

Concept Clearance

Branch: Exposure, Response, and Technology Branch

Council Period: 201605

Concept Title: People not Projects: NIEHS Implementation of the R35 Mechanism - Resourcing Innovative, Visionary, Environmental health Research (RIVER)

Introduction

NIH is placing increasing emphasis on enhancing the transformative impact of the research we support. It is recognized that while the traditional focus on hypotheses, specific aims, and preliminary data result in a steady growth of knowledge, the rigidity of the R01 process can limit creativity and innovation. Similarly, there is a perception that the most successful researchers are increasingly devoting a larger portion of their effort to grant writing. To that end, NIH has developed a new Research Project Grant mechanism, the R35, which is intended to fund people, not projects, and reward researchers with a broad vision and track record of impactful research with increased scientific flexibility and stability in funding.

NIEHS is designing our implementation of the R35 around identifying those rare individuals among our grantees who are most likely to benefit from a program emphasizing innovation and impact through flexibility and sustained support.

Research Goals and Scope

NIH Guidance on the R35

The R35 mechanism, as designed by NIH, is intended to provide support for the majority of an investigator's research activities built around a broadly stated theme rather than testing specifically defined hypotheses or specific aims. In addition to providing the PI with more scientific flexibility, this approach also allows the PI to focus more of their effort on their research rather than continually writing multiple new grant applications to support their research program. NIH has granted individual ICs flexibility in adapting the R35 mechanism to their individual mission and priorities within the following guidelines: 1) The PI must devote a minimum of 50% research effort to the project, and 2) The PI may request up to \$750,000 in direct costs annually, for a maximum of 8 years. Each of the five ICs (NCI, NIGMS, NINDS, NIDCR and NHLBI) which have released R35 programs to date has implemented the mechanism in a distinct way within these guidelines and NIEHS has crafted this proposed implementation on lessons learned from their experiences.

NIEHS implementation of the R35

NIEHS will focus its implementation around using the R35 mechanism as an opportunity to break new ground to extend existing research in new directions that may lead to transformative impacts across the scientific domains supported by the Institute. The solicitation will be designed to provide sole support for the investigator's individual research program.

Eligibility:

NIEHS Extramural Staff have evaluated a number of models for determining potential eligibility for the mechanism within the Institute. The other ICs to solicit R35 awards have established eligibility models based on a number of factors emphasizing either longevity of funding from the IC (NCI, NINDS), scope of funding (NIGMS, NHLBI), or career stage (NIDCR). NIEHS staff prefer a model with a broad catchment, recognizing that innovative ideas and transformative research can result from researchers at any stage of their careers, and, in particular, that investigators should be encouraged to follow novel directions resulting from their research and take risks early in their research careers. We, therefore, propose an approach that requires an applicant's home institution to nominate them for consideration and which emphasizes mid-career investigators. The number of nominees will be limited to two per institution, one of whom must be a mid-career investigator (defined as having 10 years or less of support from NIH on an R01 equivalent project). Applicants must have an NIEHS funded, investigator initiated, single-PI, R01 (or equivalent such as an R37 or DP1) ending in the next fiscal year, such that an awarded R35 will take the place of a competitive renewal of the existing R01.

Program Cost and Project Consolidation

The large budget and extended project period of the R35 mechanism is designed to allow an investigator to support the majority of their research program with a single grant. Two potential concerns with the R35 mechanism are 1) that leading

investigators are unlikely to have 50% of their research effort available for a new project, and 2) that with an annual funding level greater than that of two average R01s and a potential duration of up to eight years, the R35 awards may have a significant adverse effect on NIEHS's competitive pay lines. To mitigate these concerns, each IC that has implemented the mechanism thus far has utilized a model which requires the consolidation of some, or all, of the investigator's currently funded projects into the R35. NIEHS will adopt a similar approach, requiring relinquishment and consolidation of all NIEHS-supported investigator-initiated research projects and incorporation of that effort into the R35, with the following exceptions:

- Research that is targeted to specific or non-independent research goals:
 - Clinical Trials
 - NIEHS solicited programs (RFAs, PARs, and select PAs)
 - Multi-PI research projects
 - Small Business awards
- Efforts that are not focused on the individual's research enterprise
 - Center grants
 - Institutional Training/Career Development awards
 - Conference Grants

The long-term risk to the NIEHS grant budget due to the extended project length will be mitigated by incorporation of a mid-course programmatic review, to take place in the fifth year of funding, in order to secure funding for years seven and eight. This is described in more detail below.

Application and Review

The application will be much like the NIH Pioneer award: a brief application focused not around specific aims and methodological details, but on a description of a broad research program which poses a provocative question in a focused area of research and a focus on future creativity and exploration. Applicants will be allowed to request up to six years of support at a level equal to the current costs of their to-be-consolidated research projects plus 10% per year (with a maximum of \$750,000 annual direct costs). During the fifth year, the grantee will be able to request an administrative review for an additional two years of funding at the current level; the basis for this review will be programmatic assessment of successfully taking advantage of the flexibility of the R35 to identify new directions in their research endeavor and the likelihood of transformative impact in the extended project.

Applications will be reviewed using the standard NIH review criteria with an emphasis placed heavily on the factors of significance, innovation, and investigator with extensive pre-review orientation of reviewers.

Program Management

A fundamental goal of the R35 will be to support flexibility to pursue novel directions in existing research across the breadth of the science supported by NIEHS; therefore, the program will be overseen by a trans-Divisional team with representatives from each program branch, grants management, review, and program analysis which will be tasked with developing an innovative scheme for review, management, and evaluation as well as working with the assigned program officers for each awarded project.

Mechanism and Justification

Mechanism: R35

- Pilot program to be updated and renewed annually for three years
- Total of five-six awards annually
- Total cost for the program: \$6 M TC per year; largely cost neutral due to relinquishment and consolidation of existing awards
- Expected cost per grant: Up to \$750k based on current NIEHS support to be consolidated;

Timeline:

- Concept presentation – May 2016
- RFA on street July, 2016
- Receipt September/October, 2016
- Review February 2017

- Council – May 2017
- Fund July 2017