Maximizing Investigators’ Research Award for Early Stage Investigators (R35)

August 6, 2020
**Disclaimer**

- This webinar and accompanying slides are for informational purposes only. They serve as an overview of the ESI MIRA program and are not meant to be comprehensive in coverage of all required components of an application.

- Applicants are responsible for following the instructions detailed in the program-specific FOA and any Related Notices included in the FOA’s Overview Information section.

- Weblink to Current FOA: PAR-20-117
NIGMS ESI MIRA Program

• NIGMS ESI MIRA is intended to provide support for research within the NIGMS mission in the laboratory of an Early Stage Investigator (ESI)

• NIGMS supports research on basic biological processes as well as translational and clinical research in certain areas

• Within the scope of the MIRA, investigators will have the freedom to explore new avenues of inquiry that arise during the course of their research, as long as they remain within the mission of NIGMS

• Work involving the addition of human subjects, clinical trials, vertebrate animals, stem cells, select agents, or a new foreign component require prior approval by NIGMS staff according to existing policies and procedures
NIGMS ESI MIRA Program Goals

- Improve the efficiency and effectiveness of its support for basic biomedical research
- Enable investigators to apply earlier in their independent research careers
- Enhance investigators’ ability to move into research areas that are distinct from that of their postdoctoral mentors
- Increase the stability of investigator funding
- Increase the flexibility for investigators to follow important new research directions
- Improve the distribution of funds to improve overall scientific productivity and the chances for important breakthroughs
- Reduce the time spent by researchers writing and reviewing grant applications
- Enable investigators to devote more time and energy to mentoring activities
Eligibility for PAR-20-117

• You must be an NIH defined **Early Stage Investigator**

• This means you must be within 10 years from completion of your terminal degree (PhD or equivalent)

• MD and other medical professional degrees within 10 years of completing residency training (or the equivalent)

• Only single PD/PI applications are allowed

• Foreign institutions are not eligible

• You must not have received substantial NIH funding as the PI of an independent research award

• ESI status may be **extended upon request** for family care responsibilities, extended training, disability or illness, active military service, and certain other reasons
Research must be in the mission of the NIGMS

• NIGMS supports basic research that increases understanding of biological processes and lays the foundation for advances in disease diagnosis, treatment and prevention. See: Overview Divisions and Program Contacts

• NIGMS also supports research in certain clinical areas: anesthesiology; clinical pharmacology; sepsis; injury & critical illness. Mechanistic clinical trials at a single site are allowed

• Work supported by NIGMS Division for Research Capacity Building (IDeA, COBRE, INBRE, NARCH) includes broad research areas, and they may or may not be appropriate for NIGMS support using the MIRA grant mechanism

• Contact Scientific/Research Staff (listed on the FOA) prior to submission for advice on the suitability of the proposed research for NIGMS. Applications that are determined to be outside of the NIGMS mission will not be accepted for review.
PAR-20-117 Award Information

- Requests up to $250,000 direct costs (DC) per year for 5 years are allowed, but annual inflationary increases **should not** be included.

- NIGMS expects to fund approximately as many early stage investigators through all its grant mechanism as it has in recent fiscal years.

- Foreign collaborations are allowed, but funding will be provided only when a consortium arrangement is essential to the research program, represents a unique scientific opportunity, and cannot be supported by the collaborator. **This situation is expected to be rare.**
Application Submission Information

• Research Strategy ≤ 6 pages
  o Background, gaps, challenges
  o Recent Progress
  o Proposed Research
  o Preliminary data is neither required nor expected (feasibility of the program may be demonstrated through literature citation, data from other sources, or data generated by the applicant as a graduate student or postdoctoral fellow)

• Cite papers in bibliography
• Letter of Support from Dean or Chair
• Appendix, standard NIH policies apply

• Non-compliant applications will be returned without review!
• ESIs can have BOTH an R01 & R35 application under consideration simultaneously (but even if both score well only one will be awarded)
Letter from the Dean or Chairperson

- Describes the institutional commitment to development of the investigator, including a mentoring plan for the PD/PI.

- Could include information on start-up packages and other institutional research support; space available to the PD/PI; salary support commitment; skills and career development opportunities; mentoring during the promotion and tenure process; and career advancement prospects for non-tenure track applicants.

- Letters from former mentors are not required, nor encouraged, except in the case of continuing collaborations.
Application Budget Information

- Follow FOA budget instructions under Section IV carefully – varies from traditional RPG detailed budget instructions (modular budget form unacceptable for R35’s)
  - Use R&R Detailed Budget Form - exclude traditional Itemized budget information, instead provide:
    - **Total requested direct cost** amount (up to $250K) for each budget period, including requests for equipment and consortium DC (should be rare)
    - Other than years when equipment is requested, annual DC should remain constant in outyears

- **Budget Justification** includes the following **minimal** information:
  - Equipment (quote(s) may be included here)
  - Consortium: Not anticipated in most cases; must be extremely well justified. List individuals/organizations with whom consortium arrangements made; indicate whether foreign/domestic; list total consortium costs for each budget period (broken down into DC and F&A costs separately).
  - Explain F&A base exclusions (i.e. equipment, tuition, etc.)
Receipt and Referral

All applications are due on October 2, 2020

• No late applications will be accepted for this FOA

• Applications will be reviewed for completeness by the Division of Receipt and Referral, CSR, NIH

• Eligibility to apply is defined by the ESI status of the PI in the NIH record system on the receipt date

• Applications will be reviewed for responsiveness to the FOA by NIGMS staff

• Applications not in the NIGMS mission will be returned
Review Information

• Applications will be reviewed by Study Sections organized by the Center for Scientific Review (CSR)

• Panels will review only applications in response to PAR-20-117 (MIRA for Early Stage Investigators)

• Reviews will use modified review criteria that emphasize the importance of the questions being asked, past productivity and future potential of the PI, and whether the environment is conducive to the success of the PI, and will deemphasize details of approach

• Only a single overall impact score will be voted, no separate criterion scores. Depending on numbers of applications, the lower one-third to one-half of applications may not be discussed
Review Criteria

• **Significance**
  Is the research program substantive in scope/adequately broad and ambitious? Will it permit the PI to establish a uniquely independent place in the field?

• **Investigator**
  Does the PI have appropriate training, have a record of productivity/impact, and shown evidence of creativity/adaptability, potential to establish successful independent program of research, promise as a mentor of others?

• **Innovation**
  Is there evidence that creative strategies will be employed as needed and appropriate to address the research questions posed?
Review Criteria (Continued)

- **Approach**
  Is there a sound basis for the proposed research and evidence that the research program will evolve appropriately as the work is performed? Where preliminary data are not included, are the relevant concepts and methods sufficiently established by the prior literature? Is there a logical plan for sustained progress across a research program for the five-year award period?

- **Environment**
  Is there evidence that the PI has an independent research position, that the environment will be conducive to the development of the PI, and of institutional support and mentoring?
Award Administration

• PI must commit 51% of research effort to MIRA award (Just in time information)
• Other NIGMS funding must be relinquished and pending applications withdrawn except for the funding mechanisms allowed by the ESI MIRA FOA
• Permanent change of PI not permitted, usual temporary change exceptions apply
• Transfer to new U.S. institution allowed (not to foreign institution)
• Changes in scope require prior approval, including for example addition of animals, human subjects, clinical trials, foreign component, etc.
• Research Performance Progress Report (RPPR) is required annually with some supplemental instructions –mainly dealing with changes in research direction, training and professional development, and other support of the lab
MIRA Resources


• NIGMS MIRA Website: https://www.nigms.nih.gov/research/mechanisms/mira/pages/default.aspx

• ESI MIRA FAQs: https://www.nigms.nih.gov/Research/mechanisms/MIRA/Pages/faqs-esi-mira-par-20-117.aspx


• NIH website to applicants: How to Apply-Application Guide

• Application form instructions: Application Guide Research-forms-f.pdf

Contacts for MIRA

• Sailaja Koduri, Ph.D.; Program Officer, NIGMS; Sailaja.Koduri@nih.gov

Please contact Dr. Koduri or a program director in your area of research BEFORE you submit your application for advice on the suitability of the proposed research for NIGMS

• Maqsood Wani, Ph.D.; Office of Scientific Review, CSR; wanimaqs@csr.nih.gov

• Lisa Moeller; Grants Administration Branch, NIGMS; moellerl@mail.nih.gov

Thank you for interest in the MIRA program!