

Concept Clearances

Branch: Exposure, Response, and Technology Branch

Council Period: 202010

Concept Title: Focusing on People, rather than Projects: Launching and Sustaining Outstanding, Innovative, Environmental Health Research

Introduction

NIEHS has two programs focused specifically on enhancing research by outstanding researchers: The Outstanding New Environmental Scientist program (ONES) and the Revolutionizing Innovative, Visionary Environmental health Research (RIVER) program. These programs are utilized to identify 1) promising and highly motivated early stage investigators who intend to make a long-term commitment to environmental research and provide a mechanism to jump-start their career trajectory in pursuit of novel science programs (ONES) and 2) currently funded NIEHS grantees that have demonstrated the potential for continued innovative research and provide support for the majority of their established independent research program (RIVER).

An essential element of the mission of the National Institute of Environmental Health Sciences is to promote career advancement for the future generation of young investigators who will further our understanding of the impact of environmental exposures on human health. The NIEHS has long supported several programs for pre- and post-doctoral training, and mentored career development awards for junior faculty. In May 2005, the NIEHS presented a concept for a new program at its NAEHS Council Meeting - the Outstanding New Environmental Health Sciences (ONES) Award, an imaginative concept to identify the best new biomedical investigators and facilitate their establishing vibrant, independent research programs in the environmental health sciences. This program was initiated in response to NIH data which showed that the average age of a junior faculty member receiving their first R01 had been increasing over the previous decade. In addition, first time investigators were less likely to be successful in the first renewal of their grant. The ONES program was announced yearly for six years by a special Funding Opportunity Announcement (FOA) and between 2006-2012 forty-two awards were made representing the spectrum of research areas supported by the NIEHS. During this time, NIH adopted the designation of Early Stage Investigator (ESI) and developed a review forum to allow the investigators to present their science prior to funding decisions. There was a hiatus in the NIEHS FOA announcement of the ONES program, but following NAEHS Council approval, the ONES program was reinstated in 2014. When the FOA was reissued, the amount of research funding available was increased for applicants proposing population-based research to make the program more attractive for applicants from that discipline. In response to the resulting FOA, an additional thirty-three awards have been made.

The Revolutionizing Innovative, Visionary Environmental health Research (RIVER) program represents the NIEHS implementation of the R35 mechanism which was approved by the NAEHS Council in May 2016. As designed by NIH, this mechanism 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 allows the PI to focus more on their research efforts 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 seven ICs (NCI, NIGMS, NINDS, NIDCR, NIEHS, NHGRI, and NHLBI) which have released R35 programs to date has implemented the mechanism in a distinct way within these guidelines.

The NIEHS has released four separate FOAs resulting in an R35 portfolio that includes nineteen awardees, at various stages in their careers, whose research spans a range of disciplines (e.g., genome stability, exposure biology, xenobiotic metabolism, mitochondrial dysfunction, and epigenetics/epitranscriptomics), exposures, and disease foci including liver disease, autism, Parkinson's Disease, lupus, and cancer. Progress and success are being measured in new and different ways than with traditional R01s to account for the impact of the two key features/benefits of mechanism: 1) freedom from traditional focused specific aims and a structured research plan and 2) more time to devote effort to research, mentoring, and scientific service due to reduced time writing and managing multiple grant applications and awards. In addition to providing an annual update on overall research progress, R35 awardees have been reporting on how they are taking advantage of these key features/benefits of the R35 mechanism.

The applications and awards for both the ONES and RIVER program are distributed across the Division based on the science of the applicant and these programs have therefore enriched and strengthened many areas of research in the environmental health sciences. To date, there have been more than 1,500 publications citing ONES grants and nearly seventy-five percent of ONES awardees have been promoted to tenure since receiving their award. ONES awardees have also been successful in obtaining additional ES support or other NIH grant awards (69% and 45% respectively). Taken together, these data suggest that the ONES program continues to be a valuable tool in identifying promising junior scientists and in meeting the Institute's goal for supporting ESIs. Though the RIVER program is in its infancy, there have already been more than 100 publications citing

ES R35 grants and evidence of increased reach and visibility of EHS research, increased scientific service and mentorship, and perhaps most importantly, enhanced creativity and excitement on the part of awardees.

Research Goals and Scope

ONES:

The goal of this program is to provide a funding opportunity which will attract the most promising Early Stage Investigators. The award includes a career enhancement budget and advisory committee which are designed to put in place career resources and career guidance to increase the likelihood of renewal of the award or successful competition for new grants. By targeting a program specifically to ESI investigators, NIEHS will be able to identify the top echelon of new biomedical investigators and provide them additional start-up funds to facilitate their future success. The requirement for an environmental health focus will give NIEHS a competitive edge in the search for talented researchers.

RIVER:

RIVER is intended to support the majority of the independent environmental health sciences research program of investigators who demonstrate the potential to conduct outstanding, innovative, and transformative research and who articulate a clear and compelling vision for using the R35 mechanism as an opportunity to break new ground to extend the PI's existing research in new directions that may lead to transformative impacts across the scientific domains supported by the Institute. The NIEHS continues to prefer an R35 model with a broad catchment, recognizing that innovative ideas and transformative research can result from researchers at any stage of their careers, and that investigators should be encouraged to follow novel directions resulting from their research and take risks early in their research careers.

Mechanism and Justification

ONES:

The NIEHS is proposing a continuation of a program of research grants intended for the Early Stage Investigator applicant. The program will continue to be designed as highly competitive and only a limited number will be awarded per year. Applicants to the FOAs will be expected to demonstrate how the proposed research will have a defined impact on the environmental health sciences and be responsive to the mission of the NIEHS, which is distinguished from that of other Institutes by its focus on research programs seeking to discover how the environment affects people in order to promote healthier lives. The FOA will be issued with multiple yearly spaced receipt dates.

Applications submitted in response to ONES FOA's will be required to include all the elements of research grant applications appropriate for the mechanism to be used. However, the research grant applications in this concept are distinguished from other research grant applications in four other respects. First, additional emphasis will be given on the applicants' previous research experience and achievements, their future career goals and objectives, and their plans for enhancing their careers. Second, applicants will be required to describe the active participation of an advisory committee composed of senior internal and external scientists to provide mentorship and scientific feedback on the research project and career. Third, applicants are expected to have a tenure track or equivalent position and demonstrated commitment by the institution to the continued faculty development of the Principal Investigator. Because active support from a new investigator's department is crucial to their career development, applicants will be required to demonstrate this support in the form of dedicated space, institutional resources, and letters of support from their Institution. Fourth, since NIEHS is proposing to make a substantial commitment to the research career of the principal investigator, it is proposed that budgets submitted in response to this program will include a separate budget specifically devoted to resource development and career enhancement activities.

The ONES program is designed to build a long-term association between the ONES awardees and the NIEHS. This is accomplished by regular grantee meetings at the NIEHS campus which are open to all NIEHS scientific investigators, and which also include informal sessions with the NIEHS Grants Administrators. Also, the NIEHS staff will work closely with the ONES grantees to facilitate their inclusion in sessions and panels at national meetings focused on environmental health to provide other opportunities to promote interactions among the ONES grantees and to highlight their research. Because of the special competitive nature of this program, institutional balance will be considered in the selection of the junior faculty to whom awards are made.

RIVER (R35)

The NIEHS is proposing that the RIVER (R35) program continue operating within the NIH guidelines of the program and modifying factors such as eligibility, timing, and budget based on a continuing evaluation of the program. A fundamental goal of the R35 is to support flexibility to pursue novel directions for existing research across the breadth of science supported by the NIEHS; therefore, the program will continue to be overseen by a trans-Divisional team with representatives from each program branch, grants management, review, and program analysis tasked with maintaining the scheme for review, management, and evaluation as well as, working with the assigned program officers for each awarded PI.

The research strategy is expected to evolve over the duration of a RIVER award; therefore, applications will continue to focus on general scientific themes and approaches to be taken to address broad but critical questions within the area of study/and or related to the goals of the research program rather than specific aims and methodological details. 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 for reviewers. Because of the highly selective nature of the program, RIVER will continue to require a Letter of Recommendation from a peer working in a similar domain of the environmental health sciences as well as a Letter of Support from the applicant Institution.

As it is intended to provide support for the majority of the PI's independent environmental health sciences research program, acceptance of the R35 award requires a relinquishment and consolidation of single PI investigator-initiated research projects funded by NIEHS at the time the R35 is issued, dedication of at least 6 person months (i.e., the equivalent of 50% effort on a full-year appointment, 66.67% on a 9-month appointment, or 100% on a 6-month appointment) of the PD/PI's total effort to the project throughout the R35 award, and agreement to refrain from submitting single PI investigator-initiated grants to the NIEHS until the last year of the R35 award.