Maximizing Investigators' Research Award (MIRA, R35) for ESIs, PAR-23-145

Updated March 2025

Funding Opportunity Terminology

- To standardize terminology across the government, NIH is joined other federal agencies in using the term Notices of Funding Opportunities (NOFOs) rather than Funding Opportunity Announcements (FOAs).

- NOFO is the term we will use going forward.

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Disclaimer

- 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 NOFO and any Related Notices included in the NOFO's Overview Information section.

- Current ESI MIRA NOFO: PAR-23-145

Outline

- ESI MIRA Program Overview

- Application Overview

- Budget Overview

- Peer Review Overview

NIGMS ESI MIRA Program

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

- A Principal Investigator (PI) may only have one MIRA grant

- For the purposes of the ESI MIRA NOFO, a research program is defined as a collection of scientific projects in an investigator's lab that are related to the mission of NIGMS

- Requires 51% total research effort

- Upon ESI MIRA award, PI must relinquish other NIGMS research support with some exceptions, (e.g., resource, training, small business grants)

ESI MIRA Program Goals

- Enable investigators to apply earlier in their independent research careers

- Enhance investigators' ability to move into research areas that are distinct from those of their postdoctoral mentors by not requiring or expecting preliminary data

- Increase the stability of funding for NIGMS-supported investigators

- Increase flexibility for investigators to adapt to important new research directions as opportunities arise, rather than being bound to specific aims

- Reduce the time spent by researchers writing and reviewing grant applications, allowing them to spend more time conducting research

- Enable investigators to devote more time and energy to mentoring trainees in a more stable research environment

NIGMS Research Areas

- NIGMS supports basic research that increases understanding of biological processes and lays the foundation for advances in disease diagnosis, treatment and prevention. See: [Research areas supported by NIGMS](#)

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

- Some types of research (e.g., clinical studies, team science, or work supported by the NIGMS Division of Research Capacity Building) may be better suited to other activity codes.

- Contact [Scientific/Research Staff](#) **at least 6 weeks** 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.
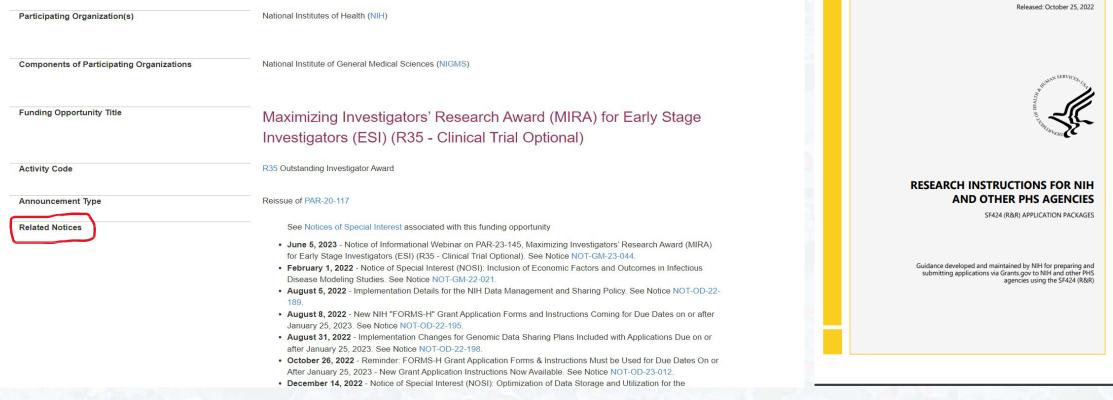
ESI MIRA NOFO and SF424 (R&R)

Follow the instructions detailed in the ESI MIRA NOFO (PAR-23-145), its Related Notices in the Overview Information section, and the SF424 (R&R) Application Guide.

Eligibility

- Principal investigators who meet the following requirements are eligible to apply:
  - proposes research in an area within the NIGMS mission
  - has an ESI status = 'Yes' in eRA Commons
  - has an independent research appointment at an eligible organization

- Only single PD/PI applications are allowed; Foreign institutions are not eligible

- ESI status may be extended upon request for family care responsibilities, extended training, disability or illness, active military service, and certain other reasons

> **Early Stage Investigator (ESI):** A PD/PI who has completed their terminal research degree or **end of post-graduate clinical training** (whichever date is later) within the **past 10 years** and **who has not previously competed successfully as PD/PI for a substantial NIH independent research award.**

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Application Receipt, Review, and Award Start Dates

Receipt Date	Scientific Merit Review	Advisory Council Review	Earliest Start Date
October 03, 2023	March 2024	May 2024	July 2024
February 01, 2024	July 2024	October 2024	December 2024
October 03, 2024	March 2025	May 2025	July 2025
February 03, 2025	July 2025	October 2025	December 2025
October 03, 2025	March 2026	May 2026	July 2026
February 03, 2026	July 2026	October 2026	December 2026

Resubmissions are not allowed. A PD/PI may submit a new MIRA application as long as the PD/PI remains eligible as an ESI.

ESI MIRA Application

- No specific aims section

- Research strategy: 6 pages (background, recent progress, future research)

  - Scientific topics: within the scientific mission of NIGMS ([NIGMS research areas](#))

- Biographical sketch (tailored): as per the NOFO and SF424(R&R)

- Institutional commitment letter from Chair or Dean

- Data management and sharing plan

- Resource sharing plan

- Biohazards (if applicable)

- Vertebrate animal and human subject sections (if applicable)

- Budget forms

- Other forms and attachments (as required by SF424 R&R; standard policies apply for the Appendix)

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Research Strategy

Typical page allotment for Research Strategy (6 pages) section:

- **Background on the area(s) of research and key gaps (1-1.5 pages)**
- **Recent progress by the PI (1-1.5 pages)**
    - Focus on the past 5 years, give context for the overview of future research.
- **Overview of future research plans (3-4 pages)**

    - Include a description of the key questions or challenges that will be addressed and the general strategies that might be used to approach them.
    - A detailed experimental plan should not be provided. (Preliminary data are neither expected nor required, and PDs/PIs may wish to indicate this prominently in the Research Strategy).
    - Do not use the typical Research Strategy headings of Significance, Innovation, and Approach.

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Biographical Sketch

- Use the sample format on the [Biosketch Format Page](#)
- A biosketch should only be provided for the PD/PI
- **Personal Statement:**
  - Tailored to the unique attributes and requirements of MIRA
  - Service to the scientific community (beyond your institutional duties)
  - List ongoing and completed research projects from the past 3 years, and briefly indicate the overall goals of the projects and your responsibilities. (Current and pending support document not required).
  - Do not include the number of person months or direct costs.
  - *If you wish to explain factors that affected your past productivity, such as family care responsibilities, illness, disability, or military service, you may address them in this "A. Personal Statement" section.*
- **Contributions to Science:**
  - This section of the biosketch should emphasize contributions over the past 5 years*.
- Include a link to your [My Bibliography](#) complete list of publications (no other hypertext permitted).

*Do not present or include figures or preliminary data in biosketch.

Letters of Support

- A letter of support **must** be included from the department chair, dean, or other academic unit leader that describes institutional commitment to the development of the investigator (**Applications will be withdrawn if it is missing**).

  - It could include information on institutional commitment, 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 collaborators **must be limited to 1 page each, if included.** Do not include biosketches for collaborators.

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

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Data Management and Sharing Plan

- A data management and sharing plan (DMSP) **is required.**

- All instructions in the [SF424 (R&R) Application Guide](#) must be followed, with the following additional instructions:

  - All applicants planning research (funded by NIH) that results in the generation of scientific data are required to comply with the instructions for the DMSP.

  - All applications, regardless of the amount of direct costs requested for any one year, must address a DMSP.

  - This attachment must be uploaded under "**Other Plan(s)**"

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ESI MIRA Budget

- Follow *updated* budget instructions in NIH Guide Notice [NOT-GM-23-049](#)

- Requests for up to $275,000 direct costs (DC) per year for 5 years are allowed ([NOT-GM-24-042](#))
  - Cap includes equipment, consortium DC, *Data Management and Sharing costs*

- No detailed budget (only Equipment, total DC, F&A, and Total Costs for each year)

- *In Section F "Other Direct Costs": Must add line item titled Data Management and Sharing Costs; enter "0" in "Funds Requested" column. Excluding this will cause an ERROR message to prevent submission*

- *Any funds requested for DMS will be included under "Requested Direct Costs" (also in Section F).*

- No inflationary escalations

- Indirect costs should be requested

- 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.

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Budget Justification

- Include categories listed below only (where applicable):
  - Equipment
  - Data management and sharing costs **(include even if "0" costs requested)**
    - Most NIGMS grantees will not need to significantly change their DMS practices; additional costs, if any, will be modest.
    - Clearly label as "Data Management and Sharing Justification"; include requested dollar amount. If no costs requested, state "0". Follow instructions in the F424 Application Guide for the [Data Management and Sharing Justification](#).
  - Consortium/subaward costs
  - Exclusions from F&A base

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PD/PI Effort Requirements

- PD/PI required to devote at least 51% of the PD/PI's total research effort to MIRA

- Total research effort should include the PD/PI's combined research effort at all institutions where the PD/PI holds an appointment

- Report effort in person-months

- NIGMS staff will verify the MIRA research effort requirement met by using the Other Support documentation and will exclude support for which the purpose is education or training

Review Information

- Scientific and technical merit of applications is determined by scientific peer review at Study Sections organized by CSR
    - MRAA (https://public.csr.nih.gov/StudySections/DBIB/MGG/MRAA)
    - MRAB (https://public.csr.nih.gov/StudySections/DBIB/MBBC/MRAB)
    - MRAC (https://public.csr.nih.gov/StudySections/DBIB/CDB/MRAC)
    - MRAD (https://public.csr.nih.gov/StudySections/DBIB/CDB/MRAD)
    - MRAE (https://public.csr.nih.gov/StudySections/DBIB/MBBC/MRAE)
    - MRAF (https://public.csr.nih.gov/StudySections/DBIB/MGG/MRAF)
    - SEPs as needed

- Panels review only ESI MIRA applications

- Approximately 75% of applications are discussed

- The discussed applications are assigned an overall impact score, no individual criterion scores

- All applications receive a written evaluation

Review Criteria*

Scorable Review Criteria

- Significance
- Investigators
- Innovation
- Approach
- Environment

Additional Scorable Review Criteria

- Study Timeline for applications involving clinical trials and Inclusion Plans associated with Human Subjects
- Protection for Human Subjects
- Vertebrate Animals
- Biohazards

Non-Scorable Review Criteria

- Authentication of Key Biological Resources
- Budget and Period of Support
- Resource Sharing Plans
- Data Management and Sharing Plan (DMSP)

Specific Considerations for MIRA Review

- Are the topics of the research program substantive and appropriate for long-term pursuit?

- Is the rationale for the approach compelling?

- Are the relevant concepts and methods sufficiently established by the prior literature, previous work, or preliminary data?

- Is there a logical plan for sustained progress of the research program?

- Will creative strategies be employed as needed and appropriate to address the research questions?

- Is there evidence that the research program will evolve appropriately?

- Is there evidence that the freedom and flexibility of the MIRA will lead to innovation?

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Specific Considerations for MIRA Review (Cont'd)

- Is the PD/PI the intellectual driver of the research program?

- Does the PD/PI have a strong potential to establish and sustain a successful independent research program?

- Does the PD/PI have a record of productivity and scientific impact commensurate with the applicant's current career stage?

- Does the PD/PI show promise as a mentor and the potential to establish a record of professional service to the scientific community?

- Is the environment conducive for the PD/PI to develop as an independent researcher?

- Does the PD/PI have facilities and institutional support for advancing as an established investigator?

Frequently Asked Questions

- **Is my research topic eligible for ESI MIRA?**

  The specific areas of research that fall in NIGMS mission can be found on our [Contacts by Research Area](#) page. We strongly encourage you to send an abstract (matching as closely as possible to the proposal you'd like to submit) by email to an NIGMS program officer in your specific research area (at least 6 weeks prior to submission) for consultation.

- **Can the topic of a MIRA be in multiple distinct research directions?**

  Yes, applicants can propose multiple projects that may be disparate, and there is no obligation to develop a single unifying theme.

Frequently Asked Questions (Cont'd)

- **Will revised MIRA grant applications be accepted?**
  - **No**, revised applications may not be submitted in response to PAR-23-145.
  - A NEW application on the same general topic can be submitted if you are still an ESI.
  - The new application should make no reference to the previous application or its review.

- **Can I submit other research program grant applications while a MIRA application is pending?**
  - A PD/PI may submit both R01 and ESI MIRA applications for the same council round.
  - Submission of other research grant applications (e.g., R15, R16, R21) to NIGMS is not allowed while an ESI MIRA application is pending review (summary statement is not released).
  - Submission of ESI MIRA application is not allowed if other research grant applications (except R01) are pending review with NIGMS.

Application Withdrawal

Common reasons:

- Research proposed is not in NIGMS mission
- PI is not an ESI at the time of submission
- Missing required attachments (e.g., Institutional support letter and DMSP)
- Specific Aims are listed in the application
- Biosketch is not in NIH format
- Unallowable hypertext (hyperlinks and URLs) in application
- Overstuffing: unallowable information in non-page limited sections
- PI received an R01-equivalent award before review (lost ESI status)
- Another RPG application (except R01) pending review with NIGMS*

* Please review PAR-23-145 for policies regarding submitting simultaneous research project grant applications.

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Award Administration

- PI must commit 51% of research effort to MIRA award (Just in Time information)

- Other NIGMS research funding must be relinquished and pending applications withdrawn except for the funding mechanisms allowed by the ESI MIRA NOFO

- Permanent change of PI not permitted, some temporary change exceptions apply

- Transfer to new U.S. institution may be allowed (not to a foreign institution)

- Some changes do require NIGMS prior approval (e.g., addition of animals, human subjects, clinical trials, and foreign components)

- 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 PI

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ESI MIRA Resources

- ESI MIRA NOFO: PAR-23-145

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

- ESI MIRA FAQs: https://nigms.nih.gov/Research/mechanisms/MIRA/Pages/faqs-esi-mira

- Does your work fit in NIGMS mission? https://loop.nigms.nih.gov/2020/01/how-do-i-know-if-my-work-fits-in-the-mission-of-nigms/

- Application and Funding Trends in FY 2024: https://loop.nigms.nih.gov/2024/03/application-and-funding-trends-in-fy23/

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

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Contacts for ESI MIRA

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

- Program Contacts, NIGMS; NIGMS-ESIMIRA@nigms.nih.gov

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

- Grants Management Contacts, NIGMS; MIRA2019FINANCIAL@nigms.nih.gov

Thank you for interest in the ESI MIRA program.