Division of Extramural Research
Update

June 11, 2019
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Overview

• Inclusion of IDD Populations in Clinical Research

• Providing Long-Term Support for Meritorious Investigators

• Staff Updates
Inclusion of IDD Populations in Clinical Research
Inclusion of IDD Populations

- Exploring this issue in response to Council comments on potential exclusion of intellectually and developmentally disabled (IDD) populations in NICHD’s extramurally funded clinical research.
- Examining current commitments in clinical research, clinical trials, and ongoing efforts.
RCDC – FY2018 from across the NIH:

- Women’s Health: $5.048B
- Pediatrics: $4.499B
- Intellectual and Developmental Disabilities (IDD): $515M
- Pregnancy: $419M
- Sexual and Gender Minorities (SGM/LGBT): $354M
Using ClinicalTrials.gov:

- Downloaded clinical trials data for all NICHD sponsored clinical trials (~1,400)
- Using a random sampling of these clinical trials
  - ~20% (n=273)
- Reviewed exclusion criteria to determine if IDD populations are excluded from NICHD sponsored clinical trials and, if so, to what extent
Results

• ~89% of studies reviewed do not exclude IDD populations (n=232)

• ~11% of studies exclude IDD populations

• No difference across intervention type, phase of trial, or age range of participants

• Comparable to other published research examining the issue
Ongoing Efforts

• NIH’s Inclusion Governance Committee
  • Trans-NIH group that focuses on the NIH policy for inclusion of women and children in research involving human subjects, including IDD populations

• INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE)

• NICHD’s Intellectual and Developmental Disabilities Branch (IDDB)
  • Leadership across NIH in studying research and research training aimed at understanding, preventing, and ameliorating intellectual and related developmental disabilities
Additional comments or questions?
Providing Long-Term Support for Meritorious Investigators
Long-term Support for Meritorious Investigators

• Exploring this issue in response to Council comments on potential use of alternative long-term support mechanisms for meritorious investigators

• Previous working group of Council examined using R35 in 2015 & 2016; decision to wait and see how other ICs were utilizing the mechanism
Examples of R-series supported by NIH:

- **R01 (Research Project):** Supports discrete, specified, and circumscribed projects to be performed by the named investigators. Up to 5 years of support.

- **R37 (MERIT Award):** Provides the investigators with distinctly superior records a 5-year award with the possibility of extension for up to 5 additional years. Up to 10 total years of support.

- **R35 (Outstanding Investigator Award):** Provides long-term support to experienced investigators with an outstanding record of research productivity. Encourages investigators to embark on long-term projects of unusual potential. Up to 8 years of support.

**Objectives of R35:**
- Provides long-term support to PIs to conduct innovative and high-impact research
- Reduces administrative burden and grant writing
- Provides flexibility to PIs to pursue new research directions (limited constraints)
- Gives NIH participating ICs the opportunity to tailor it to suit their mission-specific needs
<table>
<thead>
<tr>
<th>NIH ICs</th>
<th>NIGMS</th>
<th>NCI*</th>
<th>NHLBI</th>
<th>NINDS*</th>
<th>NIEHS*</th>
<th>NIDCR*</th>
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<tbody>
<tr>
<td>Eligibility</td>
<td>2 or more NIGMS R01s or 1 R01 &gt;$400K DC</td>
<td>PI on NCI grant 5 or more years; nominated by institution; high productivity</td>
<td>2 NIHHLBI R01-equivalent awards, of which 1 must be an NHLBI-funded ESI R01 award</td>
<td>1 NINDS R01; continuous funding for at least 5 years (at least 1 renewal)</td>
<td>Current PD/PIs on at least 1 single investigator R01 equivalent project for at least 4 years</td>
<td>PD/PIs with at least 1 active NIDCR-supported R01 equivalent &amp; 5 years of continuous support</td>
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<td>Budget in DC</td>
<td>$750K ($250K for ESIs) 5 years</td>
<td>$600K 7 years</td>
<td>$600K 7 years</td>
<td>Minimum $350K, Maximum $750K 8 years</td>
<td>$600K (potentially $750K) 8 years</td>
<td>$650K 8 year</td>
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<tr>
<td>Other Grants</td>
<td>Must relinquish other research grants from IC</td>
<td>Re-negotiation of effort on other grants expected</td>
<td>Does not eliminate the eligibility of the PD/PI for the separate sources of NHLBI funding</td>
<td>Must relinquish other research grants from IC</td>
<td>Must relinquish and consolidate projects from IC</td>
<td>Must consolidate NIDCR single PD/PI research grant support</td>
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<tr>
<td># of Awards</td>
<td>798</td>
<td>133</td>
<td>91</td>
<td>55</td>
<td>13</td>
<td>9</td>
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<td>Total Invested</td>
<td>$357M</td>
<td>$116M</td>
<td>$74M</td>
<td>$44M</td>
<td>$8M</td>
<td>$8M</td>
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*denotes IC currently using MERIT (R37)
NICHD MERIT Awards (FY2015 – 2018)

X = Mean RCR

= Median RCR
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<thead>
<tr>
<th></th>
<th>NICHD’s R37</th>
<th>NICHD’s R01</th>
<th>Other Participating ICs’ R01</th>
<th>Other Participating ICs’ R35</th>
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<tbody>
<tr>
<td>% involving Human Subjects</td>
<td>45%</td>
<td>68%</td>
<td>28%</td>
<td>15%</td>
</tr>
<tr>
<td>% not involving Human Subjects</td>
<td>55%</td>
<td>32%</td>
<td>72%</td>
<td>85%</td>
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NICHD R01 Awards – FY2018

- 1 Award: $583M
- 2 Awards: $148M
- 3 Awards: $32M
- 4+ Awards: $13M
Additional comments or questions?
Staff Updates
Staff Transitions from NICHD Extramural

Minki Chatterjii
SRB

Rose Higgins
PPB

Meredith Temple O’Connor
DER

Katerina Tsilou
OPPTB
New to NICHD

Vicky Haines  
GMB

Clay Mash  
NCMRR

Ronna Popkin  
PDB
More To Come…

DER is hiring!

https://www.nichd.nih.gov/about/jobs
Funding the Best Science at NICHD...

to Advance Science & Health for All