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Writing a Successful Grant Application in D&I Research Helpful Tips and Resources

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Presented to CCCR-CTRIS November 13, 2018





Center for Prevention Implementation Methodology



- What is D&I research and how does it differ from other related areas?
- NIH PARs and RFAs in D&I Research
- Key Ingredients in D&I Applications
- Study Section: DIRH vs. Others
- Resources for D&I Research Training and Grant Writing



A Little About Me

- Training in IR: NIMH T32, TIDIRH, CHIPS, IRI
- Family-centered prevention of childhood obesity (adaptation to context and population; scaling up and scaling out; primary care integration; home visiting) (CDC, USDA)
- implementation research methods (trial designs; hybrid trials; measurement; developing and testing strategies) (NIDA)
- Implementation of behavioral health in medical settings (NCI, AHRQ, NMHWB)
- Implementation research in: Depression prevention (RWJF), employment services (NIMH, KF), HIV/AIDS prevention (NIMH, HRSA, NIAID, CDC), technology-based assessment (NIMH)



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Why is implementation science Needed?









Brown et al., 2017

O **17 years** to move effective interventions into practice

O **14%** of interventions reach their intended population in the real-world

Balas et al., 1998



Terminology

Implementation (**practice**) is the use of strategies to adopt and integrate evidence-based health interventions and change practice patterns within and across specific systems

Implementation research evaluates of the <u>use of strategies</u> to integrate interventions into real-world settings to improve patient outcomes

Implementation Science is the study of <u>methods</u> to promote the integration of research findings and evidence into healthcare policy and practice

- Frameworks and Models
- Implementation Strategies
- Measurement
- Modeling and Testing

Improvement Science/Continuous Quality Improvement/Learning Health Systems determine which improvement strategies work as systems strive to assure effective and safe patient care





- 1) Implementation research produces generalizable knowledge
- 2) Implementation practice produces local knowledge



Emphasis in Implementation Research?



- Effectiveness-Implementation Hybrid Trial Designs -



Brown, Smith, Villamar, & Benbow, 2016

The Delivery System Matters in Implementation

"The use of effective interventions without [effective] implementation strategies is like a serum without a syringe; the cure is available, but the delivery system is not."

Testing EBPs in the real world requires a paradigm shift in the way we think about research and data



Fixsen, Blase, Duda, Naoom, Van Dyke, 2010

Setting the Stage

- <u>Frameworks, models, and theories</u> guide the implementation process, inform the selection of outcomes to measure, and help the implementer/researcher anticipate and proactively address barriers through implementation strategies.
- <u>Implementation strategies</u> are manipulations to the system to support adoption, implementation, and institutionalization of new innovations.
- Implementation can be rigorously evaluated through use of rigorous <u>research designs</u> and the use of appropriate <u>outcome metrics</u>.



NIH PARs and RFAs in Implementation Research

• Dissemination and Implementation Research in Health (PAR-18-007, 017, 16-237)

Specific Objectives and Scope of this FOA

This FOA invites research grant applications that will identify, develop, test, evaluate and/or refine strategies to disseminate and implement evidence-based practices (e.g. behavioral interventions; prevention, early detection, diagnostic, treatment and disease management interventions; quality improvement programs) into public health, clinical practice, and community settings. In addition, studies to advance dissemination and implementation research methods and measures are encouraged.

Examples of relevant research directions include but are not limited to:

- Studies of strategies to implement health promotion, prevention, screening, early detection, and diagnostic interventions, as well as effective treatments, clinical procedures or guidelines into existing care systems.
- Studies of the implementation of multiple evidence-based practices within community or clinical settings to meet the needs of complex patients and diverse systems of care.
- Studies of the local adaptation of evidence-based practices in the context of implementation that systematically identify intervention components that surpass or fall short of
 expected intervention effects.
- · Longitudinal and follow-up studies on the factors that contribute to the sustainability of evidence-based interventions in public health and clinical practice.
- Studies testing the effectiveness and cost-effectiveness of dissemination or implementation strategies to reduce health disparities and improve quality of care among rural, minority, low literacy and numeracy, and other underserved populations.
- Studies of the de-implementation of clinical and community practices that are not evidence-based, have been prematurely widely adopted, yield sub-optimal benefits for patients, or are harmful or wasteful.
- Studies of the relationship of context and local capacity of clinical and community settings to adoption, implementation and sustainability of evidence-based practices.
- Prospective or retrospective studies of the adoption, implementation and sustainability of health policies and their interaction with programs and contextual factors.
- · Studies of influences on the creation, packaging, transmission and reception of valid health research knowledge.
- Studies of systems interventions to impact organizational structure, climate, culture, and processes to enable dissemination and implementation of clinical/public health information and effective clinical/public health interventions.
- Studies that focus on the development and testing of theoretical and evaluation models for D&I processes.
- Development of D&I relevant outcome and process measures and suitable methodologies for dissemination and implementation approaches.
- Studies of the dissemination of varied strategies to promote effective patient and caregiver communication, leading to improved healthcare delivery and outcomes.
- Studies of the dissemination and implementation of effective and cost-effective strategies for incorporating genomic medicine, sequence-based diagnostics and therapeutics in clinical care.
- Studies testing the implementation and use of genomic information, family history risk information, and/or pharmacogenetic information for improved diagnosis and treatment.



NIH PARs and RFAs in Implementation Research Dissemination and Implementation Research in Health (PAR-18-007, 017, 16-237)

In order to take advantage of existing resources and knowledge in the field, investigators are encouraged to consider the relationship of the following key characteristics of dissemination and implementation (D&I) research to their applications, which may include but are not limited to:

- · Use and testing or refinement of conceptual models appropriate for D&I
- Understanding of the complexity of health interventions, including those with multiple components and those for low resource settings and for populations traditionally underrepresented in research, for which D&I may not be a simple process
- · Understanding the incentives and/or barriers to the D&I of novel tools and practices to improve public health
- Incorporating the identification of mediators, moderators, and mechanisms of action, where applicable, that explain the impact of dissemination or implementation strategies
- · Consideration and characterization of the multi-level context and environment in which the proposed research will be conducted
- Development and/or use of applicable outcomes, measures and analyses related to the models used and the project specific aims. Applicants are encouraged to review available
 resources where possible and use more harmonized and standard measures, rather than developing their own measures for each study.
- · Attention to issues of resources expended, programs costs, cost-effectiveness or other economic outcomes
- Incorporation of stakeholder relevant outcomes of research (including relevant outcomes for patients, families, providers, administrators, policymakers).

Collaborative Research: In addition, given the range of expertise that may be needed for conducting dissemination and implementation research, applicants are encouraged to form trans-disciplinary teams of scientists and practice stakeholders to work together to develop and/or test conceptual models of dissemination and implementation that may be applicable across diverse community and practice settings and patient populations, and design studies that will accurately and transparently assess the outcomes of dissemination and implementation and implementation and implementation and implementation efforts.



NIH PARs and RFAs in Implementation Research

• Research Centers for Improving Management of Symptoms During and Following Cancer Treatment (UM1) (RFA-CA-17-042)

Research Objectives and Main Requirements

Overview. The focus of the Research Consortium supported by this FOA is to use implementation science approaches to accelerate adoption of integrated systems that collect patient-reported symptom data and use these data to trigger a clinical response consistent with evidence-based guidelines. Implementation science approaches to be proposed for this FOA must be systematically planned with a goal to accomplish sustaining changes in clinical practice.

Goals and Expected Role of Research Centers. Each Research Center is expected to deploy an integrated symptom monitoring and management system in a group of clinical practices and to test that system using a randomized design. This approach is expected to yield a rigorous evaluation of the extent to which elements of the system are adopted and the impact of the system on patient outcomes, cancer treatment delivery, and healthcare utilization.

The proposed Research Centers should be capable of (and plan for) accomplishing the following goals during the project period:

- · Yield optimal models for implementing integrated systems into routine clinical practice;
- · Verify whether adoption of integrated systems to be assessed can reduce the harmful effects of poorly controlled symptoms; and
- · Create the foundation for effective, scalable and sustainable symptom management approaches in routine cancer care.

General Requirements on Study Design

The proposed studies must use a pragmatic, randomized design that:

- · Provides an integrated symptom monitoring and management system to a group of clinical practices based on implementation science principles;
- · Measures the extent of adoption and identifies processes that contribute to success in adopting the system; and
- Determines the impact of the integrated system on patient outcomes (e.g., symptom reports, functional status), cancer treatment delivery (e.g., adherence to prescribed medications), and healthcare utilization (e.g., emergency room visits).



Key Ingredients for D&I Grant Applications

Proctor et al. Implementation Science 2012, 7:96 http://www.implementationscience.com/content/7/1/96



DEBATE

Open Access

Writing implementation research grant proposals: ten key ingredients

Enola K Proctor^{*}, Byron J Powell, Ana A Baumann, Ashley M Hamilton and Ryan L Santens

Concocting that Magic Elixir: Successful Grant Application Writing in Dissemination and Implementation Research

Ross C. Brownson, Ph.D.^{1,2}, Graham A. Colditz, M.D., Dr.P.H.², Maureen Dobbins, R.N., Ph.D.³, Karen M. Emmons, Ph.D.⁴, Jon F. Kerner, Ph.D.⁵, Margaret Padek, M.P.H., M.S.W.¹, Enola K. Proctor, Ph.D.⁶, and Kurt C. Stange, M.D., Ph.D.⁷



Ingredients

Proposal ingredient	Key question	Review criteria
1. The care gap or quality gap	The proposal has clear evidence that a gap in quality exists?	Significance Impact
2. The evidence-based treatment to be implemented	Is the evidence for the program, treatment, or set of services to be implemented demonstrated?	Significance Innovation
 Conceptual model and theoretical justification 	The proposal delineates a clear conceptual framework/theory/ model that informs the design and variables being tested?	Approach Innovation
4. Stakeholder priorities, engagement in change	Is there a clear engagement process of the stakeholders in place?	Significance Impact Approach Environment
5. Setting's readiness to adopt new services/treatments/programs	Is there clear information that reflects the setting's readiness, capacity, or appetite for change, specifically around adoption of the proposed evidence-based treatment?	Impact Approach Environment
6. Implementation strategy/process	Are the strategies to implement the intervention clearly defined, and justified conceptually?	Significance Impact Innovation
7. Team experience with the setting, treatment, implementation process	Does the proposal detail the team's experience with the study setting, the treatment whose implementation is being studied, and implementation processes?	Approach Investigator team
8. Feasibility of proposed research design and methods	Does the methods section contain as much detail as possible, as well as lay out possible choice junctures and contingencies, should methods not work as planned?	Approach Investigator team
9. Measurement and analysis section	Does the proposal clarify the key constructs to be measured, corresponding to the overarching conceptual model or theory?	Approach Investigator team
	Is a measurement plan clear for each construct?	
	Does the analysis section demonstrate how relationships between constructs will be tested?	
10. Policy/funding environment; leverage or support for sustaining change	Does the proposal address how the implementation initiative aligns with policy trends?	Impact Significance



	Grant proposal development									
Grant section	Competency (number)	Expertise*								
Aims										
	Create a clear, rationale and realistic action plan for transforming research ques- tions on D&I into grant proposal aims (A1).	В								
Significance										
	Identify how to pose an innovative and significant D&I research question, justify its importance, describe the knowledge gap it addresses, and when possible, connect it to priorities of the funding agency (S1).	В								
	Describe how to ground the proposal in an important quality gap that is address- able through the D&I of an evidence-based intervention, program or policy (S2).	В								
Innovation										
	Articulate how to identify products from the D&I study, including implementation toolkits, to guide practice and policy (11).	А								
	Report on the consistency of the proposed practice change (to be addressed in the study) with the policy trends and priorities (12).	А								
Approach										
	Utilize an appropriate D&I model or framework to organize a proposal and integrate research questions with clear and measurable study objectives; aims; measures, and analysis strategies (AP1).	1								
	Explain how to document or propose measurement of the setting's need, ap- propriateness and readiness of the practice change required through the D&I strategies addressed in the proposal (AP2).	1								
	Identify measures that clearly assess the constructs of interest in the proposed study and are practical to apply in the proposed settings (AP3).	1								
	Identify how to build a team with the expertise and experience for the proposed research, including D&I expertise and stakeholder experience (AP4).	1								
	Create a strategic dissemination plan for various target audiences that goes be- yond the traditional publications and presentation at meetings (AP5).	A								
	Develop an analysis plan that addresses each specific aim and hypothesis and considers the different levels of analyses (AP6).	A								
Human Subjects										
	Describe the ethical (human subjects) issues that are particular to and relevant for D&I research (HS10).	В								

Common Pitfalls

- Terminology/ Language
- Too clinical lacks focus on implementation
- Implementation <u>Science</u> Expert
- Clear specification of "the problem" (aligns with methods)
- Preliminary Activities
 - Partnership Development (CBPR, CEDI) and Evidence of Collaboration
 - Organizational status, buy-in/commitment, generalizability
 - Pilot work (assessed/identified barriers \rightarrow selection of feasible strategies)
- Use of Models and Frameworks
 - Round peg, square hole
 - Application of framework types
- Underpowered design
 - Multilevel studies, randomization at higher-level units, measurement



Study Sections

- Dissemination and Implementation Research in Health (DIRH)
 - Standing study section for D&I research proposals
 - Frameworks, Models, Theories
 - Addressing a research-practice gap AND advancing the field of IS
 - Speak the language
 - Implementation scientist (with legitimate FTE)
- Special Emphasis Panels and Other Standing Study Sections
 - Less consistency in expectations for methods, terms, models, etc.
 - Varies highly by RFA/culture/content area
 - Use the IS language in the RFA
 - Best to infuse IS into a more traditional research design and question (if not, it probably should have gone to DIRH)



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Example of an IR Study

Example of IR Study: Purpose

 Demonstrate application of implementation research frameworks/ models/theories, metrics, and research designs to HIV-related implementation studies

Research Questions, Hypotheses, Specific Aims

Selection and application of Frameworks/Models/Theories How to determine (research designs) and rigorously evaluate the impact of implementation strategies



Premise for Example IR Study

- A large health system with 54 primary health care clinics in a high HIV prevalence urban area wants to increase PrEP uptake by 50%.
- Leaders in the health system have decided to compare whether referring potentially-eligible patients to specialty STI/HIV clinics for PrEP or providing PrEP in their clinics will result in better outcomes.
- Health system has partnered with an implementation scientist to devise a study to test this question.



Research Question

Effectiveness Research: Does referring to a specialty STI/HIV clinic for PrEP prescribing result in fewer new HIV infections compared to PrEP in routine care?

Implementation Research: Does training primary care physicians to identify and prescribe PrEP as part of routine preventive care lead to provider adoption and to reaching more eligible patients compared to referring them to specialty STI/HIV clinics?



Implementation and Clinical Outcomes





Proctor et al., 2009



Does training primary care physicians to identify and prescribe PrEP as part of routine preventive care lead to provider adoption and to reaching more eligible patients compared to referring them to specialty STI/HIV clinics?

Implementation Strategies





Does training primary care physicians to identify and prescribe PrEP as part of routine preventive care lead to provider adoption and to reaching more eligible patients compared to referring them to specialty STI/HIV clinics?

Implementation Outcomes





Does training primary care physicians to identify and prescribe PrEP as part of routine preventive care lead to provider adoption and to reaching more eligible patients compared to referring them to specialty STI/HIV clinics?

Comparison-based trial design





- 1. Train primary care physicians to identify and prescribe PrEP as part of routine preventive care.
- 2. Increase primary care provider adoption of PrEP screening and prescribing.
- 3. Identify most effective practice for reaching PrEP eligible patients (i.e., integrated within routine care or referral to specialty STI/HIV clinics).





H₁: Provider, clinic, and PrEP-related factors will be related to primary care physicians' adoption. Training can overcome these potential barriers.

H₂: Improving leadership support of provider delivery of PrEP will improve rates of adoption.

H₃: Providing PrEP in primary care will lead to more prescriptions than referring out.



Hypothesis 1

H₁: <u>Provider, clinic, and PrEP-related factors</u> will be related to primary care physicians' adoption. Training can overcome these potential <u>barriers.</u>

Determinants Framework





Hypothesis 1

H₁: Provider, clinic, and PrEP-related factors will be related to primary care physicians' adoption. Training can overcome these potential barriers.



Exploration, Preparation, Implementation, Sustainment





H₂: Improving leadership support of provider delivery of PrEP will improve rates of adoption.







H₃: Providing PrEP in primary care will lead to more prescriptions than referring out.

... lead to provider adoption and to reaching more eligible patients...

Evaluation Framework



Acceptability Feasibility Appropriateness





Adoption: Providers' prescribing PrEP **Reach:** Proportion of eligible patient's prescribed PrEP

Acceptability: Providers' perspective Appropriateness: Provider and patient perspectives Feasibility: Time with patients; wait times; total patients Cost: Is PrEP provision in the clinic cost-beneficial/cost neutral for revenue as well as effects achieved?



Trial Design 1 Between-site comparative implementation design





Trial Design 2 Randomized Roll Out Implementation Trial (n=56 Clinics, 7 clusters, 8 clinics each [4 per strategy])

	Year 1					Year 2				Year 3				Year 4				Year 5			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Cluster 1	С	С	I	I.	I	I	I	I													
Cluster 2	С				I	I	I	I	I	I											
Cluster 3			С				I	I	I	I	I	I									
Cluster 4					С				I	I	I	I	I	I							
Cluster 5							С				I	I	I	I	I	I					
Cluster 6									С				I	I	I	I	I	I			
Cluster 7													I	I	I	I	I	I			



Take Homes

- Research question(s), specific aims, and hypotheses drive the selection of:
 - Which and what type of framework, model, or theory
 - Inform the evaluation and process plan
 - Research design and metrics
 - Example: Smith & Polaha (2017, Families, Systems & Health)
- Patient outcomes?
 - None in true IR studies
 - Hybrid Effectiveness-Implementation trials collect both simultaneously

Geoff Curran 2018 PSMG: https://vimeo.com/294847740



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Resources

1

Examples of Funded Grants

https://cancercontrol.cancer.gov/IS/sample-grant-applications.html https://impsci.tracs.unc.edu/get-funded/sample-grants/







Implementation Research Training



psmg@northwestern.edu











Implementation Research Institute



NIH T32 Programs

(WashU, ASU)

TIDIRC

Implementation Methodology

FOR DRUG ABUSE AND HIV

Center for Prevention

Implementation Science Trainings

Brown, Smith, Benbow, & Villamar (2016)

Implementation Science: An Introductory Workshop for Researchers, Clinicians, Policy Makers, and Community Members

Brown, Smith, & Benbow (2017)

Overview of Experimental Designs for Implementation Research with applications to HIV

http://cepim.northwestern.edu/

http://cepim.northwestern.edu/trainings/







Implementation Science Resources

TRAINING

- <u>Training Institute in Dissemination and</u> <u>Implementation Research in Health (TIDIRH)</u>
- Implementation Research Institute (IRI)
- <u>Mentored Training in Dissemination and</u> <u>Implementation Research in Cancer (MT-DIRC)</u>
- <u>Certificate Program in Implementation Science</u> (UCSF CTSI)
- <u>Prevention Science and Methodology Group</u>
 (PSMG)
- <u>NCI D&I Webinar Series</u>
- Brownson RC, Colditz GA, Proctor EK, eds. Dissemination and Implementation Research in Health: Translating Science to Practice (2nd Edition). London: Oxford University Press; 2017.

JOURNALS

- Implementation Science
- Clinical Translational Science
- Translational Behavioral Medicine
- Administration and Policy in Mental Health



WEBSITES

- <u>Ce-PIM/Bridges</u> Websites at NU
- Implementation Science
- <u>SIRC instrument repository</u>
- <u>NIH Resources on Dissemination and</u>
 <u>Implementation Research in Health</u>
- <u>Knowledge Translation Resources from</u> <u>Canadian Institutes of Health Research</u>
- <u>WHO's Implementation Research</u> <u>Platform</u>
- <u>UNC Chapel Hill's North Carolina</u> <u>Translational and Clinical Sciences</u> <u>Institute: D&I portal</u>
- UNC Chapel Hill's Active Implementation
 Hub
- <u>NIH Fogarty International Center's</u>
 <u>Implementation Science site</u>
- Prevention Science
- Medical Care
- BMC Health Services Research
- New journal through SIRC! Late 2019

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Questions?