

AACN Doctoral Education Conference

Federal Funding Update

January 20, 2017

Overview

- Mission and 2016 Strategic Plan
- Research and Funding Opportunities
- Training Opportunities
- New NIH Policies



NINR Mission

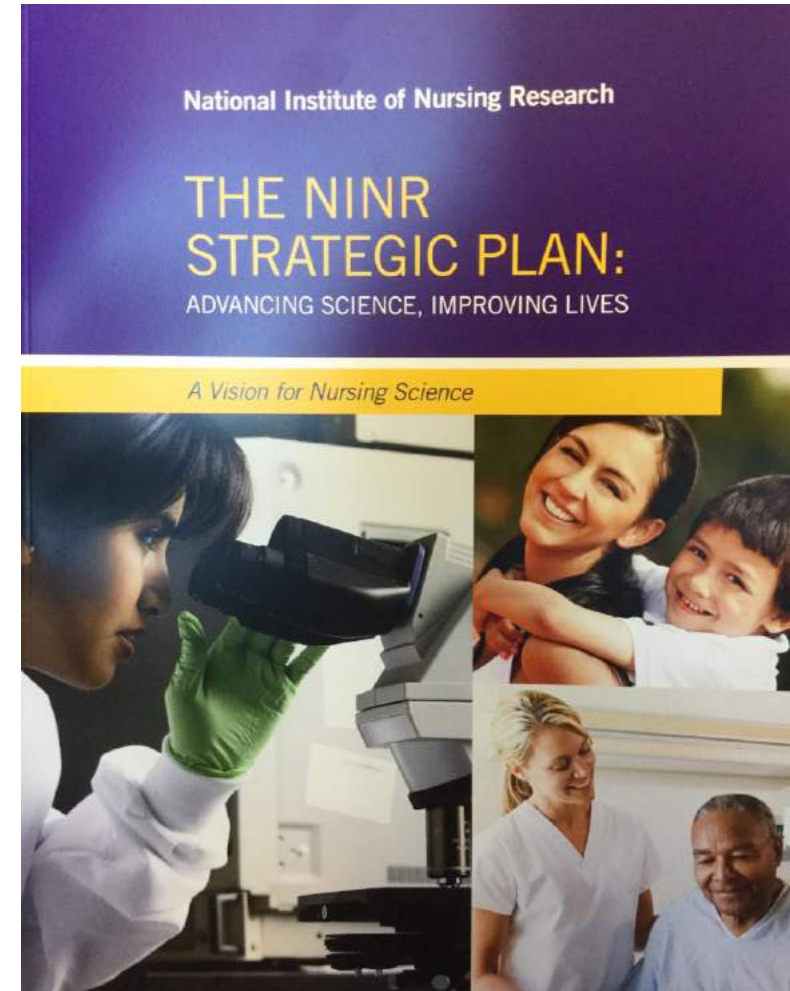
Enhance nursing science to improve the health care outcomes of individuals, families, communities and populations

by:

- integrating the biological sciences into health care
- applying new technologies to healthcare
- promoting health equity in healthcare
- developing scientists of the future



- Building the scientific foundation for clinical practice
- Preventing disease and disability
- Managing and eliminating symptoms caused by illness
- Improving palliative and end-of life care
- Pre and Post-Doctoral training



Overview

- Mission and Strategic Plan
- **Research and Funding Opportunities**
- Training Opportunities



NINR Budget

- 80 % spent on extramural research grants
 - Research Program grants (RPG's)
 - Training
 - Centers of Excellence
 - Other(PCRC)
- 6 % spent on intramural research
- 11 % Administrative costs
- 3 % R & D



Applying for Research Funding



“Is it just me or are these review panels getting a lot tougher?”

New Program Announcements for FY 17

- ☐ Use of Technology to Enhance Patient Outcomes and Prevent Illness
- ☐ Self-Management Interventions and Technologies to Sustain and Optimize Functional Capabilities
- ☐ Promoting Caregiver Health Using Self Management
- ☐ Addressing Unmet Needs in Persons with Dementia to Decrease Behavioral Symptoms and Improve Quality of Life
- ☐ Improving Individual and Family Outcomes through Continuity and Coordination of Care in Hospice
- ☐ Palliative Care Needs of Individuals with Advanced Rare Diseases and Their Family Caregivers

NINR Supported Funding Mechanisms

Grant Types	Direct Costs Allowed	Notes	Renewable
R01	≤ \$ 500K/yr. up to 5 yr.	DC > \$ 500K requires NINR advanced approval	Y
R15	≤ \$ 300K DC over 3 yr.	Purpose to stimulate research in eligible academic institutions	Y
R21	≤ \$ 275K DC over 2 yr.	DC not to exceed \$ 200K/yr. Supports exploratory and developmental research	No
R34	≤ \$150K DC for 1 yr.	To support planning, design, and preparation of the documentation necessary for implementation of investigator-initiated clinical trial that would enhance the probability of reaching definitive outcomes in a clinical trial	No
P20	Variable	Submitted in response to RFA	N
P30	Variable	Submitted in response to RFA	N

Small Business Grants

Grant Type	Costs	Notes
R41 S	Phase I $\leq \$ 150K$ DC + IDC Phase II $\leq \$ 1,000,000$ DC + IDC	For small businesses seeking to commercialize biomedical innovations. Phase I not to exceed 6 mon. Phase II up to 2 yr.
R42	Same as R41	Similar to R41 but small business must collaborate with research institution
R43	Phase I $\leq \$ 150K$	Purpose to establish technical merit and feasibility leading to commercialization.
R44	Phase II $\leq \$ 1,000,000$	Supports research and continued R & D.

Research and Funding: ESI and NI

- Early Stage Investigator (ESI)
 - NI within 10 years of terminal research degree completion
 - R01 applications only
- New Investigator (NI)-no substantial NIH funding
- NI/ESI applications clustered for review



**Stop goofing around and stand up straight!
This figure is for the grant renewal.**

Research and Funding

NINR Program Directors

Contact NINR Program Directors for topics including:

- Ideas for research proposals
 - Fit with the NINR mission
- Questions regarding FOAs
- Guidance with application preparation
- Questions regarding Inclusion Management System
- Issues regarding your funded application
- Data Safety Monitoring Plans/Boards
- General concerns/comments

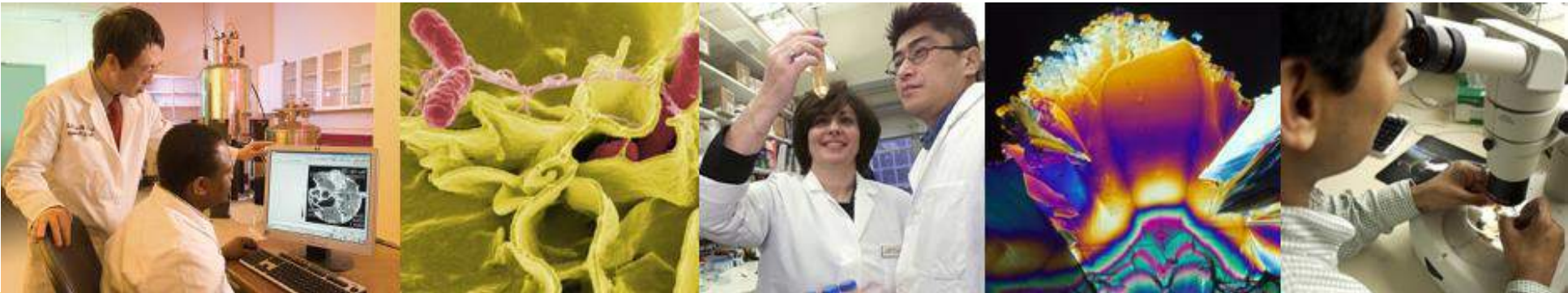


Research and Funding

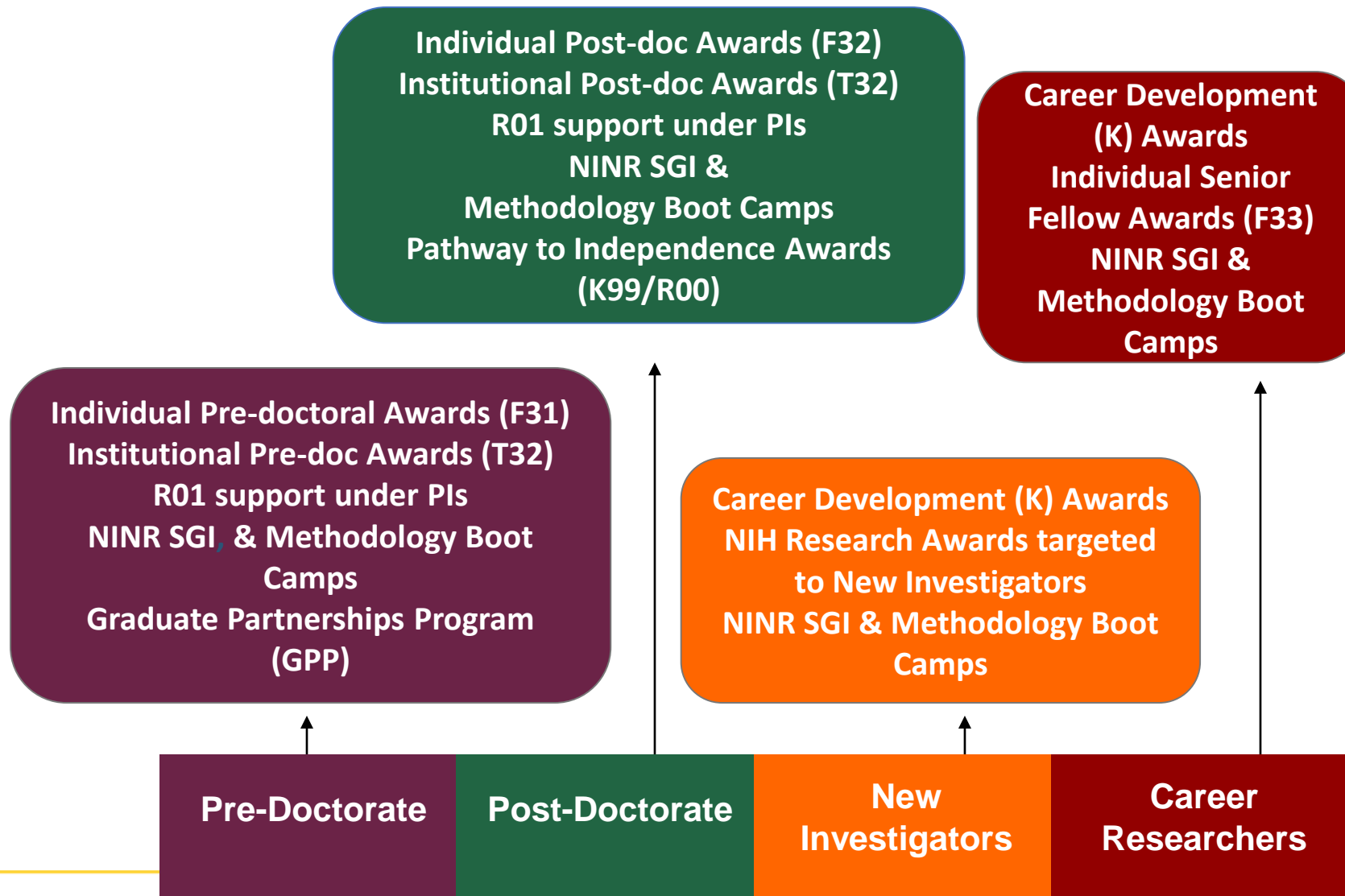
NIH Common Fund Opportunities

- Highly innovative
 - Cross-cutting
 - Transformative
 - Catalytic
 - Emphasis on innovation
-
- <http://commonfund.nih.gov/newinnovator/>

- Mission and Strategic Plan
- Research and Funding Opportunities
- **Training Opportunities**



Marguerite Littleton Kearney, PhD, RN, FAAN



<http://www.ninr.nih.gov/Training>

National Research Service Awards (NRSA)

- **Individual NRSA** (F31, F32, F33)
 - Predoctoral (F31) PA-14-147; PA-14-148 (Diversity)
 - Postdoctoral (F32) PA-14-149
 - Senior NRSA (F33) PA-14-151
- **Institutional NRSA** (T32) Centers
 - PA-14-015



Research Supplements to Promote Diversity in Health-Related Research

- PA-15-322
 - Applications accepted 15 January, 15 April, 15 August only
 - Priority to candidates at the pre- and postdoctoral level and some very early stage investigators



Career Development (K) Awards

- K01 Mentored Research Scientist Development Award (PA-14-044)
- K23 Mentored Patient-Oriented Research Career Development Award (PA-14-049)
- K24 Mid-Career Investigator Award in Patient-Oriented Research (PA-14-047)



NIH Pathway to Independence Award (K99/R00)

- **PA-15-083**
 - 1 – 2 years mentored support
 - Postdoctoral scientists
 - Up to 3 years independent support



Training Funding Opportunities

Selected Institutional Student Research Programs

Student Research Training
Bridges to the Baccalaureate (R25)
Bridges to the Doctorate (R25)
Diversity Student Research Training
Post-baccalaureate Research Education Program (PREP) (R25)
Initiative for Maximizing Student Development (IMSD) Program (R25)

www.nigms.nih.gov/Training/Pages/TWDPrograms.aspx

Notification Your Content Deleted



NINR Intramural Research and Training

Training and Career Development Opportunities in 2017:

- Summer Intern Program
- Postdoctoral Fellowships (and K99, F33)
- Graduate Partnerships Program
- Summer Genetics Institute
- Symptom Research Methodologies Boot Camp



Adverse Event Information Tables

- Table 1: **all serious adverse events**
- Table 2: **other adverse events** (> 5 % frequency in any arm of trial)
- Table 3: **all-cause mortality** (any cause or arm) including
 - 1) number of deaths
 - 2) frequency of deaths

Adverse Event Information Tables

- Information is aggregated summary level data
- Requires submission of clinical trial protocol and statistical analysis plan when results submitted

Scope: All NIH-Funded Clinical Studies

Includes phase 1 clinical trials and all types of health interventions

- Submission of a plan for compliance with clinical trial information policy
- Compliance date 90 days from effective date of **January 18, 2017**



Good Clinical Practice Training

- GCP required for all involved in clinical trials
 - Design and conduct
 - Oversight and management
- May be achieved through
 - Class or course
 - Academic training program
 - Certification clinical research professional organization
- **Effective January 1, 2017**



Anticipated Attachments for Clinical Trial Applications

- Clinical protocol synopsis
- Clinical and data monitoring plan
- Milestone plan
- Common data elements applicability plan
- Material safety data sheet (investigational devices)

Clinical Protocol Synopsis Attachment

- Intervention to be tested
- Primary and secondary endpoints
- Study population
- Recruitment plans
- Retention plans

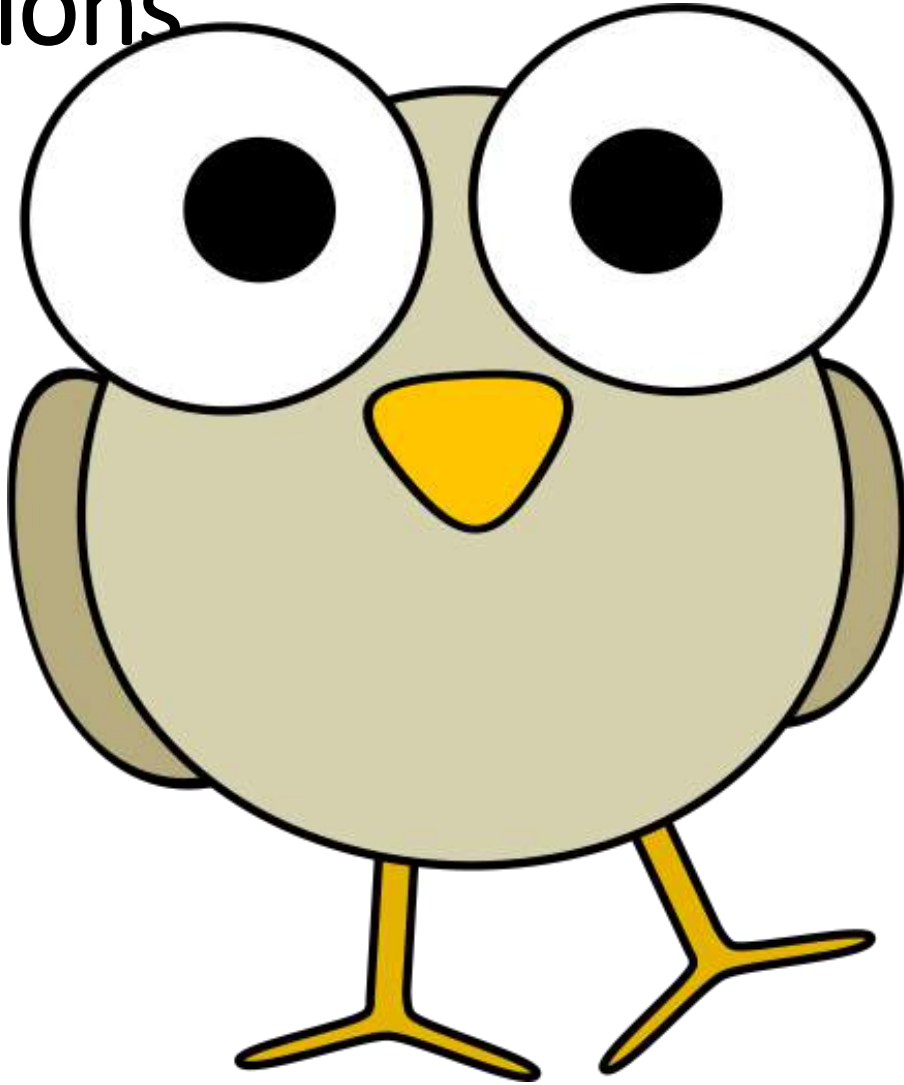
Clinical Protocol Synopsis Attachment

- Group assignment
- Subject participation duration
- Study duration
- Availability of investigational product (if applicable)
- Eligibility criteria

Rigor and Reproducibility

- Scientific premise
 - Description of general strengths & weaknesses
 - Attention to rigor of previous designs
- Scientific rigor-strict application of scientific method
- Biological variables
 - Sex
 - Weight
 - Age
 - Underlying health conditions
- Key biological and/or chemical resources
 - cell lines
 - specialty chemicals
 - antibodies

Questions



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U.S. Department of Health and Human Services



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AACN Doctoral Education Conference Federal Funding Update - AHRQ

Richard Ricciardi

Director, Division of Practice Improvement

20 January 2017



AHRQ's Mission

To produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within HHS and with other partners to make sure that the evidence is understood and used.

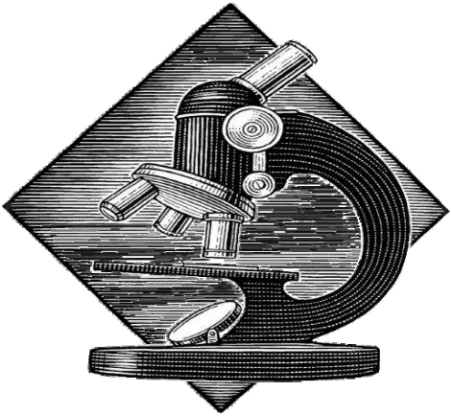


How AHRQ Makes a Difference

- AHRQ **invests in research and evidence** to understand how to make health care safer and improve quality
- AHRQ creates materials to **teach and train** health care systems and professionals to **catalyze** improvements in care
- AHRQ **generates measures and data** used to track and improve performance and evaluate progress of the U.S. health system

HHS Organizational Focus

NIH



Clinical research to develop effective new treatments

CDC



Population health and community-based interventions to improve health

CMS



Payment and incentives for delivery of effective treatments

AHRQ



Research to help health care systems deliver safe and effective treatments



Legislative History

- Created in 1989 as Agency for Health Care Policy and Research
 - ▶ Dual mission of supporting research and implementation of findings
- Reauthorized in 1999 as Agency for Healthcare Research and Quality
 - ▶ New centers for primary care research and patient safety
- Patient Safety Quality Improvement Act of 2005 creating patient safety organizations



NIH & AHRQ Grant Application Similarities

- Announcement publication:
 - ▶ NIH *Guide for Grants and* <http://www.grants.gov>
- Application forms:
 - ▶ Form 424 Research and Related (SF 424 R&R)
<http://grants.nih.gov/grants/funding/424/index.htm>
- Application submission and referral – NIH Center for Scientific Review (CRS)



<http://www.ahrq.gov/funding/index.html>



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Information

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For
Professionals

For
Policymakers

Research Tools
& Data

Funding
& Grants

Offices, Centers
& Programs

News &
Events

A A A

Home

Funding Opportunity
Announcements

Research Policies

Funding Priorities

Training & Education
Funding

Contracts

Grant Application, Review
& Award Process

Post-award Grant
Management

Funding & Grants



Policies and procedures, grant announcements, contract solicitations, special initiatives, call for partners, small business innovation research, and research dissertations, training, and career development.

Funding Opportunity Announcements

Grant announcements from the Agency for Healthcare Research and Quality for supporting research to improve the quality, effectiveness, accessibility, and cost effectiveness of health care.

Research Policies

Policies and procedures, agency requests, and notices



GRANTS ON-LINE DATABASE (GOLD)



Searchable database of
AHRQ Grants, Working
Papers & HHS Recovery Act
Projects



Application Process

- Applications sent from NIH to AHRQ
 - ▶ Assigned to an AHRQ study section
 - ▶ Assigned to a specific Program at AHRQ
- Scientific Review typically occurs 3-4 months after applications received
 - ▶ dissertations, three months later
- Funding decisions occur 1-3 months later
 - ▶ Summary Statements issued
- Resubmission – one allowed



(<http://www.ahrq.gov/funding/process/study-section/resfoci.html>)

- Healthcare Systems & Value Research (HSVR)
- Healthcare Information Technology Research (HITR)
- Healthcare Effectiveness and Outcomes Research (HEOR)
- Healthcare Safety and Quality Improvement Research (HSQR)
- Healthcare Research Training (HCRT)



Scoring Individual Criteria

- There are 5 “core” criteria for most types of grant applications
- For example, the core criteria for R01s are:
 - Significance
 - Investigator(s)’ Qualifications
 - Innovation
 - Approach
 - Environment
- Use the 9-point scale (1 = exceptional, 9 = poor) for the five “core” review criteria.
- Overall Impact Score (9-point scale)



What Determines Which Awards Are Made?

- Scientific merit
 - ▶ Significance, Innovation and originality – Overall Impact
 - ▶ Methods - Qualifications of Investigators
- Program considerations
 - ▶ What is uniquely AHRQ
 - ▶ Existing portfolio balance
 - ▶ Anticipated IMPACT of research
- Availability of funds



Key Points to Promote Success

- Talk with an Agency program officer(s)
- Previously funded work can be informative. See AHRQ Grant Database: www.gold.ahrq.gov/
- Consult/team with senior investigators regarding grantmanships



Key Points to Promote Success

- Bottom Line – Go/No Go
 - ▶ Priority Populations
 - ▶ IRB/Human Subjects Protection & Inclusions
 - ▶ Data Monitoring Plans
- Common Problems
 - ▶ Flaw(s) in the Proposed Methodology
 - ▶ No apparent translatability of research into practice or policy
 - ▶ Not unique to AHRQ or relevant to mission or in line with AHRQ's research portfolio

AHRQ Peer Review Scoring Descriptor Table

	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:

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

- Applications that are not discussed at the meeting will not be given an overall Final Impact Score, but the applicant, as well as the AHRQ staff will see the preliminary scores for each review criteria as additional feedback on their summary statement
- For each criterion rating, the strengths and weaknesses within that review criterion should be considered



Summary Statement

Once applications are reviewed, the results are documented by the Scientific Review Officer (SRO) in a summary statement and posted on the eRA Commons & IMPACII system.

The summary statement contains:

- ▶ Overall Resume and Summary of Review Discussion**
- ▶ Essentially Unedited Critiques provided by the Reviewers**
- ▶ Priority (Impact) Score and Percentile Ranking**
- ▶ Budget Recommendations**
- ▶ Appropriate Human Subjects Protections and Inclusions Coding**
- ▶ Administrative Notes**



Funding Opportunity Announcements

- PA-17-077 Utilizing Health Information Technology to Scale and Spread Successful Practice Models Using Patient-reported Outcomes (R18)
- PA-17-008 Large Research Projects for Prevention of Healthcare-Associated Infections (R01)
- PA-17-007 Large Health Services Research Demonstration and Dissemination Projects for Prevention of Healthcare-Associated Infections (R18)
- PA-16-424 Developing Measures of Shared Decision Making (R01)
- PA-16-423 Large Research Projects for Combating Antibiotic-Resistant Bacteria (R01)
- PA-16-422 Large Health Services Research Demonstration and Dissemination Projects for Combating Antibiotic-Resistant Bacteria (R18)



Funding Opportunity Announcements

- PA-16-453 AHRQ Conference Grant Programs (R13)
- PA-16-421 Advancing Patient Safety Implementation through Safe Medication Use Research (R18)
- PA-16-420 Advances in Patient Safety through Simulation Research (R18)
- PA-16-283 Scaling Established Clinical Decision Support to Facilitate the Dissemination and Implementation of Patient-Centered Outcomes Research Findings (R18)



Funding Opportunity Announcements

- PA-16-282 Developing New Clinical Decision Support to Disseminate and Implement Patient-Centered Outcomes Research Findings (R18)
- PA-15-339 AHRQ Health Services Research Projects: Making Health Care Safer in Ambulatory Care Settings and Long Term Care Facilities (R01)
- PA-15-180 Understanding and Improving Diagnostic Safety in Ambulatory Care: Incidence and Contributing Factors (R01)



Funding Opportunity Announcements

- PA-15-179 Understanding and Improving Diagnostic Safety in Ambulatory Care: Strategies and Interventions (R18)
- PA-14-291 AHRQ Health Services Research Projects (R01)
- PA-14-290 AHRQ Health Services Research Demonstration and Dissemination Grants (R18)



AHRQ Special Emphasis Notices

- Interest in Innovative Methods Research to Increase the Utility of Systematic Reviews
- Advancing the Collection and Use of Patient-Reported Outcomes and Patient Contextual Data to Improve Quality and Outcomes in Ambulatory Care through Health Information Technology
- Optimizing Care for People Living with Multiple Chronic Conditions through the Development of Enhanced Care Planning
- Interest in Innovative Research in Primary Care
- Interest in Research that Uses Shared Decision Making as a Tool to Improve the Quality of Care for Low Income and Racial and Ethnic Minority Patients

Moving Evidence to Frontlines: The Problem



- 17-year gap from evidence generation to practice implementation
 - Delays health benefits
 - Contributes to disparities



Nomination of PCOR Findings for Dissemination

- AHRQ is inviting researchers and other stakeholders to nominate PCOR findings that have been shown to improve health outcomes, but need further investment to achieve widespread adoption.
- AHRQ will assess nominations according to the quality of the evidence, potential impact on health outcomes, and feasibility of implementation.
- Based on AHRQ's assessment, the Agency will then consider them for potential dissemination and implementation activities.

<https://www.ahrq.gov/pcor/ahrq-dissemination-and-implementation-initiative/index.html>



Data Sources (Research Opportunities)

- Consumer Assessment of Healthcare Providers and Systems (CAHPS)
- Healthcare Cost and Utilization Project (HCUP)
- Medical Expenditure Panel Survey (MEPS) – Insurance and Household components



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AHRQ Research Education and Training Programs

Overview



Training & Career Development Grant Programs

Pre-Doctoral

- Health Services Research Dissertation Awards (R36)
- Institutional Predoctoral Research Training (T32)*

Post-Doctoral

- Institutional Postdoctoral Research Training (T32)*

Career Development

- Mentored Clinical Scientist Development Award (K08)
- Mentored Research Scientist Development Award (K01)

*Supported by the National Research Service Award (NRSA) Program



Dissertation Grants (R36)

- Supports dissertation research focusing on health services research
- Provides 9 to 17 months of support
- Applicants must be full time students and all degree requirements must be completed
- Application due dates are February 1, May 1, August 1, and November 1



Institutional Pre/Postdoctoral Research Training (T32)

- Provides stipends and partial tuition coverage
- Curriculum and length of support varies by institution
- Contact institution directly for more information



Career Development Award (K)

- Provides an intensive and supervised research and career development experience in preparation for an independent research career
- Provides salary and research support (Up to \$90,000 salary and up to \$25,000 for research related expenses)
- Awards are 3 to 5 years and are non-renewable
- Minimum 75% of full time professional effort



Career Development Award *continued*

- Current K Award Programs:
 - ▶ K08: AHRQ Mentored Clinical Scientist Career Development Award
 - ▶ K01: AHRQ Mentored Research Scientist Career Development Award
- Application due dates are February 12, June 12, and October 12 annually




General Tips on Getting Started

- Proposed aims should be unique to AHRQ and in line with AHRQ mission and priorities
- Explore previously funded research projects
 - ▶ AHRQ GOLD Database: www.gold.ahrq.gov
- Talk with a program officer (*share specific aims*)



For More Information

www.ahrq.gov/training



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Offices, Centers & Programs

News & Events

AAA

Home > Funding & Grants

Funding Opportunity Announcements

Research Policies

Funding Priorities

Training & Education Funding

Contracts

Grant Application, Review & Award Process

Post-Award Grant Management

Research Training and Education

Sign up: Research Training and Education Email updates

AHRQ-Sponsored Training Opportunities

AHRQ provides an array of pre-doctoral and postdoctoral educational and career development grants and opportunities in health services research training. Research Training and Career Development activities are administered by the Division of Research Education in the Office of Extramural Research, Education and Priority Populations (OEREP).

Select for more information on Research Education and Career Development Opportunities.

Training Programs for Individuals	Investigator Stage		
	Predoctoral	Postdoctoral	Early Career
Health Services Research Dissertation Awards (R36)	X		
AHRQ National Research Service Award (NRSA) Individual Postdoctoral Fellowship Award (F32)		X	
AHRQ National Research Service Award (NRSA) Institutional Health Services Research Training Program (T32)	X	X	
AHRQ Mentored Clinical Scientist Research Career Development Award (K08)			X
AHRQ Mentored Research Scientist Research Career Development Award (K01)			X

Announcements

Thank you!

Your questions?

