for recruitment, data collection, analysis, instrument design, and any other components of the project. You have the option to write an abridged methods section or a fully detailed method section.

Timeline -- provides a range of time for completion of the project, highlighting key elements for each stage of the project. This section provides structure for managing sections of the project within a realistic time frame.

References -- provides references to the material cited in the literature review and elsewhere in the concept paper.

### ***Seven Questions to Get Started***

1. What is your research question (if it's not finalized, what is it presently)?



2. What already is known about this topic?
3. Who will be the participants in the study? Or, if you will you be using existing data, what data source(s) will you use?
4. What will the study measure or assess?
5. How will you collect data? (or access existing data?)
6. What feasibility issues do you need to consider? (access to population/data, time, skills, funding, etc.)
7. Why is the study worth doing?

## References

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## **Appendix C. Specific Aims Assignment**

### **Developing a Specific Aims Section**

A Specific Aims section is a 1-page document that functions as an abbreviated version of a full grant application, and is generally considered to be the most important part of the proposal. With guidance from your mentor, draft a Specific Aims section based on your concept paper.

In addition, identify a funding opportunity announcement that your Specific Aims section could target. This can be a request for applications from a federal agency or from a foundation, although your Specific Aims should follow the general NIH format for Specific Aims sections. Identify the funding agency (eg, NCI, PCORI, Robert Wood Johnson Foundation), the funding mechanism (eg, R21, R01, etc), the FOA name, its focus, the maximum number of project years permitted, the maximum allowable annual budget, and explain why the RFA is a good fit for your line of inquiry.

You are not required to pursue the funding opportunity that you identify, rather the purpose of this assignment is to gain experience in identifying funding opportunities that are suitable your line of inquiry. **Provide information about the funding opportunity on the second page of the Specific Aims document.**

### *Guidance*

A general guide to writing an NIH Specific Aims section is provided below (*NIH Grant Applications: The Anatomy of a Specific Aims Page*). It discusses in detail the components of a Specific Aims section and the purpose of each. It uses colored highlighting in explanations of the Aims, so be sure to view or print it in color.

It will be helpful to obtain a few examples of Specific Aims sections from funded grant applications from your colleagues and mentors. If your mentor uses a different approach in structuring Specific Aims sections, it is fine to use the structure he or she prefers. **The Specific Aims section is due May 1.**

### ***NIH Grant Applications: The Anatomy of a Specific Aims Page***

Source: <http://www.biosciencewriters.com/NIH-Grant-Applications-The-Anatomy-of-a-Specific-Aims-Page.aspx>

Release Date: April 09, 2015

Category: Scientific Grant Writing

Author: *Michelle S., Ph.D.*

The Specific Aims section is the most vital part of any NIH grant application. In this section, you must quickly gain the reviewers' trust and confidence while simultaneously convincing them that your work is important to fund. You must also convey that you and your team are the best people to complete the work you've proposed. For these reasons, the Specific Aims can be one of the most difficult sections to write. In this article, we provide some tips on structure, content, and organization of your Specific Aims page.

The Specific Aims section is central to your grant proposal. Therefore, it should be the first section you write. You may think of your Specific Aims page as an abbreviated version of the full grant. By having this page written and well-thought out, the remainder of grant application will be easier to write. The Specific Aims section is due on

### The Introductory Paragraph

In this paragraph, your goal should be to introduce your research subject to the reviewers and quickly capture their attention. This paragraph should describe the significant gap in knowledge

that directly relates to the critical need the funding entity deals with. It is critical to know your funding entity's mission statement and ensure the critical need you are trying to fill fits well within its mission. It should include the following information:

*First Sentence/Hook:* In this sentence, briefly describe what your proposal will be about. Ideally, this sentence should convey a sense of importance or urgency to your research. Explain quickly WHAT your research topic is and WHY it is critical that you conduct the research (i.e. saving lives, preventing cancer, etc.)

*What is Known:* State what is currently known in the specific field. This part should not be very long (3-5 sentences) but it should ground the reader in the subject of your research. Provide the reader with only the necessary details to understand why you are proposing the work. Remember to be concise and focused on only the key points.

*Gap in Knowledge:* The gap in knowledge is the piece of information that is not known. Clearly state the gap in knowledge that needs to be addressed. Convey that your research will fill this gap using the funding that you are requesting. In the example Specific Aims page we use here (See Figure 1), the most critical piece of the gap in knowledge has been italicized. This technique can be useful to emphasize the most important words or phrases in your Specific Aims page. If you choose to use *italics* or underline to emphasize key points, remember to do so moderately. Overuse of italics or underlining can be distracting.

*The Critical Need:* The critical need is the knowledge (hypothesis-driven), technique, new compound, or treatment that you propose to develop. This need is important to increase medically relevant knowledge or improve health care. The critical need is the reason your proposal should be funded. Emphasize the significance of the problem you are trying to address. Additionally, it should be clear in this paragraph that your research proposes the next logical step to advance the field.

Below is an example of an introductory paragraph:

Viruses are thought to be involved in 15% to 20% of human cancers worldwide, thus providing critical tools to reveal common mechanisms involved in human malignancies. As the etiologic agent of adult T cell leukemia/lymphoma (ATLL), human T cell leukemia virus type I (HTLV-1) is just such a virus. HTLV-1 encodes a potent oncoprotein, Tax, which regulates important cellular pathways including gene expression, proliferation, apoptosis, and polarity. Over the years, Tax has proven to be a valuable model system in which to interrogate cellular processes, revealing pathways and mechanisms that play important roles in cellular transformation. Although the Tax oncoprotein has been shown to transform cells in culture and to induce tumors in a variety of transgenic mouse models, *the mechanism by which Tax transforms cells is not well understood*. A large number of Tax mutants have been generated and their biological activities have been thoroughly characterized, primarily in cell culture systems. *Currently, a major obstacle in the field* is that the transforming activity of Tax mutants cannot be compared using available transgenic models due to random transgene integration sites, variable transgene copy

number, and inconsistent transgene expression levels, making it difficult to link the biological activities of Tax mutants with their transforming potential.

Color Key: Hook Known Information Gap in Knowledge Critical Need

*Figure 1. The Introductory Paragraph.* Sections of the paragraph have been color coded to highlight each critical component.

### The Second Paragraph

In this paragraph, your goal should be to introduce the solution that fills the gap in knowledge. It is critical to convince your reviewers that you (and your colleagues) have the solution to address the current knowledge gap and the expertise to accomplish this solution. Keep your wording simple, relevant, and to the point. You will want to address the following points:

- What do you want to do?
- Why are you doing it?
- How do you want to do it?

There is some flexibility in this paragraph, depending upon how your proposal is structured and what your goals are. For example, your research may be strictly hypothesis-driven and seek to test several elements of one general hypothesis. In other cases, you may be seeking to develop a critical tool or technique in the proposal. Based on these variations, this paragraph will shape up differently. However, it should include the following components:

*Long-Term Goal:* This is your overarching research goal. Because you are asking for support from a particular funding entity, it is important to ensure that your long-term goals align with the mission of your funding entity. Keep your wording general in this sentence—you are stating your long-term plans, and the reviewers understand that the specifics may be subject to change.

*Hypothesis and Proposal Objectives:* Your proposal should contain both of these components, depending on the long-term goal. State your central hypothesis clearly, specifically, and with simple language. You want to demonstrate to the reviewers that you have a hypothesis-driven proposal that is testable. Describe how your project addresses the critical need, and clearly state the proposed solution. In general, avoid vague hypotheses because it will be unclear to the reviewers what you expect to determine with the proposed research.

*Rationale:* Explain how you arrived at your central hypothesis (for example, using past studies and published literature). Briefly, state what your project's completion would make possible (e.g., new therapeutics), and tie it to the funding entity's mission.

*Qualifications:* Briefly state why your experimental design and your team are the best to accomplish the research goals. You can mention factors such as your preliminary data, personnel qualifications, laboratory equipment, etc., but it is important to keep it concise.

Here is an example of a second paragraph:

*To solve this problem* we will develop an innovative mouse model system in which to study Tax tumorigenesis using targeting vectors containing wild-type or mutant Tax genes that are silenced by a preceding floxed stop cassette. These vectors will be knocked in to the *Rosa26* locus of recipient mice by recombination. After crossing these mice with Lck-CRE mice, the stop cassette will be specifically excised in developing thymocytes where the Lck promoter is active, allowing conditional expression of wild-type or mutant Tax proteins in T cells, the natural target of HTLV-1 infection. The feasibility of our proposed mouse model is supported by the fact that Lck-Tax transgenic mice have been developed and produce a leukemia that closely resembles ATLL. Thus, targeting of Tax expression in cells in which the Lck promoter is active is expected to produce a similar disease in our model. In our improved model system, insertion into the *Rosa26* locus will eliminate random integration sites and standardize gene copy number resulting in consistent levels of wild-type and mutant Tax protein expression.

Color Key:    Long-term Goal    Proposal  
 Objective    Rationale    Hypothesis    Pay-off

*Figure 2. The Second Paragraph.* Sections of the paragraph have been color coded to highlight each critical component. Note: This example does not expressly contain *Qualifications* and does include some *Pay-off*, which is described in this article as part of the final paragraph. These variations highlight the flexibility you have while creating a strong Specific Aims page.

### The Aims

In this section, you will describe briefly each of the aims you will use to test your hypothesis. Ideally, the aims should be related, but not dependent, upon each other. If you do this, the failure of one aim (or an unexpected result from one aim) does not negatively influence any other aim or prevent the completion of the other aims.

Within 2-4 sentences each, you should describe the experimental approach and how each aim will help answer your larger hypothesis. A typical NIH R01 grant will have between 2 and 4 Aims. Plan to describe each aim in a separate paragraph. Additionally, these tips may help you to formulate your aims sections:

- Give your aim an active title that clearly states the objective in relationship to the hypothesis.
- Include a brief summary of the experimental approach and anticipated outcomes for each aim.
- If you have room, you may wish to include a sub-hypothesis (the small portion of the overall hypothesis) and a small description of the pay-off of each aim. Including these is helpful to creating the impression that each aim is valuable, testable, and independent of the others.
- To make it easier for the reviewers to clearly read and understand each aim, it is often helpful to use headings and/or bullets to delineate each specific aim.

Here is an example of the Aims section:

**Aim 1 will establish an innovative mouse model for HTLV-1 Tax tumorigenesis.** Targeting vectors containing silenced wild-type or mutant Tax genes will be knocked in to the Rosa26 locus of C57BL/6 mice. These mice will then be crossed with homozygous Lck-CRE mice, thereby excising the stop cassette and generating mice that express wild-type or mutant Tax proteins specifically in T cells.

**Aim 2 will examine the effect of mutations that disable specific biological functions of Tax on Tax-mediated tumorigenesis.** Tax can bind to and regulate the activity of members of the SRF, CREB, NF- $\kappa$ B and PBM protein families, each of which has been implicated in oncogenesis. Mice established in Aim 1 will allow us to compare for the first time the tumorigenic potential of wild-type and mutant Tax proteins in an effort to identify pathways that are required for Tax tumorigenesis.

Color Key: Aim Title Experimental Strategy Outcome or Impact

*Figure 3. The Aims Section.* Sections of the paragraph have been color coded to highlight each critical component. Note the active voice in the titles of each aim and the use of boldface text to highlight the titles.

### The Final Summary Paragraph

This final paragraph of the Specific Aims is often overlooked, but it is vital for the impact of your proposal. Think of your Specific Aims page as an hourglass, where the wide parts represent the general information and global significance, and the narrow parts are the fine details. If you end with the Aims Section (above) you will end on fine details and a narrow scope. An hourglass with a narrow base is unstable and will topple. Therefore, this final paragraph creates a firm, broad base to support your entire proposal.

The final paragraph should include the following important details:

*Innovation:* Plainly state what is innovative about your project. What would completion of this proposal bring to the field that is not present currently?

*Expected Outcomes:* Specifically state your expected outcomes for this project. Use plain language. What do you expect to see at the completion of each aim? Include this information only if you have not placed it in the Aims.

*Impact:* State how your project would help those who need it, (i.e. the development of a new treatment, vaccine, disease model or diagnostic tool) Include a broad impact statement about how your proposal will benefit the people or other subjects that you mentioned in the opening paragraph.

Here is an example of a Final Paragraph:

**The proposed studies will establish a new mouse model that will overcome current limitations** and provide **greater insight into the mechanism of HTLV-1 Tax tumorigenesis,**

knowledge that is currently lacking and that promises to yield novel insights into viral and cellular biology. The new and improved mouse model for Tax tumorigenesis will provide a valuable resource for the wider scientific community to pursue a multitude of studies that have not previously been possible due to limitations of existing mouse models of Tax.

Color Key: Innovation Expected Outcomes Impact/Pay-off

*Figure 4.* The Final Paragraph. Sections of the paragraph have been color coded to highlight each critical component.

### Final Thoughts

The example given here is a strong one, but it is not all-inclusive. Each Specific Aims page is unique to the proposal. Therefore, there is a lot of flexibility in how these elements can be arranged and emphasized. Consider the novelty, innovation, and significant elements of your proposal as you decide how to organize this page; however, a great Specific Aims page will possess all of these elements. The order presented here has an ideal logic for a majority of proposals, so try applying it to your proposal to see how it works for you.

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## **Appendix D. Career Development Plan**

### **Career Development Plan Assignment**

Briefly outline goals for your research career development over the next 1-3 years. Use the following outline:

- Describe your planned line(s) of inquiry over the next 1-3 years
- Identify any gaps in your knowledge and skills that you wish to address; indicate how you plan to obtain additional training or experience
- Identify your mentoring needs and your options for meeting them
- Describe your relationship with local or regional PBRN(s) and how this can be further developed
- Describe what role(s) you plan to play in the PBRN in the next 1-3 years
- Discuss current opportunities to be a member of research teams on an existing grants, and/or how you can find new opportunities
- Describe your publication opportunities over the next 1-3 years (existing opportunities and/or how you can create new opportunities)
- Describe your grant writing goals over next 1-3 years

**This document should be 1.5 - 3 pages in length and is due May 15.**

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## **Appendix E. Convocation Presentation**

### **Convocation Presentation of Concept Paper, Specific Aims, & Career Development Plan**

#### **Guidance for Fellows**

Each Fellow will give a presentation at the Certificate Program's Convocation in Bethesda, MD on June 20-21, 2017. The presentation should have 3 main components: Concept Paper, Specific Aims, and Career Development. Thirty minutes will be allotted for each fellow to present; please allow at least 10 minutes for questions and discussion.

The purpose of the presentation is to share the methods you used in developing your concept paper and specific aims section, explain the content of those documents and your career development plan, and to give you an opportunity to request input from experts in the audience. Experienced members of the audience (mentors, Steering Committee Members) may be able to offer helpful guidance and suggestions.

Use Powerpoint for your presentation and bring it with you on a USB drive. **Bring to the Convocation 15 hardcopies of your Powerpoint presentation and 15 copies of your Specific Aims document.** These copies will be provided to the mentors, Steering Committee members, and other fellows to whom you will be presenting.

Below is the outline for the presentation.

- Provide a title slide for the overall presentation.
- **Concept Paper.** Provide background on your line of inquiry – describe the topic area; indicate the specific aspects you are seeking to study; briefly describe past research or clinical experience you have had in this area, if any; and indicate why this area interests you.
- Describe the PBRN you worked with, who the stakeholders were, how you accessed them and how you engaged them in the development of your concept paper. Share the steps in the process and your timeline. Ideally, the process should mirror the steps laid out in the concept paper assignment, however, things don't always go according to plan. Describe any challenges you faced and how you dealt with them.
- Succinctly present the following sections from your concept paper: Goal Statement, Research Questions, Methods, and Timeline. (You will spend more time covering these topics in the portion of the presentation on the Specific Aims section.)



- Describe the stakeholder input you obtained and indicate how it shaped your concept paper. What changes did you make (if any) in your concept paper in response to stakeholder input? Describe these changes in detail. What aspects of your final concept paper would be missing or different if you hadn't obtained their input? What did you learn about the value and utility of stakeholder input? If you could go back to the beginning of the process knowing what you know now, what would you do differently?
- **Specific Aims**. To begin the Specific Aims portion of your presentation, share the title of the research project that the Aims will propose.
- Walk the audience through the components of the Aims section as outlined below (or the portions that correspond to your mentor's preferred structure if it is different):
  - Introductory paragraph
  - The second paragraph
  - The Aims
  - The final summary paragraph
- Describe any challenges you had in formulating the Specific Aims section and any issues or parts that still need to be worked out, modified, or improved. Feel free to ask the audience for their input on any parts of your Specific Aims Section that you may be wrestling with.
- Describe a funding opportunity announcement that your Specific Aims section could target. This can be a request for applications from a federal agency or a foundation, although your Specific Aims should follow the general NIH format for Specific Aims sections. Identify the funding agency (eg, NCI, PCORI, Robert Wood Johnson Foundation), the funding mechanism (eg, R21, R01, etc), the FOA name, its focus, the maximum number of project years permitted, the maximum allowable annual budget, and explain why the RFA is a good fit for your line of inquiry.
- **Career Development Plan**. Briefly outline goals for your career development over the next 1-3 years. Limit this portion of the presentation to 3 minutes or less. Use the following outline:
  - Describe your planned line(s) of inquiry over the next 1-3 years
  - Identify any gaps in your knowledge and skills that you wish to address; indicate how you can obtain additional training or experience in these areas
  - Identify your mentoring needs and your options for meeting them
  - Describe your relationship with local or regional PBRN(s) and how this can be further developed
  - Describe your publication opportunities over the next 1-3 years (existing opportunities and/or how you can create new opportunities)
  - Describe your grant writing goals over next 1-3 years

**The due date for the Convocation Presentation is June 20-21, 2017 (it is due at the program's Convocation).**