

Consideration of NICHD implementing an Outstanding Investigator Award (R35)

R35 Working Group Members



Cliff Tabin (Council Member), Co-Chair Dennis Twombly (NICHD), Co-Chair Michael Boninger (Council Member) Catherine Gordon (Council Member) Tony Wynshaw-Boris (Council Member)

NICHD Staff Contributors:

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NIH Research Projects (R-series)



- **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, based on a specific project, 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. Allows investigators to continue, or to embark on, long-term projects of unusual potential. Up to 8 years of support.

Objectives of R35:

- Providing long-term support to PIs to conduct innovative and high-impact research
- Reducing administrative burden and grant writing
- Providing 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

Key differences between the R35 and R37



- The R37 is nominated by the IC after an RO1 has gone through the traditional peer review process. In contrast, the assessment of an R35 grant is a separate process and emphasizes the investigator and broad vision (rather than Specific Aims and experimental details)
- An R37 is an extension of a single exceptional grant, while an R35 bundles together all existing R-series grants into a single, new entity
- An R37 allows investigators to extend existing projects without need to go through a peer-review process, while an R35 allows investigators to develop new longer-term innovative programs without the need to quickly generate the preliminary data required of a traditional funding mechanism



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 NIHLBI 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



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- Program parameters must impart a minimal cost to NICHD ie have no significant impact on other IC programs
- At minimum must be equity neutral (can not disadvantage underrepresented groups)
- Funded applications must be congruent with goals of the new NICHD Strategic Plan



- Award Amount: Not to exceed the average total NICHD-sponsored DC over the most recent 4-year period
- Award Maximum: \$750,000
- Award Duration: 8 years, with administrative review after 5 years
- Eligibility: PD/PI of 2 or more active R01 or equivalent (R01, R37, DP1, DP2, SC1 etc), at least one must be in year -06 or beyond
- All existing IC-funded projects must be consolidated and replaced by R35
- Vision outlined in the 6-page application must be explicitly related to goals of the NICHD strategic plan



- 40 NICHD investigators met the criteria in 2018 of having > 1 grant and at least one in year 6 or beyond
- 15 of those were viewed as good candidates for an R35, with total grants within striking range of the \$750K cap. Most are basic/translational. Half are funded by one Branch, the rest distributed among other branches
- Of the 15, all had quite high renewal rates, above 80%.
- As such, costs are likely to be low, in the range of \$3-6.9 M (over 8 years) if all 15 PIs were funded
- To bring in more clinical investigators one would need to raise the cap above 1M
- Could also broaden the criteria to bring in holders of single large RO1s, but this changes the cost the number of eligible PIs goes up but their renewal rates are significantly lower
- Note: This analysis did not include the administrative burden of implementing the program



- Available to limited set of established, well-funded investigators (likely PIs are all in basic/translational fields, some eligible PIs would not be tempted to participate with stated cost limits, almost all PIs with clinical grants are far above the \$750K limit)
- As with any new grant mechanism, instituting such a program carries potential of a not-insignificant amount of work for the NICHD Review Branch, as well as a Grants Management cost (consolidating/re-issuing awards)
- Projects do not undergo peer review for renewal of all consolidated grants for duration of R35
- Does not address important issues around increasing diversity



- Benefits the IC in promoting innovative work relevant to the strategic plan; allows outstanding PIs to pursue new creative research directions
- Supports the Investigator as opposed to supporting specific project(s)
- Emphasis on outstanding PI track record as metric for future productivity
- Consolidates all NICHD grants into a single R35 award
- Longer duration of support: supports all combined grants for 8 years



While the committee agreed on the pros and cons of instituting such a program, taking them into account, there was a range in level of enthusiasm for moving forward. For perspective, two committee members will explain their reasoning, followed by open discussion:

- Catherine Gordon
- Tony Wynshaw-Boris