

Notice of Funding Opportunity

Application due  
October 2, 2026,  
February 3, 2027,  
October 4, 2027,  
February 3, 2028,  
October 3, 2028,  
February 6, 2029










National Institute of General Medical Sciences (NIGMS)

# Maximizing Investigators Research Award (MIRA) for Early Stage Investigators (ESI) (R35 - Clinical Trial Optional)

Opportunity number: PAR-27-032



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# Before you begin

If you believe you are a good candidate for this funding opportunity, secure your [SAM.gov](#), [Grants.gov](#), and [eRA Commons](#) registrations now. If you are already registered, make sure your registrations are active and up-to-date.

## **SAM.gov registration (this can take several weeks)**

You must have an active account with SAM.gov. This includes having a Unique Entity Identifier (UEI).

[See Step 2: Get Ready to Apply](#)

## **Grants.gov registration (this can take several days)**

You must have an active Grants.gov registration. Doing so requires a Login.gov registration as well.

[See Step 2: Get Ready to Apply](#)

## **eRA Commons registration**

Once an organization has established its unique organization identifier, organizations can [register with eRA Commons](#) in tandem with completing Grants.gov registration. You must have all registrations in place at the time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.

[See Step 2: Get Ready to Apply](#)

## **Apply by the application due date**

Applications are due by 5:00 p.m. local time on October 2, 2026, February 3, 2027, October 4, 2027, February 3, 2028, October 3, 2028, February 6, 2029.



To help you find what you need, this NOFO uses internal links. In Adobe Reader, you can go back to where you were by pressing Alt + Left Arrow (Windows) or Command + Left Arrow (Mac) on your keyboard.



# Step 1:

# Review the Opportunity

## In this step

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# Basic information

## National Institutes of Health (NIH)

National Institute of General Medical Sciences (NIGMS)

Empowering promising Early Stage Investigators (ESIs) to pursue bold, impactful science.

## Summary

The Maximizing Investigators' Research Award (MIRA) for Early Stage Investigators (ESIs) provides support for ESIs with a research program that aligns with the NIGMS [mission](#).

MIRA distributes funding among promising investigators across the country. The goal is to boost scientific productivity and the chances for important breakthroughs.

Through this program, investigators can:

- Receive independent research funding early to start and sustain strong research careers.
- Explore new, unique research areas in the NIGMS mission.
- Take on ambitious, creative projects.
- Shift focus to include emerging techniques and technologies as needed.
- Devote more time to mentoring trainees in a stable research environment.

## Funding details

**Funding type:** Grant

**Expected awards:** The number of awards is subject to available funds and program priorities.

**Project period:** Up to five years in 12-month budget periods.

**Application type:** [New](#), [Revision](#)

**Clinical Trial?:** Optional. We accept applications that either propose or do not propose clinical trials. ([Need help determining whether you are doing a clinical trial?](#))

**Expected total program funding over the performance period:** N/A

**Maximum budget per year:** \$275,000 in direct costs



**Have questions?**

Go to [Contacts and Support](#).

## Key dates

**Application due dates:**

**2026:** October 2

**2027:**  
February 3, October 4

**2028:**  
February 3, October 3

**2029:** February 6

See all [important dates](#).

## Key facts

**Opportunity name:**  
Maximizing Investigators Research Award (MIRA) for Early Stage Investigators (ESI) (R35 - Clinical Trial Optional)

**Opportunity number:**  
PAR-27-032

**Assistance listing:** 93.859

**Activity Code:** [R35](#)  
Outstanding Investigator Award

**Announcement type:**  
Reissue

**Companion funding opportunity:** PAR-26-121

**NOFO version:** Original

## Important dates

NOFO posting date: May 12, 2026

Open Date (Earliest Submission Date): September 2, 2026

Expiration date: February 7, 2029

Application due date	Scientific merit review	Advisory council review	Earliest start date
October 2, 2026	March 2027	May 2027	July 2027
February 3, 2027	July 2027	October 2027	December 2027
October 4, 2027	March 2028	May 2028	July 2028
February 3, 2028	July 2028	October 2028	December 2028
October 3, 2028	March 2029	May 2029	July 2029
February 6, 2029	July 2029	October 2029	December 2029

# Eligibility

## Eligible applicants

Only these types of organizations may apply:

### Higher education institutions

- Public/state-controlled institutions of higher education.
- Private institutions of higher education.

### Nonprofits other than institutions of higher education

- Nonprofits with 501(c)(3) IRS status.
- Nonprofits without 501(c)(3) IRS status.

### For-profit organizations

- Small businesses.
- For-profit organizations (other than small businesses).

### Local governments

- State governments.
- County governments.
- City or township governments.
- Special district governments.
- Indian/Native American tribal governments (federally recognized).
- Indian/Native American tribal governments (other than federally recognized).

### Federal governments

- Eligible agencies of the federal government.
- U.S. territory or possession.

### Other

- Independent school districts.
- Public housing authorities and Indian housing authorities.
- Native American tribal organizations (other than federally recognized tribal governments).
- Faith-based or community-based organizations.
- Regional organizations.

## Foreign institutions

- Foreign components, as defined in the [NIH Grants Policy Statement](#), **are** allowed.

These types of organizations are **not** eligible to apply:

## Foreign institutions

- Non-domestic (non-U.S.) entities (foreign institutions).
- Non-domestic (non-U.S.) components of U.S. organizations.

# Eligible program directors and principal investigators

## Qualifications

For this Notice of Funding Opportunity (NOFO), we limit eligibility to NIH-defined [Early Stage Investigators](#) (ESIs). We confirm ESI eligibility after you submit your application.

For certain life or career events, you can request to extend your ESI status. See the policy on the [Early Stage Investigator Extensions](#).

## Total research effort

The Program Director/Principal Investigator (PD/PI) must devote at least 51% of their total research effort to this award. The total research effort should:

- Include the PD's/PI's combined research effort at all institutions where they hold an appointment.
- Be expressed in person-months.
- Not include time spent on teaching or administration that is not directly related to the PD's/PI's research or clinical duties.

We will verify that the PD/PI meets the MIRA research effort requirement by using the [Other Support](#) documentation. Do not submit Other Support documentation with your application. We will collect this information as needed after review.

## Number of PDs/Pis

We allow only single PD/PI applications. We will not accept applications with multiple PDs/Pis.

## Ineligible PDs/Pis

PDs/Pis who are not ESIs are not eligible for this NOFO. A PD/PI who is a [New Investigator](#) but not an ESI should apply instead through PAR-26-121 or its equivalent.

We will withdraw, without review, applications from investigators who are not eligible to receive the award.

## Unsuccessful applications

This NOFO does not allow resubmissions. A PD/PI may submit a new application to this NOFO after an unsuccessful attempt as long as the PD/PI remains eligible as an ESI and the summary statement from the prior application has been issued.

## Responsiveness criteria

We will review your application to make sure it meets the standard NIH requirements and the following NOFO-specific requirements.

We won't accept an application that:

- Proposes a program of research with projects that are not within the NIGMS [mission](#).
  - Note: Studies aimed at specific diseases, organ systems, stages of life, or populations may be more appropriate for NIH Institutes and Centers focused on those missions.
- Is from a PD/PI who is not an ESI at the time of submission.
- Is from multiple PDs/Pis.
- Is from a foreign organization.
- Includes a specific aims page.
- Uses specific aims or similar designation, including "aims", in the application (for example, using this language in the abstract or research strategy sections).
- Overlaps with an NIGMS research grant application under review. (Exceptions noted in [Overlap During Peer Review](#)).
- Is incomplete. For example, we will not accept an application missing the required Institutional Commitment Letter of Support from the chair or dean.

Applications deemed to be non-responsive will not proceed to review and will be withdrawn.

## Cost sharing and matching funds

This program does not have a [cost-sharing requirement](#), meaning you do not need to contribute to the costs of this project.

## Post-award requirements

Before you apply, make sure you understand the requirements that come with an award.

See [Step 6: Learn What Happens After Award](#) for information on regulations that apply, reporting, and more.

# Program description

## Purpose

The NIGMS Maximizing Investigators' Research Award (MIRA) for [Early Stage Investigators \(ESIs\)](#) provides support for a program of research in an ESI's laboratory. For this NOFO, we define the "program of research" as a collection of projects in an investigator's laboratory that are within the [NIGMS mission](#).

Under a MIRA, investigators can explore new avenues of inquiry if the work stays within the NIGMS mission.

NIGMS strives to maintain a broad research portfolio that spans various scientific areas, approaches, regions, institutions, and individuals. This approach can increase the range of ideas explored and maximize the chances for important breakthroughs.

The NIGMS MIRA supports a majority of NIGMS R01-equivalent awards.

## Overview

NIGMS supports basic research on biological processes as well as translational and clinical research in [specific areas](#). MIRA investigators have the flexibility to explore new ideas, techniques, and approaches that remain within NIGMS' scientific mission.

Although we encourage mutually beneficial collaborations, the MIRA supports the research of an independent investigator's laboratory. The MIRA's intent is to support a significant and ambitious program of research.

## Expected MIRA for ESIs achievements

We expect that a MIRA for ESIs award will:

- Enable investigators to apply early in their independent research careers. Doing so allows them to secure grant funding to launch and sustain productive research careers.
- Allow investigators to move into research areas that are distinct from those of their postdoctoral mentors.

- Provide sufficient funding to encourage a robust research program.
- Increase funding stability for NIGMS-supported investigators.
- Encourage investigators to take on ambitious scientific projects and approach problems creatively.
- Increase flexibility for investigators to adapt to important new research directions, instead of being bound to specific aims proposed in advance.
- Widely distribute funding among the nation's talented and promising investigators to increase scientific productivity and the chances for important breakthroughs.
- Reduce the time spent by researchers writing grant applications. The goal is to allow them to spend more time conducting research.
- Enable investigators to devote more time to mentoring trainees in a stable research environment.

## Allowable and unallowable activities

For this NOFO, we allow:

- Research within the mission of NIGMS, including programs that focus, solely or in part, on technology development and computational approaches.
- Research that involves human subjects.
- Clinical research within the context of the NIGMS clinical areas:
  - Anesthesiology and perioperative pain.
  - Clinical pharmacology.
  - Sepsis.
  - Injury and critical illness.
  - Wound healing.
  - Systemic immune/inflammatory responses.
- [Mechanistic](#) NIH-defined [clinical trials](#) that are essential parts of the research program.
- Foreign Components, as defined in the [NIH Grants Policy Statement](#), if the foreign component does not require NIH funding. We encourage you to consult NIGMS before proposing a foreign component.

For this NOFO, we **do not** allow:

- Support for domestic or foreign subawards.
- Clinical trials designed to test safety and efficacy of interventions (Phase I, II, III) for future clinical treatment or regulatory approval.
- Studies that propose:
  - Clinical dissemination and implementation research.

- Comparative effectiveness research.
- Pragmatic clinical trials.

## Prior consultation with IC staff

We encourage you to contact an NIGMS program officer before submission to help you determine if your project is suitable for NIGMS. To find a point of contact, you may consider using the Matchmaker tool that is part of the [NIH RePORTER](#). Provide as complete a summary of your research program as you can to achieve the best results. This tool uses data from current and past NIH awards to identify similar projects and relevant program officials. The tool provides a range of possibilities and does not provide a precise match to an NIH Institute or Center. Keep in mind that funding priorities of NIH Institutes and Centers change over time.

Select **one** NIGMS program officer whose interests best align with your research and contact that person by email, providing a one-page summary of the proposed MIRA research program. Please do not contact multiple staff members at the same time, as this can cause confusion. We recommend contacting a program officer at least **six weeks before** the application due date.

If your research includes clinical trials, you should also visit the [Research Methods Resources](#) website for information about developing statistical methods and study designs.

We will not accept applications that we determine to be outside of the NIGMS mission. Research with the overall goal to gain knowledge about a specific organ or organ system or the pathophysiology, treatment, or cure of a specific disease or condition will, in most cases, be more appropriate for another Institute or Center. We routinely withdraw applications before review when the proposed research falls outside the NIGMS mission.

## Overlap during peer review

An application is under review from the time of submission until NIH issues the summary statement from that review. We limit the types of applications you may have as a PD/PI under concurrent review with a MIRA for ESIs.

- You may **not** have other research grants being considered by NIGMS (such as R15, R16, R21, DP2, or additional MIRA applications) under review concurrently, regardless of which application was submitted first.
- These application types are permitted under concurrent review with a MIRA for ESIs:
  - An application that is being considered for funding by another NIH Institute or Center.
  - An R01 application being considered by NIGMS.

- The following grant applications are not primarily research focused and constitute an exception list that may be under concurrent review with a MIRA for ESIs. You may also receive funds from these awards if a MIRA is awarded (see Resolving overlap with other NIGMS research grants):
  - Grants that support research community resources, such as the NIGMS National and Regional Resources program.
  - Collaborative Program Grant for Multidisciplinary Teams.
    - You may be a PD/PI as part of your required 51% MIRA research effort.
    - You may not receive additional funds from the Collaborative Program Grant for Multidisciplinary Teams award.
  - Biomedical Technology Optimization and Dissemination Center (BTOD) grants.
    - You must maintain the 51% research effort toward MIRA, and 3 person months on the BTOD.
  - Training or workforce development grants, such as Institutional National Research Service Awards (T32 and T34) and Science Education Partnership Awards (SEPA).
  - Grants for multi-site [clinical research](#), (clinical trials and observational studies), with costs for patient recruitment, protocol-related expenses, or community resource activities like specimen banking and dissemination.
  - Capacity building programs such as:
    - Institutional Development Award (IDeA) centers to build research capacity (for example, Centers of Biomedical Research Excellence (COBRE), IDeA Networks of Biomedical Research Excellence (INBRE)).
  - Health Research Programs for Federally recognized Tribes or Tribal Entities (for example, Native American Research Centers for Health (NARCH)).
  - Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grants.
  - Conference grants.
  - Contracts.

## Disqualifying awards

If you receive an award that removes your ESI status before we fund a MIRA for ESIs, you will no longer be eligible to receive a MIRA for ESIs. This includes awards such as R01, RM1, DP1, and DP2.

Check the NIH's [Early Stage Investigator policies](#) to see which awards affect your ESI status.

## Resolving overlap with other NIGMS research grants

If you receive a MIRA for ESIs, you may not receive funds from other NIGMS research awards (exceptions listed under ‘overlap during peer review’). If you are already supported by NIGMS funding when you receive a MIRA, we will facilitate an orderly process to transition to MIRA funding. We will provide specific details on a case-by-case basis. These scenarios provide some examples of how we address funding overlaps:

- If you are the single PD/PI for an NIGMS research grant, funding for that award will be discontinued.
- If you are a subawardee or paid collaborator on an NIGMS research grant or if you are a PD/PI on a Multiple Principal Investigator (MPI) research grant from NIGMS, you may continue to work on that grant, but funding for the work must be supported by your MIRA.
- If you receive funds as a project leader on an NIGMS multi-component grant, your MIRA funding level will be adjusted to remove any overlap with the multi-component grant. You will be required to relinquish your funding from the multi-component grant at the end of its current competitive segment.
- If you have a K award from NIGMS, you must discontinue the K award before the MIRA start date.
- If you have a K award from another NIH Institute or Center, you must adjust your effort on that award so that you can commit the required effort to your MIRA.

## Applying for awards after receiving a MIRA

We will not accept assignment of an [NIH Director’s Transformative Research Award \(TRA\) \(R01\)](#) or [NIH Director’s Pioneer Award \(DP1\)](#) application if the PD/PI has a MIRA. If assigned to NIGMS, the proposed research would fall within the mission of NIGMS and would overlap with the MIRA.

## Supplements to MIRAs

MIRAs are eligible for administrative supplements offered by NIGMS, depending on the specific supplement program’s intent and constraints.

## Renewals

MIRA for ESIs recipients will be eligible to renew their award through PAR-26-121 and reissuances of it. If a MIRA renewal application is unsuccessful, the grant will terminate when the project period ends.

## After ESI eligibility ends

After a PD/PI's ESI eligibility expires, they may be eligible to apply to the MIRA for Established and New Investigators as a [New Investigator](#) (PAR-26-121 and subsequent reissuances). We encourage you to discuss this option with the NOFO's scientific/research contact.

## Funding policies and limitations

### Changes in HHS regulations

As of October 1, 2024, HHS adopted [2 CFR 200](#), with some exceptions included in [2 CFR 300](#). These regulations replace those in 45 CFR 75. See [NOT-OD-25-059](#) "NIH Implementation of Uniform Administrative Requirements for Federal Financial Assistance."

### General guidance

- You may use funds only for reasonable program purposes consistent with the award, its terms and conditions, and federal laws and regulations that apply.
- All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](#).
- We allow pre-award costs only as described in the [NIH Grants Policy Statement](#).
- Support beyond the first budget year will depend on:
  - Appropriation of funds.
  - Satisfactory progress in meeting your program's objectives.
  - A decision that continued funding is in the government's best interest.

See also [program-specific limitations](#).

For guidance on some types of costs that we restrict or do not allow, see 2 CFR 200.420, [Considerations for Selected Items](#) of Cost.

## Program-specific limitations

### Change of PD/PI

NIGMS will review these situations on a case-by-case basis. If you cannot meet the requirements for PD/PI, or if NIGMS otherwise decides continued support is inappropriate, we may end the MIRA.

You cannot make a permanent change of PD/PI on a MIRA grant.

We may allow a temporary change with NIGMS' prior approval in cases such as:

- Sabbatical leave.

- Medical conditions.
- Disability.
- Personal family situations.

If your employment changes, you must maintain the approved commitment level to the MIRA.

## Foreign institutions and components

We will not allow transfer of a MIRA to a foreign institution. Please refer to the [Grants Policy Statement](#) for requirements associated with foreign components.

## Other awards

The MIRA will replace all current NIGMS research funding in the PD's/PI's laboratory (exceptions listed under 'overlap during peer review'). We will require institutions to discontinue their interests in current NIGMS-funded research grants and withdraw pending applications where the MIRA investigator is listed as the PD/PI or MPI.

NIGMS will not consider funding future research grant applications where a MIRA PD/PI is listed as the PD/PI or MPI during the MIRA-funded project period (exceptions listed under 'overlap during peer review'). NIGMS will not accept applications for grants from MIRA PDs/Pis that are not on the excepted list, unless the new award would begin after the MIRA ends.

## Mission relevance

MIRA allows investigators to shift focus to emerging research areas, but the work must remain within the NIGMS mission. Pursuing research that is outside of the NIGMS mission may result in termination of the award.

## PD/PI salary charged

Most institutions expect some commitment from investigators for administrative, teaching, and/or clinical duties. As a result, any salary support for the PD/PI charged to the grant should generally be less than 51% of the PD/PI's annual salary. In no case should it be more than the actual research effort the PD/PI will devote to the grant.

## Statutory authority

NIH Research Project Grants are authorized under 42 USC 241 and 284 as implemented under 42 CFR Part 52 and 2 CFR Part 200.



# Step 2:

## Get Ready to Apply

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# Find the application package

The online application package has all the forms you need to apply.

Go to Grants Search at Grants.gov and search for this NOFO's opportunity number. After opening the opportunity, select the "package" tab to see the forms. We recommend that you select the Subscribe button from the View Grant Opportunity page for this NOFO to get updates. The Apply button brings you to the login screen for preparing an application using Grants.gov Workspace. If using Grants.gov Workspace to apply, be sure to track your submitted application status in [eRA Commons](#).

Additional options to submit your application through Grants.gov to NIH:

- Use [NIH ASSIST](#) to prepare, submit, and track your application. Enter the opportunity number in the ASSIST system to initiate an application and the application package will automatically load for you.
- Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and [eRA Commons](#) to track your application. Consult with your administrative office for instructions.

## Get registered

Organizations must be registered in SAM.gov, Grants.gov, and eRA Commons to apply. You can review the requirements and get started on developing your application before your registrations are complete.

### SAM.gov

Before registering in Grants.gov or eRA Commons, organizations must have an active account with SAM.gov to apply. SAM.gov registration can take six weeks or more. Begin that process today.

To register:

- Go to [SAM.gov Entity Registration](#) and select Get Started. From the same page, you can also select the Entity Registration Checklist for the information needed to register.
- Organizations must agree to the [financial assistance general certifications and representations](#) specifically. Those for contracts are different.

Upon registration, organizations will receive a Unique Entity Identifier (UEI).

After registration:

- Organizations will have to maintain an active registration throughout the life of any award.
- If an organization has multiple UEs, use the one associated with your physical location.

## Grants.gov

Organizations must also have an active account with [Grants.gov](#). You can see step-by-step instructions at the Grants.gov [Quick Start Guide for Applicants](#).

## eRA Commons

### Register your organization

- Organizations must be registered in eRA Commons.
- Begin at least **4 weeks before** the application deadline.

### Register key people

The PD/PI, senior/key personnel, other significant contributors, and other individuals named on the R&R Senior/Key Personnel form require eRA Commons IDs which must be provided in the Credential field of the form.

**Need help?** See [Contacts and Support](#).

# Help applying

For help with the application process and tips for preparing your application, see [How to Apply – Application Guide](#) on our website.

If any instructions differ from those in this NOFO, follow the instructions in this NOFO.

For other questions, see [Contacts and Support](#).



# Step 3:

# Build Your Application

## In this step

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# Application checklist

You must follow the [research instructions](#) to complete your application. In this section, we also provide NOFO-specific guidance for some forms.

Make sure that you have everything you need to apply:

Form	Required for
<input type="checkbox"/> SF424 (R&R)	All applications.
<input type="checkbox"/> PHS 398 Cover Page Supplement form	All applications.
<input type="checkbox"/> SF424 (R&R) Other Project Information	All applications.
<input type="checkbox"/> SF424 (R&R) Project/Performance Site Locations	All applications.
<input type="checkbox"/> SF424 (R&R) Senior/Key Person Profile	All applications.
<input type="checkbox"/> R&R Budget form	All applications.
<input type="checkbox"/> PHS 398 Research Plan form	All applications.
<input type="checkbox"/> PHS Human Subjects and Clinical Trials Information	All applications.
<input type="checkbox"/> PHS Assignment Request form	Optional.

See [submission requirements and deadlines](#) to see if there are other requirements beyond the application itself.

# Application contents and format

You must follow the research instructions in the [How to Apply – Application Guide](#). We strictly enforce these requirements. If you do not follow them, we may delay or not accept your application for review.

When the NOFO-specific instructions deviate from those in the Application Guide, follow the NOFO-specific instructions.

## Check the policy notices

Recently issued [NIH-wide policy changes](#) may affect your application submission. You may also review complete and updated information on [NIH Policy & Compliance](#).

NIH requires the use of [NOT-OD-26-018: NIHs Implementation of Common Forms for Biographical Sketch and Current and Pending \(Other\) Support for Due Dates on or after January 25, 2026](#).

## Page limits

You must follow all page limitations described in the [How to Apply – Application Guide](#) and the [Table of Page Limits](#).

## SF424 (R&R)

All instructions in the [How to Apply – Application Guide](#) must be followed.

## PHS 398 Cover Page Supplement form

All instructions in the [How to Apply – Application Guide](#) must be followed.

## SF424 (R&R) Other Project Information form

All instructions in the [How to Apply – Application Guide](#) must be followed.

## Project summary/abstract

Use the abstract to provide an overview of research in your laboratory relevant to the MIRA, the goals for the next five years, and an overall vision of the research program. This attachment should serve both the needs of the public and the reviewers for an introduction to the research plan.

Do not include specific aims or use any similar designation, including “aims”, in the abstract. If you submit an application using this language, we will withdraw it prior to review.

## SF424 (R&R) Project/Performance Site Location(s) form

All instructions in the [How to Apply – Application Guide](#) must be followed.

## SF424 (R&R) Senior/Key Person Profile form

All instructions in the [How to Apply – Application Guide](#) must be followed.

### Biographical sketch

Only provide a Biographical Sketch for the PD/PI.

We require the use of [SciENCy](#) to prepare the Common Forms for the Biographical Sketch and the NIH Biographical Sketch Supplement.

### Personal statement

Tailor the personal statement to the unique attributes and requirements of MIRA. Include descriptions of notable contributions to mentoring and significant service to the scientific community beyond duties expected at your institution.

If you list ongoing and completed research projects, do not include the number of person months or direct costs.

### Contributions to science

Emphasize your contributions to science over the past five years. Do not present or include figures or preliminary data.

## R&R Budget form

All instructions in the [How to Apply – Application Guide](#) must be followed.

We do not require itemized budget information. Instead, we require a total requested direct cost amount for each budget period, including requests for equipment purchase in Year 1.

Applications may request up to \$275,000 direct costs per year. Do not request equipment except for Year 1. Do not include annual inflationary increases in out years. The direct costs requested in Year 1 cannot be higher than \$275,000, inclusive of any equipment request.

Consortia/subawards are not allowed and should not be included in the budget.

While the application package provides a 10-year R&R Budget form, applicants may not request more than 5 years of support.

To allow submission of a budget request without filling out detailed yearly budgets, you must complete some basic information for NIH to successfully process the budget form. Use the following instructions for each budget period:

## Budget type

For Budget Type, select Project.

## Budget period

Provide the budget period start date and end date.

## Section A: Senior/key person

Provide an entry for the PD/PI, including the appropriate level of effort, and enter \$0 for requested salary and \$0 for fringe benefits. Entering \$0 does not mean that the PD/PI will not receive any salary or fringe benefit support from the grant. Do not include other personnel.

## Section C: Equipment description

Enter budget request for equipment in Year 1.

## Section F: Other direct costs

Add a line item titled "Requested Direct Costs" and provide the total request for that budget period (up to \$275,000).

If you request equipment in Section C, do not add the equipment budget in Section F.

## Section H: Indirect costs

Enter your institutional "indirect cost type," "indirect cost rate," "indirect cost base" and "funds requested."

## Section L: Budget justification

When applicable, use Section L to justify equipment costs, data management and sharing costs, and any exclusions applied to the F&A base calculation.

## Equipment

Justify your equipment costs. You may also include equipment quote(s) in your justification.

## Data management and sharing costs

NIGMS expects that most grantees will incur minimal, if any, additional costs for data management and sharing. Label the justification for data management and sharing costs as “Data Management and Sharing Justification” and include any requested direct costs. If no costs are requested, state \$0 for the requested amount. Follow the [How to Apply – Application Guide](#) instructions for the Data Management and Sharing Justification.

## F&A base

Also use the Budget Justification to explain any exclusions applied to the F&A base calculation.

## R&R Subaward Budget form

Do not complete the R&R Subaward form.

## PHS 398 Research Plan form

Use the PHS 398 Research Plan form to complete your research plan. You will upload each of the following parts of the form as a separate attachment.

We may not require some parts for your application.

All instructions in the [How to Apply – Application Guide](#) must be followed, with the following additional instructions:

- Follow all instructions outlined in the research instructions under the “[R.400 - PHS 398 Research Plan Form](#)” section. We note additional instructions here.

## Research plan section

The parts for this section include:

Parts	Required for	Page limit
Specific aims	Do not submit this page.	N/A
Research strategy	All applications.	6
Progress report publication list	Renewal applications only.	N/A

### Specific aims

Do not submit a specific aims page. Do not identify specific aims or use any similar designation, including “aims”. If you submit an application including this section or using this language, we will withdraw it prior to review.

### Research strategy

Do not identify specific aims or use any similar designation in the Research Strategy, including “aims”. If you submit an application using this language, we will withdraw it prior to review.

Do not use the standard Research Strategy headings of Significance, Innovation, and Approach. Instead, include:

- Background on the area(s) of research.
- Key gaps in our understanding or important challenges the research program will address.
- Recent progress by the PD/PI, focusing on the past five years, to give context for the overview of future research. This may include the development of technical expertise and administrative skills such as mentoring. Do not repeat material adequately covered in the Biographical sketch.
- Overview of future research plans. Include a description of the key questions or challenges you plan to address and the general strategies you might use. Focus on the importance of the questions or challenges. Do not provide a detailed experimental plan. Do not use specific aims or any similar designation, including “aims”.

We do not expect or require preliminary data. If you include it, you may wish to clearly indicate it in the research strategy section.

You can show feasibility of your program through preliminary data from your independent lab, literature citation, data from other sources, or data you generated as a graduate student or postdoctoral fellow.

Because the MIRA supports a research program within the NIGMS mission and may include multiple projects on different topics, you do not need to present a single unifying theme. Explain the balance of effort and the resources for each activity, and how the activities are distinct or complementary.

If you receive a MIRA and new opportunities or directions arise during the research, you can change course and pursue them. These new directions must remain within the NIGMS mission.

The Research Strategy should address the requirements of the NIH policy on rigor and reproducibility in research as well as requirements related to sex as a biological variable as detailed in the [How to Apply – Application Guide](#).

## Other research plan section

To complete this section, use the instructions outlined under the “Other research plan section” section as detailed in the [How to Apply – Application Guide](#). The parts for this section include:

Parts	Required for	Page limit
Vertebrate animals	If you answer “Yes” to the question “Are vertebrate animals used?” on the R&R Other Project Information Form.	None
Select agent research	If your proposed activities involve the use of select agents at any time during the proposed project period.	None
Multiple PD/PI leadership plan	Do not include. Not permitted.	N/A
Consortium and contractual arrangements	Do not include. Consortia/contracts not permitted.	N/A
Letters of support	All applications.	Required institutional commitment letter: None  Other optional letters: 1 page
Resource sharing plans	If model organisms or research tools will be generated.	None
Other plans	All applications (i.e. Data Management and Sharing Plan).	None
Authentication of key biological and/or chemical resources	If applicable to the proposed science.	None

## Letters of support

You must include a letter of support from your department chair, dean, or other academic unit leader. This letter should describe the institutional commitment to your development as an investigator and any other relevant information.

If you do not include this letter, we will consider the application incomplete and will withdraw it.

The letter 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.
- Career advancement prospects for non-tenure track applicants.

We do not require or encourage letters from former mentors, except in the case of continuing collaborations.

Letters of support from collaborators may not exceed one page each.

Do not circumvent page limitations by including figures and data.

## Resource sharing plan

You must comply with the instructions for the Resource Sharing Plans as indicated in the [How to Apply – Application Guide](#).

## Other plan(s)

You must follow all instructions in the [How to Apply – Application Guide](#), with the following additional instructions:

- All applicants planning research (funded or conducted in whole or in part by NIH) that results in the generation of scientific data must comply with the instructions for and include the **Data Management and Sharing Plan**. Applicants must submit the DMS Plan at the time of application using the NIH DMS Plan Format Page. The DMS Plan must address the elements in the structured format should not exceed two (2) pages. Where the DMS Plan Format Page requires a “Yes or No” response, no additional narrative is allowed.

## Appendix

We only allow limited appendix materials. Follow all the instructions for the Appendix in the [How to Apply – Application Guide](#).

Do not include publications or other material, except for blank questionnaires or blank surveys, in the Appendix.

## PHS human subjects and clinical trials information

Follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the [How to Apply – Application Guide](#) when involving any of the following:

- Human subjects research.
- Clinical research.
- NIH-defined clinical trials (and when applicable, clinical trials research experience).

Also use the following additional instructions:

- If you answered “Yes” to the question “Are human subjects involved?” on the R&R Other Project Information form, you must include at least one human subjects study record using the Study Record: PHS Human Subjects and Clinical Trials Information form or Delayed Onset Study record.

## Study record: PHS human subjects and clinical trials information

You must follow all instructions in the [How to Apply – Application Guide](#).

## Delayed onset study

[Delayed onset](#) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). You must follow all instructions in the [How to Apply – Application Guide](#).

## PHS assignment request form

You must follow all instructions in the [How to Apply – Application Guide](#).

For this NOFO, do not suggest a Scientific Review Group. MIRA-specific study sections or special emphasis panels review applications.

## Pre-award requirements

You must follow the instructions for post-submission materials, as described in [the policy](#).



# Step 4:

## Understand Review, Selection, and Award

### In this step

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# Initial review

The Center for Scientific Review and the National Institute of General Medical Sciences will evaluate applications for completeness and compliance with application instructions. We will also review your application to make sure that it meets the [responsiveness criteria](#). If your application does not meet these criteria, is incomplete, or is non-compliant, we will withdraw it and not move it to the peer review phase.

# Peer review

Reviewers evaluate applications for scientific and technical merit through the NIH peer review system. Reviewers consider only the review criteria described below in the review process.

You can find information about the disposition of applications in the [NIH Grants Policy Statement](#).

## Process

The Center of Scientific Review convenes Scientific Review Groups to evaluate applications for scientific and technical merit. Your application will be assigned to an appropriate Scientific Review Group. The panel will review your application according to [NIH peer review policy and procedures](#) and use the stated review criteria. eRA Commons will show the Scientific Review Group assignment.

## Written critiques

As part of the scientific peer review, there is a written critique (Summary Statement) for all applications.

After peer review of the application is complete, the PD/PI will be able to access their Summary Statement in the [eRA Commons](#).

See [important dates](#) for dates for peer review, advisory council review, and earliest start date.

## Context for reviewers

For this announcement:

### Goal

The goal of the MIRA for ESIs program is to support an ESI's research program within the NIGMS mission and:

- Offer an opportunity for ESIs to receive support as early as possible in their independent careers.
- Encourage ESIs to move into research areas that are distinct from those of their postdoctoral mentors.
- Give investigators relative freedom in pursuing their NIGMS-mission relevant research goals.

### Overview vs. details

We expect applicants to provide an overview of the research program/scientific questions they plan to address and a general description of possible strategies. We do not expect experimental details.

MIRA provides support for a single PD's/PI's NIGMS mission-aligned research program. The application may include multiple projects on different topics and does not need to present a single unifying theme.

### Preliminary data and publications expectations

We do not require preliminary data in MIRA for ESIs applications.

Applicants may provide justification for the proposed work through preliminary data from their independent laboratory, literature citations, data from other sources, or data generated by the applicant as a graduate student or postdoctoral fellow.

Similarly, early career stage applicants may not have published independently as senior or corresponding authors, and the absence of these publications should not be viewed as a weakness.

# Criteria

## Overall impact

Reviewers provide an overall impact score using the following review criteria and additional review criteria (as applicable for the program proposed). Reviewers should evaluate the likelihood that the proposed research will launch and sustain a successful independent research program. The overall impact score reflects their assessment of the likelihood for the research program to exert a sustained, powerful influence on the research field(s) involved.

## Scientific merit criteria

Reviewers consider the review criteria below to determine scientific merit and the overall impact score; they will not assign individual criterion scores. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a program that is not innovative may be essential to advance a field.

## Significance

- Does the research program address an important problem or a critical barrier to progress in the field?
- Is the previous research, which forms the foundation for the proposed study, rigorous?
- If the research goals are met, how will this enhance scientific knowledge, technical capability, and/or clinical practice?
- **When the application involves clinical trials:**
  - Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported? Examples of support may include preliminary data, clinical and/or preclinical studies, information in the literature, and plausible biological mechanism.
  - For trials focusing on clinical or public health endpoints, is the trial necessary to test the safety, efficacy, or effectiveness of an intervention that could lead to a change in clinical practice or community behaviors?
  - For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?
- **Criteria specific to this NOFO:**
  - Are the topics of the research program substantial and suitable for long-term study?

- Is the proposed research program's scope and ambition adequate to address the scientific questions asked?

## Investigators

- Are the PD/PI, collaborators, and other researchers well suited to the program?
- Does the PD/PI have the appropriate experience and training?
- **When the application involves clinical trials:**
  - Do the PD/PI and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines?
  - Do the PD/PI and key personnel have appropriate expertise in study coordination, data management, and statistics?
- **Criteria specific to this NOFO:**
  - Does the PD/PI have a consistent record of productivity and scientific impact that is appropriate for the applicant's current career stage?
  - Is the PD/PI clearly the intellectual driver of the proposed research program?
  - Does the PD/PI show evidence of being creative and adaptable?
  - Does the PD/PI demonstrate an ability to recognize new opportunities and explore the use of new systems and strategies, as appropriate for the proposed research program?
  - Does the PD/PI have a strong potential to establish and sustain a successful independent program of research in their own laboratory?
  - Does the PD/PI show promise as a mentor of undergraduate and graduate students, and postdoctoral associates?
  - Does the PD/PI show potential to establish a strong record of professional service?

## Innovation

- Does the application seek to shift current research or clinical practices by using new ideas, methods, tools, instrumentation, or interventions? Are the concepts, methods, tools, instrumentation, or interventions new to a field or research or generally new?
- Is an improvement, better version, or new use of concepts, methods, tools, instruments, or interventions described?
- **When the application involves clinical trials:**
  - Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice? A proposed clinical trial application

may include study design, methods, and interventions that are not, by themselves, innovative but address important questions or unmet needs.

- **Criterion specific to this NOFO:**

- Will suitable creative strategies be used to address the research questions?

## Approach

- Is the overall strategy well-reasoned and appropriate to achieve the research goals?
- Has the investigator addressed weaknesses in the rigor of prior research?
- Are strategies included that ensure a robust and unbiased approach?
- Are potential problems, alternative strategies, and benchmarks for success adequately presented?
- If the program is in the early stages of development, will it establish feasibility and manage risks?
- Are there adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?
- If the proposed research involves human subjects and/or NIH-defined clinical research, are there plans to address the following?:
  - The protection of human subjects from research risks.
  - As required by statute, inclusion (or exclusion) of individuals on the basis of sex, race, and ethnicity.
  - As required by statute, inclusion (or exclusion) of individuals of all ages (including children and older adults)?
- **When the application involves clinical trials:**
  - **Study design quality:**
    - Is the study design justified and appropriate so that it addresses primary and secondary outcome variable(s)/endpoint(s)? Will the study provide data that will be clear, informative, and relevant to the hypothesis being tested?
    - Is the scientific rationale and/or of the premise based on well-designed preclinical and/or clinical research?
    - Do the methods used to assign participants and deliver interventions support an appropriate study design that is adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results?
    - Is the trial designed to conduct the research efficiently?

- Are the study populations (size, sex, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?
- **Study design ethical issues:**
  - Are potential ethical issues adequately addressed?
  - Is the process for obtaining informed consent or assent appropriate?
  - Is the eligible population available?
  - Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection?
  - Are the planned recruitment timelines realistic and is the plan to monitor accrual adequate?
  - Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed?
  - Are differences addressed in the intervention effect due to sex and race/ethnicity, if applicable?
- **Study design plans:**
  - Are the plans to standardize, ensure quality, and monitor adherence to the trial protocol and data collection or distribution guidelines appropriate?
  - Is there a plan to obtain required study agent(s)?
  - Does the application propose to use existing resources, as applicable?
- **Data management and statistical analysis:**
  - Are planned analyses and statistical methods suitable for the study design and the methods used to assign participants and deliver interventions?
  - Are data management and quality control procedures at clinical site or at center laboratories adequate?
  - Are the methods for standardizing procedures for data management to assess the effect of the intervention and quality control adequate?
  - Is there a plan to complete data analysis within the proposed award period?
- **Criteria specific to this NOFO:**
  - Is there a clear plan for consistent progress for the research program over the award period?
  - Is there evidence that the research program will evolve appropriately as the work is performed?

- If it is a clinical trial, does the proposal use innovative designs such as platform trials, adaptive, including real-time adaptive methods, seamless Phase I/II designs, and Bayesian designs, as applicable. Does it use decentralized trial elements, including remote informed consent, remote study visits, and use of wearables?

## Environment

- Are the institutional support, equipment, and other available resources adequate for the proposed program?
- Will the program benefit from aspects of the scientific environment, such as access to subject populations or collaborations?
- **When the application involves clinical trials:**
  - Are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the proposed trial?
  - Can the trial be effectively conducted at the proposed site or center?
- **Criterion specific to this NOFO:**
  - Will the environment help the PD/PI develop as an independent researcher?

## Additional review criteria

As applicable for the proposed research program, reviewers will evaluate the following items while determining scientific and technical merit, and in providing an overall impact score.

## Study timeline

These criteria are specific to applications involving clinical trials.

- Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment?
- Is the projected timeline feasible and well justified?
- Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?
- Are potential challenges and corresponding solutions discussed such as strategies for dealing with enrollment shortfalls?

## Protections for human subjects

- For research that involves human subjects but does not fit into the categories of research under 45 CFR Part 46, the committee will evaluate the justification for

involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria:

- Risk to subjects.
  - Adequacy of protection against risks.
  - Potential benefits to the subjects and others.
  - Importance of knowledge to be gained.
  - Data and safety monitoring for clinical trials
- For research that involves human subjects and fits into one or more of the exempt categories under 45 CFR Part 46, the committee will evaluate:
    - The justification for the exemption.
    - Human subjects involvement and characteristics.
    - Sources of materials.
    - For additional information on review of the Human Subjects section, please refer to the [Guidelines for the Review of Human Subjects](#).

## Inclusion of human subjects policies

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for inclusion. For additional information on review of the Inclusion section, please refer to the [Guidelines for the Review of Inclusion in Clinical Research](#).

## Vertebrate animals

The committee will evaluate the use of live vertebrate animals as part of the scientific assessment based on these criteria:

- Description of procedures involving animals, including species, strains, ages, sex, and total number to be used.
- Justification for using animals instead of other models.
- Justification for the use of the chosen species.
- Interventions to minimize discomfort, distress, pain, and injury.
- Justification for euthanasia method if it does NOT follow AVMA Guidelines for the Euthanasia of Animals.

For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animals Section](#).

## Biohazards

Reviewers will assess if the proposed materials or procedures are potentially hazardous to the research team or the environment, and if needed, determine whether adequate safety measures are planned.

## Additional review considerations

As applicable for the proposed research program, reviewers consider each of the following items. Reviewers will not give scores for these items and should not consider them in the overall impact score.

### Select agent research

Reviewers will assess the information in this section of the application, including:

- The select agent(s) to be used in the proposed research.
- The registration status of all entities where select agent(s) will be used.
- The procedures to monitor possession, use, and transfer of Select Agent(s).
- Plans for appropriate biosafety, containment, and security of the select agent(s).

### Resource sharing plans

Reviewers will comment on whether the Resource Sharing Plan(s) (e.g., [Sharing Model Organisms](#)) or the reason for not sharing resources is reasonable.

### Authentication of key biological and/or chemical resources

For projects involving key biological and/or chemical resources, reviewers will comment on the plans proposed for identifying and ensuring the validity of those resources.

### Budget and period of support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

## Risk review

Before making an award, we review the risk that you will not prudently manage federal funds. We need to make sure you've handled any past federal awards well and demonstrated sound business practices. We use SAM.gov [Responsibility / Qualification](#) to check this history for all awards likely to be over \$250,000. We also check Exclusions.

You can comment on your organization's information in SAM.gov. We'll consider your comments before making a decision about your level of risk.

We may ask for additional information prior to award based on the results of the risk review.

If we find a significant risk, we may choose not to fund your application or to place specific conditions on the award.

For more details, see [2 CFR 200.206](#).

## Selection process

Applications will be evaluated for scientific and technical merit by an appropriate Scientific Review Group convened by Center for Scientific Review, in accordance with [NIH peer review policy and procedures](#), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

Reviewers will only discuss and assign an overall impact score to applications they find to have the highest scientific and technical merit.

Following initial peer review, the National Advisory General Medical Sciences Council will provide a second level of review for all scored applications. Applications will compete for available funds with all other recommended applications.

Considerations for funding decisions include:

- Scientific and technical merit as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed research to NIGMS priorities.
- Portfolio breadth.
- Other funding support available to the PD/PI.

We may:

- Fund applications in whole or in part.
- Fund applications at a lower amount than requested.
- Choose to fund no applications under this NOFO.

Our ability to make awards depends on available appropriations.

# Award notices

## Just-in-time information

If your application is under consideration for funding, NIH will request “just-in-time” information as described in the [NIH Grants Policy Statement](#).

Additionally, we will require a signed letter from the institution’s Authorized Organizational Representative (AOR) agreeing to the following:

- The PD/PI will devote at least 51% of their total research effort to this award. This effort includes their combined research effort at all institutions where the PD/PI holds an appointment, including foreign institutions.
  - We will calculate the total research effort in person-months and will not include time toward teaching, administration not directly related to the PD’s/PI’s research, and clinical duties.
- The institution and PD/PI are aware of and accept that they must discontinue other NIGMS research awards, except as allowed in the [“overlap during peer review” section](#) of the NOFO, and must withdraw pending NIGMS research applications as a condition of receiving a MIRA.

## Before an award

If we ask for just-in-time information or inform you that we have selected your application for award, it is not an authorization to begin performance.

Any costs incurred before you receive the Notice of Award (NoA) are at the recipient’s risk. If selected for funding, we will only reimburse allowable pre-award costs.

## Notice of Award

If your award is selected for funding, we will email an NoA, signed by the grants management officer, to your authorized official.

The NoA is the only official award document. It tells you about the amount of the award, important dates, and the terms and conditions you need to follow.

Once you draw down funds, you have accepted all terms and conditions of the award.

If you want to know more about NoA contents, go to [Award Conditions and Information for NIH Grants](#). Also, make sure you review the [post-award requirements](#) and the [funding policies and limitations](#).



# Step 5: Submit Your Application

## In this step

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# Submission requirements and deadlines

## Application due dates:

Due on **October 2, 2026, February 3, 2027, October 4, 2027, February 3, 2028, October 3, 2028, February 6, 2029** at 5:00 p.m. local time of the applicant organization.

We encourage you to submit your application before the application deadline so that you have time to make any corrections needed to submit successfully.

Grants.gov creates a date and time record when it receives the application. If you submit the same application more than once, we will accept the last on-time submission.

When a submission date falls on a weekend or [federal holiday](#), the application deadline is the next business day.

## Submission methods

Your organization's authorized official must certify your application.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. You can find additional information in the [How to Apply – Application Guide](#).

To submit your application, you have three choices:

- Prepare and submit your application directly in Grants.gov using Workspace and use eRA Commons to track your application.
- Use NIH ASSIST, to prepare, submit, and track your application.
- Use your institution's system-to-system interface of your choice that connects to Grants.gov. You can then use eRA Commons to track your application.

## Grants.gov

For instructions on how to submit in Grants.gov, see the [Quick Start Guide for Applicants](#). Make sure your application passes the Grants.gov validation checks. Do not encrypt, zip, or password-protect any files.

See [Contacts and Support](#) if you need help.

## eRA ASSIST

The Application Submission System and Interface for Submission Tracking (ASSIST) helps you prepare your application, submit it through Grants.gov, and track it.

You must have an eRA Commons ID to use this system. The system will prompt your signing official to enter the Grants.gov Authorized Organizational Representative (AOR) credentials to submit the application.

For instructions, see [Using ASSIST](#) and [Submit the Application](#) on our website.

## Get help

- For assistance with your electronic application or for more information on the electronic submission process, visit the [How to Apply – Application Guide](#).
- See [tips](#) for avoiding common errors.
- See [Contacts and Support](#), for help with systems.

## Intergovernmental review

[Executive Order 12372, Intergovernmental Review of Federal Programs](#) does not apply to this NOFO. You do not need to take any action.



# Step 6: Learn What Happens After Award

## In this step

Post-award requirements and administration 46

# Post-award requirements and administration

When accepting a Notice of Award, the recipient agrees that any activities under the award will follow:

- All provisions currently in effect or implemented during the period of the award.
- Other Department regulations and policies in effect at the time of the award.
- Applicable statutory provisions.

We adopt by reference all materials included in the links within this NOFO.

## Administrative and national policy requirements

There are important rules you need to read and know if you get an award.

You must follow:

- All terms and conditions in the Notice of Award, including those in the NIH Grants Policy Statement:
  - Part II, [Subpart B: Terms and conditions for specific types of grants, recipients, and activities](#).
  - 4.2.1, [Acknowledgment of federal funding](#).
- The rules in [2 CFR Part 200](#), Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, or any superseding regulations.
  - As of October 1, 2024, HHS adopted [2 CFR 200](#), with some exceptions included in [2 CFR 300](#). These regulations replace those in 45 CFR 75. See [NOT-OD-25-059](#) “NIH Implementation of Uniform Administrative Requirements for Federal Financial Assistance.”
- The [NIH Grants Policy Statement](#). This document has policies relevant to your award. We will list any exceptions to the GPS in your Notice of Award.
- All federal statutes and regulations relevant to federal financial assistance, including the cited authority in this award, the funding authority used for this award, and those provisions in the [HHS Grants Policy Statement](#), Appendix D: HHS Administrative and National Policy Requirements.
- By applying for or accepting federal funds from HHS, you certify compliance with all federal anti-discrimination laws and these requirements and that complying with those laws is a material condition of receiving federal funding streams. You are responsible for ensuring subrecipients, contractors, and partners also comply.

- You are strongly encouraged to refer to the [NIH Director's Statement of Priorities](#), entitled "Advancing NIH's Mission Through a Unified Strategy."
- You are responsible for ensuring that research activities comply with all applicable federal regulations. Pursuant to [2 CFR 200.340](#), by accepting an NIH award, the recipient agrees that continued funding for the award is contingent upon the availability of appropriated funds, recipient satisfactory performance, compliance with the Terms and Conditions of the award, and may also otherwise be terminated, to the extent authorized by law, if the agency determines that the award no longer effectuates the program goals or agency priorities, in line with 2 CFR 200.340(a)(4).

All activities proposed in your application and budget narrative must align with applicable law, including but not limited to statutes, executive orders, federal regulations and applicable judicial holdings. Accordingly, discretionary awards shall not be used to fund, promote, encourage, subsidize, or facilitate; racial preferences or other forms of racial discrimination by the recipient, including activities where race or intentional proxies for race will be used as a selection criterion for employment or program participation; denial by the recipient of the sex binary in humans, or the belief that sex is a chosen or mutable characteristic; illegal immigration; or any other initiatives that compromise public safety. If an application does not align, the application will not receive funding to the extent permitted by law and applicable court orders.

Pursuant to the Cybersecurity Act of 2015, Div. N, § 405, Pub. Law 114-113, 6 USC § 1533(d), the HHS Secretary has established a common set of voluntary, consensus-based, and industry-led guidelines, best practices, methodologies, procedures, and processes.

Successful recipients under this NOFO agree that:

When recipients, subrecipients, or third-party entities have:

- ongoing and consistent access to HHS owned or operated information or operational technology systems; and
- receive, maintain, transmit, store, access, exchange, process, or utilize personal identifiable information (PII) or personal health information (PHI) obtained from the awarding HHS agency for the purposes of executing the award.

Cybersecurity plans and procedures must at minimum include the following:

- Develop cybersecurity plans and procedures, modeled after the NIST Cybersecurity framework, to protect HHS systems and data:
  - **Identify:**
    - Develop an inventory of all assets and accounts with access to HHS owned and operated information or operational technology systems or which obtain PII or PHI for the purposes of the award.
  - **Protect:**

- Limit access to HHS owned and operated systems to only those in need of access to complete reward activities.
- Require all staff to complete annual cybersecurity and privacy awareness training. Visit 405(d): Knowledge on Demand ([hhs.gov](https://www.hhs.gov)) to obtain free trainings, if needed.
- Enable multifactor authentication for all employees, subrecipients, and third-party entities to access HHS owned and operated information or operational technology systems.
- Regularly backup sensitive data and test backups.
- **Detect:**
  - Install anti-virus or anti-malware software on all devices, servers, and accounts used to connect to HHS owned and operated systems.
- **Respond:**
  - Develop an incident response plan. See Incident-Response-Plan-Basics\_508c.pdf ([cisa.gov](https://www.cisa.gov)) to learn about developing incident response plans.
  - Have cybersecurity incident reporting procedures that ensure the relevant HHS awarding agencies are notified of a cybersecurity incident within 48 hours of discovery. A cybersecurity incident is defined as an unplanned interruption to a technology service or reduction in the quality of a technology service, or an occurrence that actually or potentially jeopardizes the confidentiality, integrity, or availability of an information system or the information the system processes, stores, or transmits.
- **Recover:**
  - Investigate incidents and plug any security gaps identified.

## Other key requirements

### Data sharing

All applicants planning research (funded or conducted in whole or in part by NIH) that results in the generation of scientific data must comply with the instructions for and include the Data Management and Sharing Plan. Applicants must submit the DMS Plan at the time of application using the NIH DMS Plan Format Page. The DMS Plan must address the elements in the structured format should not exceed two (2) pages. Where the DMS Plan Format Page requires a “Yes or No” response, no additional narrative is allowed.

## Prior approvals

Research involving adding human subjects, vertebrate animals, stem cells, select agents, or a new foreign component require prior approval. Foreign subawards are not allowed for this program.

## ClinicalTrials.gov

If an award includes one or more clinical trials, by law, the “responsible party” must register and submit results information for certain trials. (See Title VIII, Section 801 of Public Law 110-85).

To comply, you must:

- Register and report on the [ClinicalTrials.gov](https://clinicaltrials.gov) Protocol Registration and Results System Information website.
- Complete registration and reporting for all trials, whether required under the law or not.

For more information, see [Requirements for Registering & Reporting NIH-Funded Clinical Trials](#).

## Institutional Review Board or Independent Ethics

### Committee approval

Recipient institutions must ensure that their IRB or IEC reviews and approves all protocols.

You need to help ensure the safety of participants enrolled in NIH-funded studies. As a result, the recipient must provide NIH with copies of documents about all major status changes in ongoing protocols.

## Data and safety monitoring requirements

The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials).

Doing so ensures the safety of participants and the validity and integrity of the data.

You can find information about these requirements at:

- [Data and Safety Monitoring](#) on our website.
- In the application instructions for [SF424 \(R&R\)](#) and [PHS 398](#).

## Investigational new drug or device exemption requirements

FDA exemptions apply if your clinical research in humans under a research protocol involves any use of:

- Investigational therapeutics.
- Vaccines.
- Other medical interventions in humans. Medical interventions include licensed products and devices used for non-licensed purposes.

This means the study must be performed under an FDA **investigational new drug** or an **investigational device exemption**.

## Reporting

If you receive a MIRA Notice of Award, you will have to submit financial and performance reports.

When multiple years are involved, recipients must submit:

- The [Research Performance Progress Report \(RPPR\)](#) each year.
- Financial statements as required in the [NIH Grants Policy Statement](#).

## RPPR modifications

For this NOFO, we have modified the instructions for the RPPR:

### Section B.1: What are the major goals of the research?

- The goals of a MIRA program of research are broader than the specific aims of a single project. As a result, you need to describe them appropriately.
- If the goals of the MIRA have changed, complete section B.1.a.
  - Provide a rationale for the changes in the context of the originally proposed research program.
  - Explain how the research continues to fit in the NIGMS mission.

### Section B.4: What opportunities for training and professional development has the project provided?

- Indicate if you have used individual development plans for any graduate students or post-doctoral fellows supported by this award.

### Section D.1. Personnel updates:

- Indicate if you have had changes in Other Support.

- In addition to the revised Other Support page, include an explanation in the Statement of Potential Overlap of how changes in other support relate to the activities supported by the MIRA.

## Reports needed for closeout

We require a final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report for closeout of an award, as described in the [NIH Grants Policy Statement](#).

## NIH review of performance

NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes you share in the RPPR, as described at [2 CFR 200.301](#).

## Evaluation

NIGMS will evaluate the MIRA for ESIs program.

When we assess the effectiveness of research grant investments, we may use information from progress reports and public databases, PDs/PIs, and individuals associated with the program.

When needed, we may contact PDs/PIs and other individuals after the completion of the grant period for updates on outcomes.

We will base the overall evaluation of the program on metrics that may include:

- Characteristics of the applicant and awardee pool, such as:
  - Number of ESI PD/PIs who apply for MIRA instead of R01s.
  - Geographic distribution of investigators.
  - Institution types.
  - Scientific topics of supported research.
  - Renewal rates.
- Indicators of scientific accomplishments and productivity, such as:
  - Peer-reviewed research publications and citations.
  - Patent activity among grantees.



# Contacts and Support

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# Agency contacts

## Scientific and research

Email: [NIGMS-ESIMIRA@nigms.nih.gov](mailto:NIGMS-ESIMIRA@nigms.nih.gov)

## Peer review

Email: [NOFORReviewContact@csr.nih.gov](mailto:NOFORReviewContact@csr.nih.gov)

## Financial and grants management

Email: [MIRA-FINANCIAL@NIGMS.NIH.GOV](mailto:MIRA-FINANCIAL@NIGMS.NIH.GOV)

# Help with systems

If you have systems issues outside of your control that threaten your ability to complete the submission process on-time, you must follow the [Dealing with System Issues](#) guidance.

See [tips](#) for avoiding common errors.

## Grants.gov

Grants.gov provides [24/7 support](#) (closed on Federal holidays).

You can call 1-800-518-4726 or email [support@grants.gov](mailto:support@grants.gov). Hold on to your ticket number.

## SAM.gov

If you need help, you can call 866-606-8220 or live chat with the [Federal Service Desk](#).

## eRA Commons

Contact the eRA Commons Help Desk for questions regarding:

- ASSIST.
- eRA Commons registration.
- Application errors and warnings.
- Tracking application status.
- Post-submission issues.

The Help Desk is open Monday through Friday from 7 a.m. to 8 p.m. ET. It is closed on federal holidays.

Find online information at: [eRA Commons Help Desk](#)

Call toll free at 301-402-7469 or 866-504-9552.

Email [commons@od.nih.gov](mailto:commons@od.nih.gov).

## Reference websites

- [How to Apply – Application Guide](#)
- [Application Instructions](#)
- [NIH Grants Policy Statement](#)
- [Electronic Research Administration \(eRA\)](#)
- [U.S. Department of Health and Human Services \(HHS\)](#)
- [Grants.gov Accessibility Information](#)
- [Code of Federal Regulations \(CFR\)](#)
- [United States Code \(U.S.C.\)](#)