Division of Extramural Research Update

January 31, 2017
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Overview

• Staff Updates
• Understanding NICHD Awards
• FY 2017 Funding Strategy
• Upcoming Changes: Clinical Trials
• Overview of the Public Council Archive Pages
Staff Transitions: Departures from NICHD Extramural

Priscah Mujuru
Scientific Review Officer
New to NICHD Extramural

Kelly Fritz  
GMB

Helen Huang  
SRB

Minki Chatterjii  
SRB

Kimberly Houston  
SRB
New to NICHD Extramuralural

Juanita Chinn
PDB

Meredith Temple-O’Connor
DER

Jennifer Jackson
NCMRR

Miguelina Perez
OCM

Samantha Calabrese
MPIDB
Understanding NICHD Awards

Data on Research Training
&
Principal Investigators by Degree
NICHD Research Project Grants: Competing Applications, Awards, and Success Rates

Awards made under Reimbursable Agreements, Appropriations to NIH for Superfund-related activities, Gift Funds and Breast Cancer Research Stamp Funds are not included. Research Projects (RPG) defined as activities (R00, R01, R03, R15, R21, R22, R23, R29, R33, R34, R35, R36, R37, R55, R56, R57, R59, R61, R62, R65, R69, P01, P42, P1, U1, UC1, UC2, UC3, UC4, UC5, UH1, UH2, UH3, UH4, UM1, DP1, DP3, DP4, RC1, RC2, RC3, RC4, UC1, UC2, UC3, UC4, RF1, UF1, PM1, RM1).

FY 2009 and 2010 exclude awards made under the American Recovery and Reinvestment Act of 2009 (ARRA) and all ARRA solicited applications and awards.

An estimate for FY 2015 RPG applications shows 53559 NIH applications and 3551 NICHD applications. These numbers are subject to change.

Source: NIH IMPAC, Success Rate File
Proportion of Type 1 Applicants by Degree

Includes R01 R03, R21, P, and U activity codes
Proportion of Type 1 Awardees by Degree

**NICHD**

**NIH**

Includes R01 R03, R21, P, and U activity codes
• NICHD success rate has been around 11-12% since 2011
  • Large increase in applications during and since doubling, without increase in budget

• Number of NICHD supported trainees on F, T, and Ks also increased during the doubling –nearly doubled
  • Recently have decreased numbers in training – yet proportion of NICHD budget in training has remained approximately 6% of budget
  • Through 2014 continued to support over 1,200 trainees a year – even during time of low success rates for research grants

• NICHD trends in applicant and awardee professional degree for Type research grants very similar to those for NIH overall since 2001
  • Largest pool has and remains to be PhDs
  • Slow decline in proportion of MD applicants and awardees
  • Relative stability in proportion of MD-PhD
  • Some growth in the proportion of “other” professions
FY 17 Funding Strategy

Funding the Best Science
Options for Improving the Payline

Clarify the Message

✓ Tighten referral guidelines
✓ Tighten transfer acceptance
✓ Clinical trials by FOA
✓ Stricter methods for large grant acceptance
✓ Limit PA, PAR, and secondary assignments
✓ Communicate priorities
Communicate Priorities

• Each branch developed up to 7 priority topics
  • Vision Document
  • Strategic Plans
  • Portfolio Assessment

• Identifying gaps and science needed to address

• Post on branch websites
FY 17 Funding Strategy: Funding the Best Science

• Increase flexibility for discretionary funding
  • No fixed pay line for investigator-initiated R01, R21, R03, R13 and R15
  • Using branch priorities, portfolio balance, and availability of funds
  • In practice for FY 17

• Be more strategic about our investments:
  • Mechanisms
  • Acceptance of large grants
  • Participation in FOAs
  • Refining referral guidelines
Clinical Trials

Changes in Policy & Implementation
Concerns about NIH Clinical Trials


  - Large investment, $3 billion/year
  - Variable quality of trial design
  - Incomplete registration and reporting of trial results
  - Inconsistent oversight and monitoring
  - Inability to assess across IC’s
NIH tackles clinical trial shortcomings

The NIH is developing new tools, and overhauling its clinical trial funding system, to improve the stewardship of NIH-funded clinical trials

Slide from Mike Lauer
Clinical Trial Life Cycle

Grant → Protocol → IRB → FDA

Data

JAMA

Diabetes Care

Blood
NIH Policy Changes for Clinical Trials

• Revised Definition of Clinical Trials
  • Notice NOT-OD-15-015; Effective October 2014

• Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research
  • Notice NOT-OD-16-094; Effective September 27, 2017

• Policy on Funding Opportunity Announcements (FOA) for Clinical Trials
  • Notice NOT-OD-16-147; Effective September 27, 2017

• NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information
  • Notice NOT-OD-16-149; Effective January 18, 2017

• Policy on Good Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials
  • Notice NOT-OD-16-148; Effective January 1, 2017
Revised NIH Definition of Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

• Purpose: Study development of reasoning ability
  • Cross-sectional with cohorts from 2.5 – 12 years
• Methods: Use MRI to examine neural reactions when presented with a reasoning task
  • Also, test changes in reasoning/MRI activity with and without memory scaffolding exercise
• Outcomes:
  • Neural correlates of reaction times during reasoning task
  • Distribution of correct/incorrect responses to task
  • Changes in neural correlates and responses following memory exercise
NIH Definition of Clinical Trial Decision Tree

Does the study involve one or more human subjects?
Yes

Does the study involve the use of one or more interventions?
Yes

Does the study prospectively assign human subject(s) to an intervention(s)?
Yes

Does the study have a health-related biomedical or behavioral outcome(s)?
Yes

The study is a clinical trial.

The study is not a clinical trial.
Clinical Trials Protocol Level Records by Primary Intervention Type
(n=540)

- Behavioral: 47.6%
- Procedure/Therapeutic: 18.9%
- Pharmaceutical: 15.6%
- Device: 13.5%
- Biologic: 4.4%
Reforms over the clinical trial lifecycle

Overview of the Public Council Archive Pages

Demo provided by Sandi Delcore
Funding the Best Science at NICHD…
to Advance Science & Health for All