Division of Extramural Research Update

September 13, 2018
Della M. Hann, Ph.D.
Overview

• Supporting the Researcher Pipeline

• Progress in Clinical Trial Reforms

• Staff Updates
Supporting the Researcher Pipeline
Subtitle C—Supporting Young Emerging Scientists

SEC. 2021. INVESTING IN THE NEXT GENERATION OF RESEARCHERS.

(a) In general.—Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following:

“SEC. 404M. NEXT GENERATION OF RESEARCHERS.
What the Law Calls For

“The Director of the National Institutes of Health shall … develop, modify, or prioritize policies, as needed … to promote opportunities for new researchers and earlier research independence, such as policies to increase opportunities for new researchers to receive funding, enhance training and mentorship programs for researchers, and enhance workforce diversity.”
Early Stage Investigators (ESI)

- Awarded Total Dollars
- Number of ESI

*FY2018 data is estimated
FY2017 NICHD Appropriations - Extramural only

- Non-competing RPGs, 48.3%
- Competing RPGs, 18.6%
- SBIR/STTR, 3.7%
- Training (F, T, Ks), 6.6%
- ** Other Research - Other, 3.1%
- * Centers and Networks, 13.4%
- Contracts, 6.2%

Total of $1.065 Billion

* Select contracts supporting networks included in Centers and Networks
** Other Research – Other: G11, U13, R13, R24, R25, P2C, U24 and T15 (and others)
Update on NIH Clinical Trials Efforts

Meredith D. Temple-O’Connor, Ph.D.
Senior Policy Advisor for Clinical Research
NIH Initiatives to Enhance Clinical Trial Stewardship

- Good Clinical Practice
- Single IRB
- Registration & Reporting
- Clinical Trial Review Criteria
- Clinical Trial FOAs
- New Application Forms

Enhancing Clinical Trial Stewardship at NIH
- Accountability
- Transparency
- Efficiency
- Dissemination

Learn more at https://grants.nih.gov/policy/clinical-trials.htm
In 2016, NIH announced initiatives targeted to enhance and improve:

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<tr>
<th>Purpose</th>
<th>Description</th>
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<td>Efficiency</td>
<td>Enhance the efficiency of how research studies involving human participants are conducted</td>
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<td>Transparency</td>
<td>Promote a culture of transparency in research in order to advance public health</td>
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<td>Accountability</td>
<td>Ensure that NIH can appropriately identify and report on their clinical trials portfolio to ensure proper stewardship</td>
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<td>Timely Reporting</td>
<td>Decrease the time it takes investigators to publicly report study results</td>
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• NIH clinical trials (CT) policies have been/are being implemented

• Important things to know right now
  • FOAs and the new form
  • NICHD-specific FOAs for investigator-initiated clinical trials
  • Monitoring and Oversight Plans
Monitoring and Oversight of Trials

- A milestone plan
  - Different types of information to understand the status of a given trial
  - Goal: Ensure that each trial stays on track
- Milestone planning and reporting
  - NICHD staff and investigators work collaboratively on milestone plans
Monitoring and Oversight of Trials: IC Perspective on Risk
Key Take Homes

• Clinical trial monitoring and oversight expectations
  • Plan expected prior to award or trial start
  • Reporting frequency based on risk

• Coming soon
  • Guide Notice to alert community regarding expectations for monitoring and oversight
Staff Updates
Staff Transitions from NICHD Extramural

Susan Parker  
GMB

Uma Reddy  
PPB
New to NICHD

Jennie Conroy
GHDB

Joe Bonner
NCMRR

Bradley Cooke
SRB

Shavon Artis Dickerson
OHE

Travis Kent
FI
More To Come...

DER is hiring!
Funding the Best Science at NICHD…
to Advance Science & Health for All