Division of Extramural Research: Update

September 21, 2016
Della M. Hann, Ph.D.
Overview

• Staff Updates & Awards
• Understanding NICHD Awards
• Funding the Best Science
• Upcoming Changes: Clinical Trials
New to NICHD Extramural

Nasreen Jones
OHE/OGH

Sanah Zia
OCM

Madjid (MJ) Karimi
OCM

Robert Borie
OCM

Shilpi Agrawala
GHDB
Staff Transitions: Departures from NICHD Extramural

Steven Hirschfeld
Associate Director for Clinical Research

Sheri Ann Hild
Scientific Review Officer

Alicia Christy
Medical Officer

Carla Walls
Scientific Review Officer
Staff Transitions: Retirements in Extramural

Mary Ellen Michel

NCMRR
Program Officer
NIH Director’s Awards

• Valerie Cotton and Lorette Javois for the Gabriella Miller Kids First Pediatric Research Program Coordination Team

• Marita Hopmann for the RPC Reviewer Guidance Working Group

• Eugene Hayunga for his dedication, commitment and leadership to the NICHD and NIH community
Understanding NICHD Awards

Data on R01 Awards by Research Type
Characteristics of scored applications

<table>
<thead>
<tr>
<th></th>
<th>NICHD</th>
<th>NIH</th>
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<tbody>
<tr>
<td>Human Study</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Animal Study</td>
<td>65%</td>
<td>36%</td>
</tr>
<tr>
<td></td>
<td>(2836)</td>
<td>(26855)</td>
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<tr>
<td>Requested Direct Costs ($M)</td>
<td>1.2</td>
<td>1.2</td>
</tr>
<tr>
<td></td>
<td>1.6</td>
<td>1.6</td>
</tr>
<tr>
<td></td>
<td>2.4</td>
<td>1.8</td>
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Data from M Lauer, OER, NIH
OER Analysis: 
Results for 
Cumulative Costs: 
Requested Direct

Requested Direct Cost of NICHD R01 grants

> 
Requested Direct Costs of non-NICHD NIH R01 grants

NICHD higher, and statistically significant for human

Data from NICHD OSPRA
OER Analysis: Results for Cumulative Costs: Committed Direct

Committed Direct Cost of NICHD R01 grants

$1.25$

$1.36$

$1.40$

$1.00$

$1.10$

$1.20$

$1.30$

$1.40$

$1.50$

$1.60$

$1.70$

$1.80$

$1.90$

$2.00$

$2.10$

$2.20$

$2.30$

$2.40$

$2.50$

Millions

Animal

Human

NICHD

NIH, Other ICs

NICHD higher, but not statistically significant

Data from NICHD OSPRA
Number of R01 Awards - Types of Research

NIH R01 Awards

Data from OER SARB

NICHD R01 Awards
Proportion of R01 Awards - Types of Research

NIH R01 Awards

- Other
- Human
- Animal and Human
- Animal

NICHD R01 Awards

Data from OER SARB
R01 Awards – Proportion of Year 1 Costs by Types of Res

NIH R01 Awards

- Other
- Human
- Animal and Human
- Animal

NICHD R01 Awards

Data from OER SARB
Summary: R01 Awards at NICHD

- Requested Costs are higher than other NIH ICs
  - For Research involving Humans, but not Animal

- Awarded Costs are more comparable to other NIH ICs – both Human and Animal

- NICHD R01 Awards higher percentage of research involving humans compared to other NIH ICs
  - Major increase in human research during doubling

- NICHD invests higher proportion of R01 funding in research involving humans
  - Notable growth during the doubling
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
Supporting the Best Science

- Using Priorities to Drive Funding Decisions
- Posting Priorities on each Branch Web Page
- We will continue to welcome, encourage, and support investigator-initiated applications that help advance our mission goals.

Director's Corner

Supporting the Best Science

Using Priorities to Drive Funding Decisions

Public health needs and scientific discovery continually evolve, and it is critical for research-funding agencies to remain ahead of the curve. As opportunities arise, agencies must be agile enough to re-prioritize funding and channel resources toward newly defined goals. A good example of this is NIH's response to the Zika virus outbreak. In February 2016, as Zika began attracting international attention, several NIH institutes, including the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), issued a funding opportunity designed to accelerate research on the virus and its complications. This rapid funding mechanism enables continuous receipt and review of grant applications and expedites funding for Zika-related projects that do not yet have preliminary data.
Contraception Research Branch (CRB)

Overview

The CRB, formerly the Contraception Discovery and Development Branch, develops and supports research and research training programs in contraceptive discovery and development. Major research areas include studies of: new contraceptive methods; mechanisms of action and effects of contraceptive and reproductive hormones, drugs, devices, and procedures as well as optimal formulations and dosages of contraceptive agents and spermicidal microbicides.

For more information on the Branch, read the Assessment of the Contraceptive Research Activities of the NICHD: Executive Summary (PDF 138 KB).

NEW: Research Priorities

Innovative Devices and Delivery Mechanisms

Gap: A key problem in contraceptive development is the delivery of pharmacologic agents to the sites of gamete production, maturation, and function.

Priority: Support research and development of novel and innovative device and delivery mechanisms for existing or novel contraceptive agents to improve ease of use, delivery schedule, and/or efficacy over current contraceptive methods. This work also should support post-marketing of the device and related behavioral research.
• Increase flexibility for discretionary funding
  • No fixed pay line for investigator-initiated R01, R21, R03, R13 and R15

• Be more strategic about our investments:
  • Mechanisms
    • Example: Strategic use of P01 for areas in need of synergy announced https://grants.nih.gov/grants/guide/notice-files/NOT-HD-16-019.html
  • Acceptance of large grants
  • Participation in FOAs
Clinical Trials

*Newly Announced Changes in Policy*
“Many stakeholders have expressed concern that the program is falling short of its potential to conduct the timely, large-scale, innovative clinical trials needed to improve patient care.”

Published in 2010
March 2016

NATIONAL INSTITUTES OF HEALTH

Additional Data Would Enhance the Stewardship of Clinical Trials across the Agency
Main Concerns

- Poorly designed trials
- Inconsistent oversight and monitoring
- Inability to assess across IC’s
Clinical Trial Life Cycle

- Grant
- Protocol
- IRB
- FDA
Series of Policy Changes: Implementation Timeline

- **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 May 25, 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 Staff Involved in the Conduct, Management, and Oversight of Clinical Trials**
  - Internal NIH Policy; Effective January 1, 2017
Interventions at All Points...

Clinical Trial FOAs

Review Criteria

FDA Phase 2 & 3 Protocol Template

ClinicalTrials.gov Registration

Clinical Trials.gov Results Reporting

Grant Application

Required Elements

Protocol

IRB

FDA

Better Health

Ongoing Clinical Trials Monitoring and Oversight

IC Trial SOPs

GCP Training

NIH data system/tools

Strategic use of trial data in ClinicalTrials.gov

DSM policy updates

Evaluation of stewardship activities
Funding the Best Science at NICHD…

to Advance Science & Health for All