

# Dissemination and Implementation Research: (Enter catchy subtitle here)

Orientation for PARs 10-038, 10-039, 10-040

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# Orientation Overview

- Trans-NIH PAR
  - Research Topics
  - Funding mechanisms
  - Changes to the application process
  - Changes to review
  - Review Criteria
  - FAQs
- Questions and Discussion



# TRANS-NIH PAR



# The Trans-NIH D&I PAR

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- Dissemination and Implementation (D&I) in Health
  - NIMH, NCI, NHLBI, NIDA, NIAAA, NIDCR, NIDCD, NINR, NIAID, NINDS, NIDDK, OBSSR, FIC
  
- PAR – program announcement with
  - Special review, receipt and referral
  
- Special Emphasis Panel reviews -
  - R03 (PAR-10-039)
  - R21 (PAR-10-040)
  - R01 (PAR-10-038)
  
- Submission every round



# Mechanisms for D&I PAR Applications

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- 5 criteria to evaluate scientific and technical merit of the application:
  - Significance, approach, innovation, investigator, and environment
  - Overall IMPACT Score
  - R01 Applications -
    - Traditional NIH research project grant
    - Typically requires pilot data
  - R21 Applications -
    - Developmental/Exploratory projects
    - Designed to support innovative ideas
    - Preliminary data not required
  - R03 Applications -
    - Pilot projects, so scope is smaller than R01s and usually R21s
    - Preliminary data not required



# Dissemination and Implementation Research

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- **Dissemination** is “the targeted distribution of information and intervention materials to a specific public health or clinical practice audience.”
- **Implementation** is “the use of strategies to adopt and integrate evidence-based health interventions and change practice patterns within specific settings.”

Adapted from Lomas (1993)



# Dissemination Research Topics

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- Analysis of factors influencing the **creation, packaging, transmission** and **reception** of valid health research knowledge
- Experimental studies to test the **effectiveness** of individual and systemic **dissemination strategies**, focusing on relevant outcomes (e.g., acquisition of new knowledge, maintenance of knowledge, attitudes about the dissemination strategies, use of knowledge in practice decision-making).
- Studies testing the utility of alternative **dissemination strategies for service delivery systems** targeting rural, minority, and/or other underserved populations.
- Studies on how **target audiences** are defined, and how evidence is packaged for specific target audiences.



# Implementation Research Topics

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- Studies of efforts to **implement** prevention, early detection, and diagnostic **interventions**, as well as **treatments** or clinical **procedures** of demonstrated efficacy **into existing care systems** to measure the extent to which such procedures are utilized, and adhered to, by providers and consumers.
- Studies on the **fidelity of implementation** efforts, including the identification of components of implementation that will enable fidelity to be assessed meaningfully.
- Longitudinal and follow-up studies on the **factors** that contribute to the **sustainability** of research-based improvements in public health and clinical practice.



# D&I Research Topics

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- Studies of the **capacity of specific care delivery settings** (e.g., primary care, schools, community health settings) to incorporate D&I efforts within current organizational forms.
- Studies that focus on the **development and testing of theoretical models** for D&I processes.
- Development of **outcome measures** and suitable **methodologies** for D&I approaches that accurately assess the success of an approach to move evidence into practice (i.e., not just clinical outcomes).



# Mechanistic D&I Research Questions

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- Can effective **measures** be created for key implementation constructs (e.g. supervision, outcomes monitoring, turnover, leadership)?
- How does implementation of effective practice impact **turnover, organizational culture and climate**?
- Is there an effective **model of (re)training** providers in effective practices?
- How can **capacity** be built within **practice settings** to support implementation of effective practices?
- What **data systems** can support ongoing **assessment** of implementation?
- What **models** enhance **sustainability** of effective practices?



# Changes to the Application Format



# Overview and Timeline



- Phase out of A2 applications
- Identification of Early Stage Investigator (ESI) R01 applications

- Enhanced review criteria
- New scoring system
- Criterion scoring
- Structured critiques
- Score order review
- Clustering of New Inv. Applications

- Restructured Applications
- Shorter Page Limits and New Instructions



# Major changes to application forms **intended** for due dates on or after January 25, 2010:

- Restructured Application Forms
  - Require the downloading of new forms (**paper and electronic**)
- New Instructions Including Shorter Page Limits

For **ALL** competing applications:  
New, Renewal, Revision, and Resubmission





## Enhancing Peer Review at NIH



- Peer Review Home
- Implementation Goals
  - ▶ Engage the Best Reviewers
  - ▶ Improve the Quality & Transparency of Review
  - ▶ Ensure Balanced and Fair Reviews
  - ▶ Continuous Review of Peer Review
- Policy Announcements
- New Scoring System
- Shortened/Restructured Applications

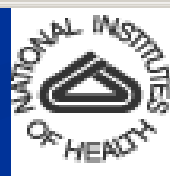
### Shortened/Restructured Applications

#### Phases of Process



- » All applications for due dates on or after January 25, 2010 require use of new forms and new instructions
- » New instructions mean **shorter page limits!**
- » Return to FOA or new **parent announcement** in December to download new forms
- » Read new instructions carefully to ensure a successful submission

Peer Review Enhancements that began in January of 2009 will culminate with a restructuring and shortening of applications submitted for Fiscal Year 2011 funding (due dates on or after January 25, 2010). All competing applications, including



# How are applications being restructured?

There are 3 major changes!

## 1. Research Plan:

- Specific Aims
  - Separate page
  - Includes new language about the **impact** of the proposed research
- Research Strategy
  - New section with 3 parts
    - Significance
    - Innovation
    - Approach
      - Preliminary Studies for New Applicants
      - Progress Report for Renewal and Revision Applications



# How are applications being restructured?

## 2. Resources:

- Better reflects the Environment criterion
- Includes institutional commitment and support for ESIs

## 3. Biographical Sketch:

- Includes a Personal Statement
- Provides guidelines for inclusion of 15 publications

NOTE: For Renewal Type 2 applications, the list of publications from the previous competing period is a separate section and is not included in the Biographical Sketch publications



# What are the new page limits?

- Introduction for resubmissions/revisions: 1 page \*
- Specific Aims: 1 page
- Research Strategy: 6, 12, or 30 pages\*

[http://enhancing-peer-review.nih.gov/page\\_limits.html](http://enhancing-peer-review.nih.gov/page_limits.html)

## Enhancing Peer Review at NIH



Peer Review Home

Implementation Goals

▶ Engage the Best Reviewers

▶ Improve the Quality & Transparency of Review

▶ Ensure Balanced and Fair Reviews

▶ Continuous Review of Peer Review

Policy Announcements

New Scoring System

### Table of Page Limits

Changes effective for due dates on or after January 25, 2010

Updated on November 2, 2009

Section of Application with Page Limits	Page Limits *
<b>Introduction to Revision Application</b> For all Activity Codes	1 page
<b>Introduction to Resubmission Application</b> For all Activity Codes, EXCEPT Training T, D43, D71, K12, and R25 applications	1 page
<b>Introduction to Resubmission Application</b> For institutional Training (T), International Training (D43, D71), Institutional Career Awards (K12), and International Education Applications (R25)	3 pages



# What are the implications for resubmissions?

- New page limits must be followed for resubmissions
  - No grandparenting of page limits
  - All activity codes! No exceptions!
- Applicants need to download the new forms and follow the new instructions

Reminder: An A2 application is allowed until January 7, 2011 if the A0 was submitted before January 25, 2009



# Changes to the Review Process



# REVIEWER ORIENTATION

## TO ENHANCED PEER REVIEW

*April 2009*



# Goals of the Changes

- Clearer understanding of the basis of application ratings
- More emphasis on impact and less emphasis on technical details
- Succinct, well-focused critiques that evaluate, rather than describe, applications
- Routine use of the entire rating scale



# Before the Review Meeting

When reading applications the assigned reviewers should:

- Address all applicable criteria and other review considerations
- Identify major strengths and weaknesses
- Assign scores to each of the 5 “core” criteria
- Assign an overall impact/priority score



# Preparation of Critiques

## When writing your critiques:

- Use bulleted points to make succinct, focused comments
- Short narratives may occasionally be appropriate, but should be rare
- Focus on major strengths and weaknesses (ones that impacted your overall rating of the application)



# Features of Critique Templates

- Boxes for evaluating:
  - Each core review criterion
  - Other applicable review criteria and considerations
  - Overall impact of the application
- A box for “advice to applicants”
- Hyperlinks to web pages providing descriptions of review criteria and additional review considerations



# Excerpt from a Critique Template: Criterion

## 1. Significance

Please limit text to ¼ page

### Strengths

- 

### Weaknesses

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- List major strengths and weaknesses that influenced the overall impact/priority score
- Limit text to ¼ page per criterion, although more text may occasionally be needed
- Do not enter scores on critiques



# Scoring Individual Review Criteria

- There are 5 “core” criteria for most types of grant applications
- For example, the core criteria for R01s are:
  - Significance
  - Investigator(s)
  - Innovation
  - Approach
  - Environment
- Use the 9-point scale for the five “core” review criteria.



# Overall Impact/Priority Scores

- Consider criterion strengths and weaknesses of each application in determining an overall impact/priority score
- Recognize this is a **NEW** scoring system and focus on the guidelines for its use
- This new scoring system is intended to reflect the “real-world” range of the quality of applications typically seen in actual study sections
- It is **ESSENTIAL** that reviewers take advantage of this unique opportunity to use the entire 1 to 9 range



# Scoring Descriptions

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses

**Non-numeric score options:** NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND = Not Discussed

**Minor Weakness:** An easily addressable weakness that does not substantially lessen impact

**Moderate Weakness:** A weakness that lessens impact

**Major Weakness:** A weakness that severely limits impact



# After the Review Meeting: Updating Scores or Critiques

- Assigned reviewers whose opinions changed as a result of discussion at the meeting can:
  - modify their criterion scores
  - post revised critiques
- Undiscussed applications will still get all criterion scores.



# Summary Statements

- Overall impact/priority scores of discussed applications will be the average of scores voted by all eligible reviewers, multiplied by 10
- Final scores will range from 10-90, in whole numbers
- Summary statements for ALL applications will include the criterion scores and critiques posted by assigned reviewers



For additional information:

Enhancing Peer Review at NIH Web Site



<http://enhancing-peer-review.nih.gov>



# Review Criteria



# SIGNIFICANCE

- Do the **intervention efficacy** data justify D&I?
- Will the D&I of the intervention achieve a **broad reach**?
- How will this study effect **concepts or methods** that drive the field?
- Will the study have a **clear positive impact** on public health, community and clinical contexts?



# APPROACH

- Does the applicant demonstrate an **understanding** of D&I research principles?
- Is the D&I approach appropriate to the problem and population?
- How appropriate are the plans to sustain effective D&I approaches once the research funding period is ended?



# INNOVATION

- Does the proposed D&I research contribute new and innovative design approaches to the study of D&I processes and/or outcomes?



# INVESTIGATORS

- Does the investigative team include specific **D&I expertise**?
- Are relevant **letters of support** from key partner D&I organizations which plan to adopt the intervention included?



# ENVIRONMENT

- Do the proposed approaches take advantage of **unique features** of the intervention delivery environment or employ useful, collaborative arrangements?
- Is there **evidence of institutional support** to sustain D&I interventions once the research funding ends?



# Reviewer Perspective



# Scientific / Research FAQs

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**Q:** Are methodological approaches other than randomized trials acceptable (e.g., quasi-experimental, qualitative, case studies)?

**A:** Yes. Because the design of a dissemination and implementation research project requires equal attention be paid to the external validity and the internal validity of the strategies being tested, this program announcement encourages consideration of a broad range of methodological approaches. The ones selected should be justified as most appropriate for the specific research question(s) being examined or hypotheses being tested.



# Scientific / Research FAQs

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**Q:** How much flexibility do I have in intervention delivery, adapting to my delivery context, versus maintaining the fidelity of intervention delivery as implemented in the original efficacy/effectiveness trial?

**A:** The impact of a particular intervention will vary both in terms of the fidelity with which the intervention is delivered and the extent to which the intervention is appropriately adapted to fit the service delivery contexts and the characteristics of the population being served. Applications are encouraged to explicitly address the balance between fidelity (internal validity) and adaptation to improve contextual fit (external validity) in the dissemination and implementation of evidence-based interventions.



# Scientific / Research FAQs

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**Q:** I have preliminary data on the efficacy of an intervention that is likely to have a very large public health impact in a high priority area. Is it appropriate at this stage to move to a dissemination trial?

**A:** If the preliminary data are so compelling that completion of the efficacy or effectiveness trial is extremely unlikely to change the intervention impact observed, then it may be appropriate to consider submitting. However, this program announcement is designed to expand the knowledge base about how to disseminate and implement interventions that have been rigorously tested and that have been shown to be effective. Thus, the applicant is encouraged to discuss with their NIH institute-specific intervention research project program director the extent to which the preliminary data may justify a dissemination/implementation research project proposal at this time.



# Scientific / Research FAQs

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**Q:** My intervention impacts a relatively small (but high risk) population. Is it appropriate for me to submit an application?

**A:** Whether in the public health or clinical practice contexts the population impact of a particular intervention will vary both in terms of the size of the intervention effect and the reach to the population at risk. A small intervention effect applied to a large at risk population may be viewed as similar to a large intervention effect seen for a small but high-risk population. Applications are encouraged that address dissemination and implementation of evidence-based interventions that impact large underserved populations and/or specific high risk groups.



# Scientific / Research FAQs

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**Q:** Does this program announcement apply to international populations outside of the U.S., or is this exclusively for study of populations within our borders?

**A:** As noted in the section on eligible institutions, foreign institutions may apply. During the peer review of international studies, the relevance of the study of international populations to US populations often emerges and the applicant should address this relevance in the application when appropriate.



# Scientific / Research FAQs

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**Q:** How do I determine whether my team has appropriate expertise and experience to conduct dissemination and implementation research studies?

**A:** Applicants should assemble a team that has the necessary skills to address the specific aims of the grant. For dissemination and implementation research studies, this may require multiple streams of expertise, including an understanding of the context in which implementation is intended, the content of the interventions being implemented, and the methods by which the study will be conducted. While investigators new to the area are encouraged, they are encouraged to explain their qualifications.



# Scientific / Research FAQs

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**Q:** How can I determine whether my grant should be submitted as an R03, R21, or R01?

**A:** The choice of mechanism should relate to the specific question being asked, the scale of the study proposed, and the availability of pilot data to justify a larger scale study. The R03 intends to facilitate a small, stand-alone study, the R21 enables exploration and development of a larger field of research that will build toward an R01, and the R01 assumes existence of pilot data and readiness to answer research questions in a more definitive way.



# Scientific / Research FAQs

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**Q:** One of the criteria described in the Significance section of the PAR emphasizes the importance of the proposed study having a positive impact on public health and community. My research focuses on understanding the mechanisms that underlie effective dissemination approaches (basic dissemination science). Is it appropriate for me to apply to this PAR.

**A:** Yes. This proposal strongly encourages proposals that span the continuum of scientific inquiry from basic dissemination and implementation science (e.g., building and/or testing models) to applied dissemination and implementation trials.



# Questions and Discussion

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- Design issues?
- Definitions?
- Research Team Construction
- Evidence of Delivery System Partnerships
- Any Others?

