

Overview of the NIGMS MIRA Programs for Early Stage and Established Investigators



National Institute of
General Medical Sciences

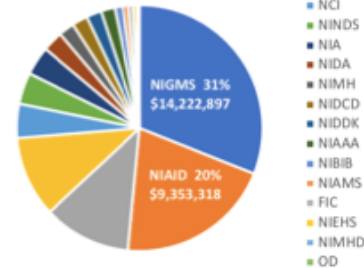
- Goals and Vision for the MIRA Program
- Eligibility
- Program Requirements and Considerations
- Application and Review Criteria

Dr. Rebecca Terns
August 2018



UGA receives more funding from NIGMS than any other NIH Institute or Center

UGA's 2018 NIH FUNDING
BY INSTITUTE



31% of UGA's 2018 NIH funding
comes from NIGMS

NIH RePORTer



Maximizing Investigators' Research Award

NIGMS's R35 Outstanding Investigator Award program

"A single grant to provide support for the program of research in an investigator's laboratory that is related to the mission of NIGMS"

- Support of *program* rather than *project*
- Intended to support *all* of the NIGMS-relevant research in your lab

Two MIRA programs:

- **Early Stage Investigators** - PAR 17-190
- **Established Investigators who currently hold an NIGMS R01** (R37, DP2, or SC1) - PAR 17-094



Goals of the MIRA Program

**"The NIGMS MIRA program ... is eventually intended to support most
NIGMS investigators."**

Maximizing Investigators' Research Award, PAR-17-094
Maximizing Investigators' Research Award for ESI, PAR-17-190



Goals of the MIRA Program

Increase the efficiency and efficacy of NIGMS funding

Increase the **stability** of investigator funding

- 5-year awards
- Mechanisms to support “close but not funded” renewal applications
- Funding can expand at renewal

Increase **flexibility** for investigators to follow important new research directions

- No specific aims

Increase **distribution** of NIGMS funding

- Currently, 5% of NIGMS-funded investigators receive 25% of the funding

Reduce the **time** spent writing and reviewing grant applications

- 1 application every 5 years



Goals of the MIRA Program

Awards to **well-funded NIGMS investigators (2 or more R01s)** will likely be **somewhat lower** than their current total budgets.

- Offset by stability, flexibility, decrease in administrative burden, and increased length of award.
- “It’s very difficult for most investigators to keep multiple R01s funded simultaneously and we expect that it will become even harder to do so in the future. ...the Institute is unlikely to award more than two R01s to a PI. ...MIRA is likely to provide better and more stable support in the long run than trying to keep multiple R01s.”

Budget determinations are done with a great deal of consideration and on a case-by-case basis.

NIGMS Feedback Loop Blog, March 9, 2018



Goals of the MIRA Program

If your current NIGMS research funding is **less than \$250,000**, you might expect an amount **similar to or even higher** than this level.

- One goal of MIRA is to raise the median award levels to reverse losses due to inflation over the past decade for investigators who have been supported by a single, modular NIGMS R01.

If this is your first substantial NIGMS funding (i.e., you are an Early Stage Investigator), you might expect the amount of a MIRA will be somewhat **larger than the current average NIGMS R01** award to ESIs

- Very few ESIs (~10%) receive a second award from NIGMS during the period of their first R01.

NIGMS Feedback Loop Blog, March 9, 2018



Goals of the MIRA Program

The intent is for the success rate of MIRA applications to be **at least as good as the R01 success rate**.

2017 Application Success Rates

	<u>New R01</u>	<u>Renewal R01</u>
• NCI	12%	24%
• NIAID	17%	37%
• NIGMS	23%	48%

NIH RePORTer Success Rates



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• NCI	12%	24%
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• NIGMS	23% (ESI ~25%)	48%

NIGMS anticipates that the success rate for the Established Investigator MIRA will be approximately the same as that of established investigators' success rates on renewing R01 grants.

NIH RePORTer Success Rates
MIRA for Early Stage Investigators Webinar, September 26, 2017



Goals of the MIRA Program

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2017 Application Success Rates

	<u>New R01</u>	<u>Renewal R01</u>	<u>New MIRA R35</u>
• NCI	12%	24%	
• NIAID	17%	37%	
• NIGMS	23% (ESI ~25%)	48%	40% (ESI ~29%)

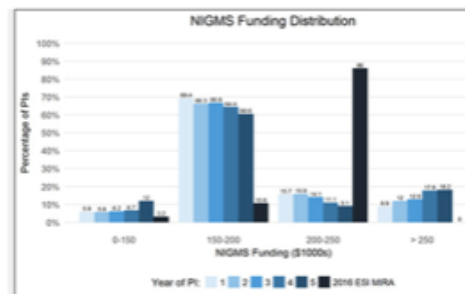
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NIH RePORTer Success Rates
MIRA for Early Stage Investigators Webinar, September 26, 2017



Goals of the MIRA Program

For **Early Stage Investigators**, it is anticipated that the amount of a MIRA will be somewhat **larger than the current average NIGMS R01 award to ESI**.



While most NIGMS ESI R01 recipients received less than \$200,000 in 2016, **50% of ESI MIRA recipients received the maximum award of \$250,000**.

Maximizing Investigators' Research Award for ESI, PAR-17-190
NIGMS Feedback Loop, April 20, 2017



Eligibility

Research must be within the Mission of NIGMS



Other institutes also support basic research relevant to the diseases, organ systems, stages of life, or populations within their mission areas. NIGMS supports basic research that is not clearly in the mission of one of the other institutes.

NIGMS-supported research may utilize specific cells or organ systems if they serve as models for understanding general principles.



Eligibility

How far is too far out for MIRA?

NIGMS MIRA Topic	NIGMS or not?
• Oogenesis in worm	• Oogenesis in human
• Neurodevelopment in fly	• Neurodegeneration in mouse
• Structure-based drug design	• Cancer drug development
• Metabolism in <i>M. smegmatis</i>	• Clinical isolates <i>M. tuberculosis</i>
• Myosins in subcellular traffic	• Kinesins in subcellular traffic
• Myosins in non-muscle cells	• Myosins in cardiac muscle
• LC-MS method development	• Application to clinical samples

Maximizing Investigators' Research Award (MIRA) for Established NIGMS
Investigators Webinar, January 31, 2017



Proposal Enhancement
Office of Research
UNIVERSITY OF GEORGIA

Eligibility

Research must be within the Mission of NIGMS

NIGMS also supports research in specific clinical areas that affect multiple organ systems:

- anesthesiology and peri-operative pain
- sepsis
- clinical pharmacology that is common to multiple drugs and treatments
- trauma, burn injury, and wound healing

Applications that don't fall within the NIGMS mission will be returned without review.

If you have questions or concerns, contact the program director in your scientific area!



Proposal Enhancement
Office of Research
UNIVERSITY OF GEORGIA

Suitability

Other support mechanisms better suited to:

- Research requiring financial support of many collaborators and subcontractors
- Clinical research requiring human subjects protocols and milestones
- Research focusing on HIV/AIDS



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MIRA Eligibility for ESIs

You must be an NIH-defined Early Stage Investigator

- Within 10 years from completion of your terminal degree (PhD or equivalent)
- 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.



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MIRA Eligibility for Established Investigators

Eligibility is restricted to PDs/PIs with **at least one NIGMS R01 equivalent award** (defined here as R01, R37, DP2, and SC1 awards)

- that was awarded funding in the fiscal year prior to the fiscal year of the MIRA application submission and
- **whose project end date is in the same or subsequent fiscal year of the MIRA application submission.**



Upcoming MIRA Application Due Dates

Early Stage Investigators

October 3, 2018
October 3, 2019

Established Investigators

January 17, 2019
May 17, 2019

Early Stage Investigators may submit an R01 application and a MIRA application in parallel. Should both applications be selected for funding, the PD/PI will be required to relinquish one of the awards.

Established Investigators cannot have an overlapping application (R01) “pending” review at time of submission. It's ok if you have the summary statement on the R01 prior to submission of MIRA (but if the R01 scored well, be sure to talk to your PO).



MIRA Award Budgets

Early Stage Investigators

- May request **up to \$250,000** direct costs per year.

Established Investigators

- May request **up to \$750,000** direct costs per year.
- In general, awards will be commensurate with average total NIGMS research funding over the past few years.
- For PIs previously supported by modest budgets (~\$250,000 or less), well-justified increases will be considered.
- For well-funded PIs (2 or more NIGMS research grants or ~\$400,000 or more in annual direct costs from NIGMS) modest reductions should be anticipated, and only in exceptionally well-justified cases would an increase be awarded.

Maximizing Investigators' Research Award, PAR-17-094
Maximizing Investigators' Research Award for ESI, PAR-17-190



Requirements of the MIRA Program

Because the MIRA is to support a significant and ambitious program of research, the investigator is required to devote **at least 51% of his/her research time** to this award.

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Maximizing Investigators' Research Award for ESI, PAR-17-190



Requirements of the MIRA Program

The MIRA will replace all current NIGMS funding of the laboratory.

Recipients are required to relinquish / will not be subsequently awarded other NIGMS research funding with the following **exceptions**:

- Grants supporting research resources
- Contracts
- Cooperative agreements whose FOAs specifically allow funding for MIRA PIs
- Grants supporting training, workforce development, or diversity building
- Grants funding clinical trials
- INBRE (P20), COBRE (P20/P30), or IDeA-CTRs (U54)
- Grants supported through NIGMS HIV/AIDS-related FOAs
- SBIR/STTR grants
- Conference grants

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Requirements of the MIRA Program

You will also no longer be able to *receive funds* from from another investigator's *NIGMS* research grant (e.g., as a collaborator and subcontractor on R01s and as a project leader on P01, P20, or P50 subprojects). You can collaborate with someone with an NIGMS grant, but cannot accept funds (other than exceptions).

Contributions from the following will be subsumed in the MIRA:

- Consortium contract as collaborator or subcontractor on another project
- Multi-PI project
- P01, P20, or P50 subproject

When the MIRA budget is assessed, NIGMS will evaluate which projects you anticipate continuing. Talk to your PO!

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MIRA for Early Stage Investigators Webinar, September 26, 2017



Requirements of the MIRA Program

PI or Project Leader on **NIGMS Multi-PI or multi-component (P01 or P50) award**

- Other project will run until end of project period
- NIH will offset the MIRA by the amount that you spend on the other
- When the other award ends, you will continue work on that project (if it continues) using your MIRA funds

Support as a co-I or paid collaborator on **another PI's NIGMS grant**

- NIH will build those funds into your MIRA grant and you will continue collaborating using your MIRA funds
- NIH will not reduce the amount of the other award – other PI will be able to re-budget those funds

GMS will contact you to discuss. Make your case in the Budget Justification and Other Support of MIRA!

Maximizing Investigators' Research Award (MIRA) for Established NIGMS Investigators Webinar, January 31, 2017



Requirements of the MIRA Program

MIRA investigators can apply for **Research Supplements to Promote Diversity in Health-Related Research, and other types of administrative supplements**, including equipment supplements that may be offered by NIGMS.

MIRA investigators can have/apply for funding from other NIH institutes.

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MIRA for Early Stage Investigators Webinar, September 26, 2017



Renewals

NIGMS anticipates a **higher success rate for MIRA renewals** than is the case for current research project grants.

NIGMS also anticipates there will be **opportunities for increases in the budget** of MIRAs awarded (to ESIs) upon renewal.

If an application for renewal of the MIRA is unsuccessful, NIGMS will consider **interim/bridge support mechanisms**.

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Interim Support

NIGMS expects funding decisions on MIRA renewals to be more flexible than the all-or-none approach typical of R01s.

For renewal applications that are "meritorious but not commensurate with the level of funding provided during the previous MIRA budget period"

- Some **Early Stage Investigators** may be considered for **bridge funding** (modest supplemental funding for a short period of time) to allow them to submit a revised MIRA or an R01 application.
- Some **Established Investigators** may receive a **renewal award at a reduced level of support** or, in rare cases, may be considered for bridge funding.
- Not guaranteed. Decisions will be made on a case-by-case basis.

Interim support for R01s will only be provided in rare and extremely well-justified situations.

NIGMS Interim Support Policy (last reviewed 12/11/2017)



MIRA Subaward Budgets

Consortium/Contractual Arrangements (to support an investigator at another institution) are not anticipated in most cases.

- Direct support of long time essential collaborators can be accommodated. Letter should describe the expertise that they are contributing and why/that the work could not be otherwise supported (from their own sources of support).
- NIGMS will only provide funding for a foreign consortium arrangement when the collaboration is essential to the PD's/PI's research program, represents a unique scientific opportunity, and cannot be supported by the collaborator.

A collaborator at *your institution* can receive support from your MIRA.

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Maximizing Investigators' Research Award (MIRA) for Established
NIGMS Investigators Webinar, January 31, 2017



MIRA Application

- **Project Summary / Abstract**
 - 30 lines of text
- **BioSketch**
 - 5 pages
- **Research Strategy**
 - 6 pages

The MIRA webpage has an example BioSketch and a template for current and pending support.



MIRA Application

Project Summary / Abstract:

- Provide an overview of research in the laboratory and the goals for the next five years, and overall vision of the research program.
- This document should serve both the needs of the public and the needs of the reviewers for an introduction to the research plan.

Very important since the application does not include Specific Aims

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MIRA Application

Biographical Sketch:

- Use the Personal Statement to address MIRA specific elements of the Investigator Review Criterion.
- Include descriptions of significant service and contributions to the research community.
- Under the section on Research Contributions, **emphasize contributions in the past five years.**

Establish the impact of your research here.

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MIRA Application

Research Strategy:

- **Background** on the area(s) of research and key gaps in our understanding or important challenges to be addressed;
- **Recent Progress by the PD/PI**, focusing on the past five years, to give context for the overview of future research. Do not repeat material adequately covered in the Biosketch. Do NOT include a Publication List.
- **Overview of Future Research.** Describe the key questions or challenges the PD/PI plans to address and the general strategies that might be used to approach them. The focus should be on the importance of the questions or challenges. A detailed experimental plan is not expected.

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MIRA Application

Research Strategy:

You can describe multiple distinct projects – there is no obligation to develop a single unifying theme.
In this case, directly address the balance of effort and the resources dedicated to each activity, and how the activities are distinct or complementary.

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MIRA Application

Letters of Support:

The application must include a letter from the institution's Authorized Organizational Official indicating that they are aware of and accept the conditions of the MIRA.

In addition, for an **ESI** application, a letter of support should be included from the department chair, dean, or other academic unit leader testifying to the **institutional commitment to development of the investigator** and any other pertinent information. This information could include start-up packages and other institutional research support, space available to the PD/PI, salary support commitment for the PD/PI, skills and career development opportunities for the PD/PI, mentoring during the promotion and tenure process, and career advancement prospects for non-tenure track applicants.

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MIRA Review

Applications are reviewed by Special Emphasis Panels organized by CSR. CSR will recruit appropriate experts, but there will likely be less detailed expertise in your area on the review

Reviewers will consider all criteria but will only provide an overall impact score.

- Significance
- Investigator
- Innovation
- Approach
- Environment



MIRA Review

Notes from Maximizing Investigators' Research Award (MIRA) for Established NIGMS Investigators Webinar, January 31, 2017

- Previous productivity counts more than in R01 applications. What have you done lately and is it important?.
- Possible impact of overall direction of your work is evaluated. Are your questions important, how will answering them advance the field, and why are you the person to do it?
- How efficiently are funds being used in lab?
- Your plans are evaluated in less detail than in R01 applications. More big picture.

Maximizing Investigators' Research Award (MIRA) for
Established NIGMS Investigators Webinar, January 31, 2017



MIRA Review Criteria

Significance

- Does the program address an important problem or a critical barrier to progress in the field?
- Is there a strong scientific premise for the program?
- If the overall goals of the program are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
- How will successful completion of the research change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

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MIRA Review Criteria

Significance

MIRA-specific

- Are the theme and/or topics of the research program substantive and appropriate for long-term pursuit?
- Is the proposed research program appropriate in scope and ambition to address the scientific questions posed?
- **ESI:** Will the proposed research program permit the investigator to establish a uniquely independent place in the field of research?

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MIRA Review Criteria

Investigator

- Are the PD(s)/PI(s), collaborators, and other researchers well suited to the program?
- Do they have appropriate experience and training?

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MIRA Review Criteria

Investigator

MIRA-specific

- Does the PD/PI have a consistent record of productivity and scientific impact commensurate with the applicant's current career stage?
- Is s/he clearly the intellectual driver of the proposed research program?
- Has the PD/PI shown evidence of being creative and adaptable, able to recognize new opportunities and to explore new areas of scientific inquiry, and openness to the use of new systems and strategies, as appropriate for the proposed research program?

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MIRA Review Criteria

Investigator

MIRA-specific

- **ESI:** Does the PD/PI have strong potential to establish a successful independent program of research in his/her own laboratory?
- **ESI:** Does the PD/PI show promise as a mentor of undergraduate and graduate students, and postdoctoral associates, and the potential to establish a record of professional service?
- **EI:** Does the PD/PI have a record of conducting and reporting rigorous, reproducible, transparent, and cost-effective research?
- **EI:** Does the PD/PI have a record of significant service and contributions to the research community?

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MIRA Review Criteria

Innovation

- Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?
- Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?
- Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

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MIRA Review Criteria

Innovation

MIRA-specific

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

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MIRA Review Criteria

Approach

- Is the overall strategy well-reasoned and appropriate to accomplish the overall goals of the research program?
- Has the PD/PI presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
- Are potential problems, alternative strategies, and benchmarks for success presented?
- If the program is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?
- Has the PD/PI presented adequate plans to address relevant biological variables, such as sex, for studies invertebrate animals or human subjects?

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MIRA Review Criteria

Approach

MIRA-specific

- Is there a logical plan for sustained progress across a research program for the five-year award period?
- Is there evidence that the research program will evolve appropriately as the work is performed?
- Do the plans reflect sensitivity to the need for cost effectiveness in research?

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MIRA Review Criteria

Environment

- Will the scientific environment in which the work will be done contribute to the probability of success?
- Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?
- Will the project benefit from features of the scientific environment, subject populations, or collaborative arrangements?

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MIRA Review Criteria

Environment

MIRA-specific

- **ESI:** Is the environment conducive for the PD/PI to develop as an independent researcher?
- **ESI:** Are there appropriate facilities and institutional support to facilitate the advancement of the PD/PI as an established investigator whose laboratory will have a sustained impact on biomedical science?

Maximizing Investigators' Research Award for ESI, PAR-17-190



UGA Office for Proposal Enhancement

 **Contact us with questions and requests for assistance!**

