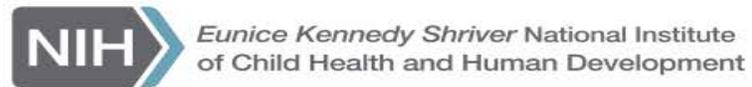


Division of Extramural Research Update

June 11, 2019

Della M. Hann, Ph.D.

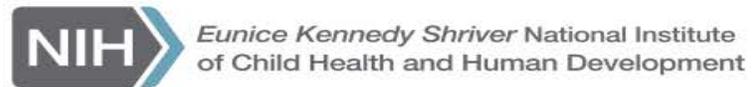




Overview

- Inclusion of IDD Populations in Clinical Research
- Providing Long-Term Support for Meritorious Investigators
- Staff Updates

Inclusion of IDD Populations in Clinical Research





- 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



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

NIH U.S. National Library of Medicine
ClinicalTrials.gov

- ~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*



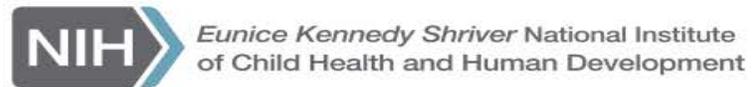
- NIH's Inclusion Governance Committee
 - Trans-NIH group that focuses on the NIH policy for inclusion of women and children in research involving human subjects, including IDD populations
- INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE)
- NICHD's Intellectual 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





- 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

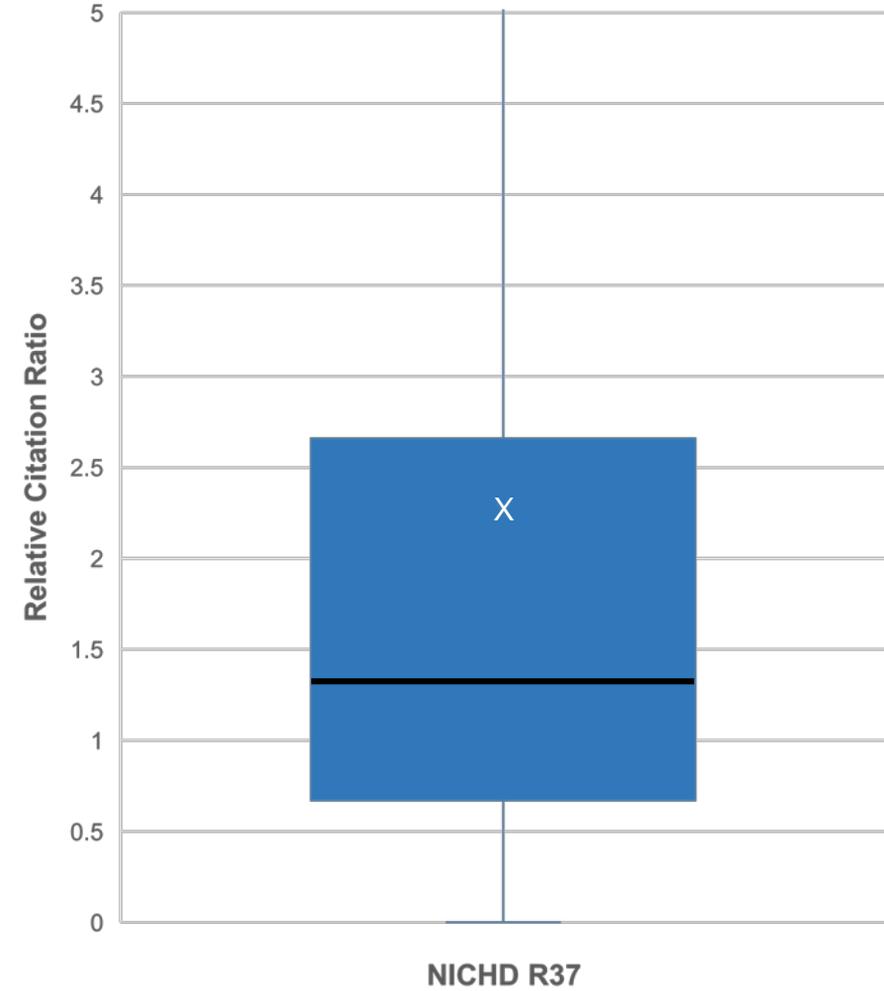
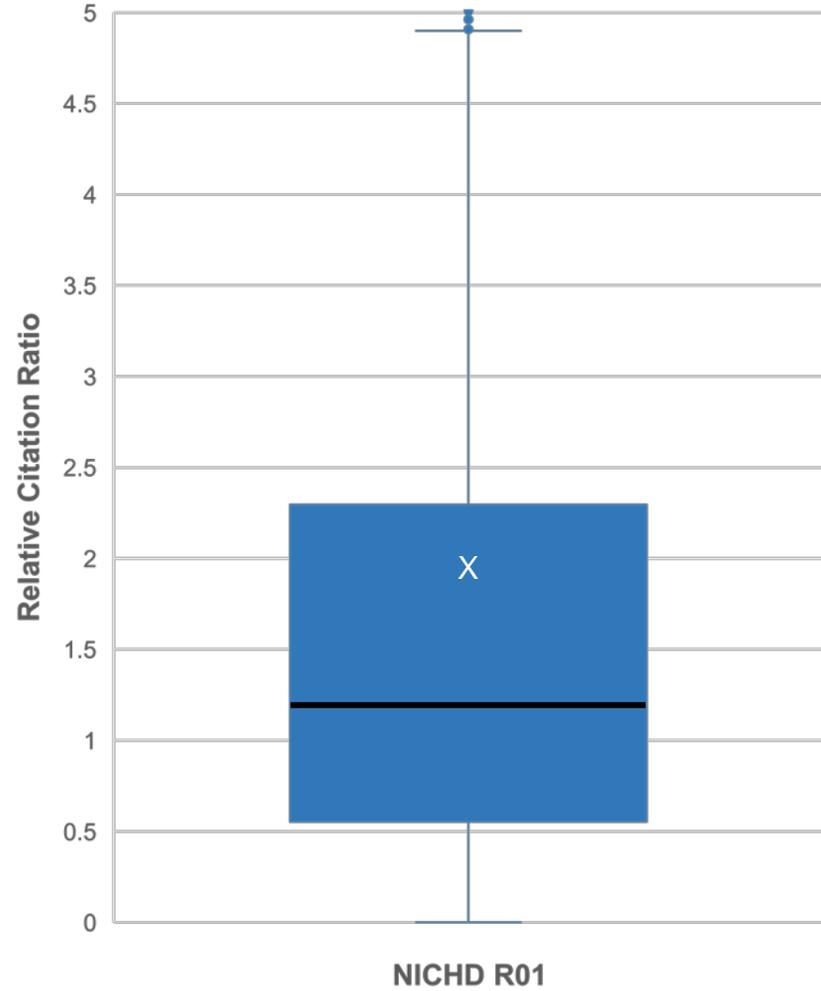
Typical Provisions of NIH ICs Supporting R35



NIH ICs	NIGMS	NCI*	NHLBI	NINDS*	NIEHS*	NIDCR*
Eligibility	2 or more NIGMS R01s or 1 R01 >\$400K DC	PI on NCI grant 5 or more years; nominated by institution; high productivity	2 NIHHLBI R01-equivalent awards, of which 1 must be an NHLBI-funded ESI R01 award	1 NINDS R01; continuous funding for at least 5 years (at least 1 renewal)	Current PD/PIs on at least 1 single investigator R01 equivalent project for at least 4 years	PD/PIs with at least 1 active NIDCR-supported R01 equivalent & 5 years of continuous support
Budget in DC	\$750K (\$250K for ESIs) 5 years	\$600K 7 years	\$600K 7 years	Minimum \$350K, Maximum \$750K 8 years	\$600K (potentially \$750K) 8 years	\$650K 8 year
Other Grants	Must relinquish other research grants from IC	Re-negotiation of effort on other grants expected	Does not eliminate the eligibility of the PD/PI for the separate sources of NHLBI funding	Must relinquish other research grants from IC	Must relinquish and consolidate projects from IC	Must consolidate NIDCR single PD/PI research grant support
# of Awards	798	133	91	55	13	9
Total Invested	\$357M	\$116M	\$74M	\$44M	\$8M	\$8M

**denotes IC currently using MERIT (R37)*

NICHD MERIT Awards (FY2015 – 2018)



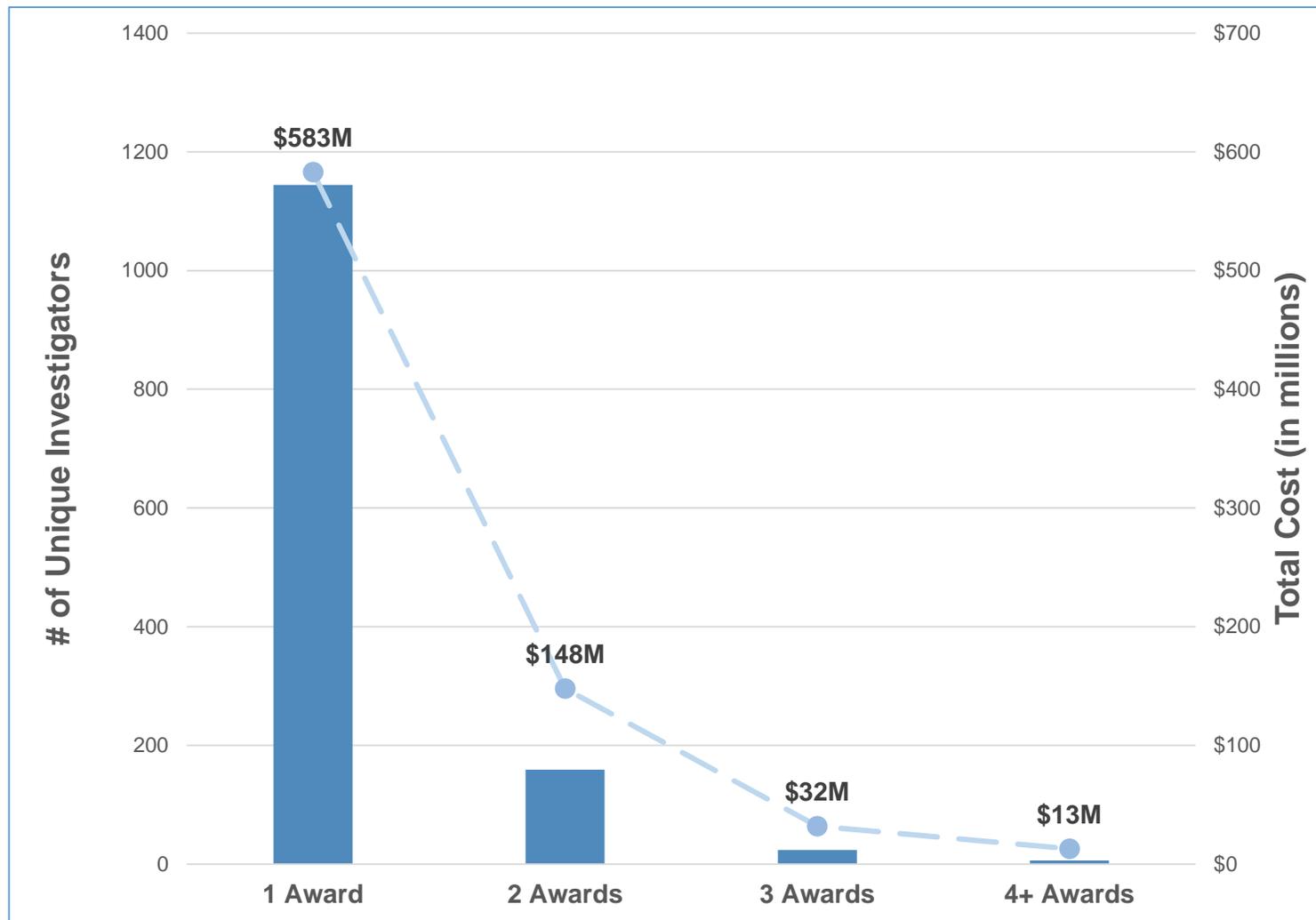
X = Mean RCR
— = Median RCR

Human Subjects Coding Comparisons FY (2015 – 2018)



	NICHD's R37	NICHD's R01	Other Participating ICs' R01	Other Participating ICs' R35
% involving Human Subjects	45%	68%	28%	15%
% not involving Human Subjects	55%	32%	72%	85%

NICHD R01 Awards – FY2018





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

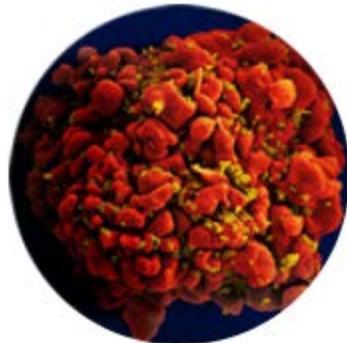
More To Come...



DER is hiring!

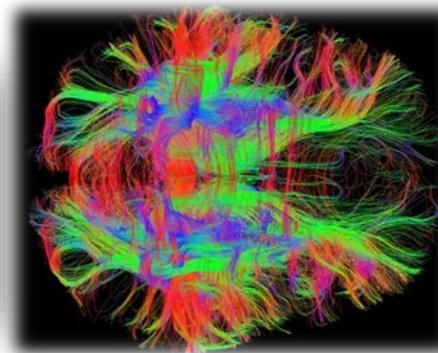


<https://www.nichd.nih.gov/about/jobs>





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to Advance Science & Health for All

