

# Department of Health and Human Services

## Part 1. Overview Information

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**Participating Organization(s)**

National Institutes of Health ([NIH \(http://www.nih.gov\)](http://www.nih.gov))

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**Components of Participating Organizations**

National Institute of General Medical Sciences ([NIGMS \(http://www.nigms.nih.gov\)](http://www.nigms.nih.gov))

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**Funding Opportunity Title**

Collaborative Program Grant for Multidisciplinary Teams (RM1) (Clinical Trial Not Allowed)

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**Activity Code**

[RM1 \(//grants.nih.gov/grants/funding/ac\\_search\\_results.htm?text\\_curr=RM1&Search\\_Type=Activity&Search.x=0&Search.y=0\)](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=RM1&Search_Type=Activity&Search.x=0&Search.y=0) Research Project with Complex Structure

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**Announcement Type**

New

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**Related Notices**

[NOT-GM-17-016 \(https://grants.nih.gov/grants/guide/notice-files/NOT-GM-17-016.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-GM-17-016.html)

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**Funding Opportunity Announcement (FOA) Number**

PAR-17-340

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**Companion Funding Opportunity**

None

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**Number of Applications**

Only one application per institution per review cycle is allowed, as defined in [Section III. 3. Additional Information on Eligibility](#).

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**Catalog of Federal Domestic Assistance (CFDA) Number(s)**

93.859

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## Funding Opportunity Purpose

This funding opportunity announcement (FOA) is designed to support highly integrated research teams of three to six PD/PIs to address ambitious and challenging research questions that are important for the mission of NIGMS and are beyond the scope of one or two investigators. Collaborative program teams are expected to accomplish goals that require considerable synergy and managed team interactions. Project goals should not be achievable with a collection of individual efforts or projects. Teams are encouraged to consider far-reaching objectives that will produce major advances in their fields.

Applications that are mainly focused on the creation, expansion, and/or maintenance of community resources, creation of new technologies or infrastructure development are not appropriate for this FOA.

## Key Dates

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### Posted Date

September 22, 2017

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### Open Date (Earliest Submission Date)

December 25, 2017

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### Letter of Intent Due Date(s)

30 days prior to the application due date

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### Application Due Date(s)

January 25, 2018; May 25, 2018; January 25, 2019; May 25, 2019; January 25, 2020; May 25, 2020, by 5:00 PM local time of applicant organization. All [types of non-AIDS applications](#) allowed for this funding opportunity announcement are due on these dates.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

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### AIDS Application Due Date(s)

[https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11112](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11112) May 7, 2018; September 7, 2018; May 7, 2019; September 7, 2019; May 7, 2020; September 7, 2020 by 5:00 PM local time of applicant organization. All [types of AIDS and AIDS-related applications](#) allowed for this funding opportunity announcement are due on these dates.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

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### Scientific Merit Review

July 2018; November 2018; July 2019; November, 2019; July 2020; May 2020

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### Advisory Council Review

October 2018; January 2019; October 2019; January 2020; October 2020; January 2021

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### Earliest Start Date

For all applications submitted in 2018: April 1, 2019

For all applications submitted in 2019: April 1, 2020

For all applications submitted in 2020: April 2, 2021

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### Expiration Date

September 8, 2020

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### Due Dates for E.O. 12372

Not Applicable

## Required Application Instructions

It is critical that applicants follow the Research (R) Instructions in the [SF424 \(R&R\) Application Guide](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=12000) ([//grants.nih.gov/grants/guide/uri\\_redirect.htm?id=12000](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=12000)), except where instructed to do otherwise (in this FOA or in a Notice from the [NIH Guide for Grants and Contracts](https://grants.nih.gov/grants/guide/) ([//grants.nih.gov/grants/guide/](https://grants.nih.gov/grants/guide/))). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in [Section IV](#). When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

**IMPORTANT:** Per [NOT-OD-17-062](https://grants/guide/notice-files/NOT-OD-17-062.html) ([//grants/guide/notice-files/NOT-OD-17-062.html](https://grants/guide/notice-files/NOT-OD-17-062.html)) updated application forms (FORMS-E) will be used for this opportunity. The updated forms are not yet available and will be posted no later than November 10, 2017. Once posted, you will be able to access the forms using one of the following submission options:

1. NIH ASSIST
2. An institutional system-to-system (S2S) solution
3. Grants.gov Workspace

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# Part 2. Full Text of Announcement

## Section I. Funding Opportunity Description

### Purpose

Many research questions in biomedical science can be pursued by single investigators and their close collaborators and are adequately supported by individual and multiple PD/PI research grants. However, the scope of some scientific problems is beyond the capabilities of a small group of investigators. Such complex and challenging research questions benefit from the integrated efforts of teams of research laboratories employing complementary approaches and having diverse areas of intellectual and technical expertise, and the necessary resources to accomplish a unified scientific goal. Such team-based efforts can produce convergent, lasting scientific benefits with high impact, such as the creation of new disciplines of study, resolution of long standing or intractable problems, or definition of new areas that challenge current paradigms.

This funding opportunity announcement (FOA) encourages Collaborative Program Grant applications from institutions/organizations that propose to conduct research to address complex and challenging biomedical problems, important for the mission of NIGMS, through deeply integrated, multidisciplinary research teams. The Collaborative Program Grant is designed to support research in which funding a team of interdependent investigators offers significant advantages over support of individual research project grants. Applications should address critical issues and be sufficiently challenging, ambitious, and innovative that objectives could not be achieved by individual investigators.

### Background

Recent reports (e.g., [enhancing the effectiveness of team science](#) (<https://www.teamsciencetoolkit.cancer.gov/public/TSResourceBiblio.aspx?tid=3&rid=3253>)) have evaluated the benefits of a team science approach to scientific inquiry, and the need to create flexible funding opportunities that enable interdisciplinary research teams to accomplish goals that could not be achieved individually. The Collaborative Program Grant draws on our past experience and is designed to improve support for interdisciplinary collaborative research across different scientific domains. We also anticipate that these grants will enhance the diversity and interdisciplinarity of participating investigators, and may encourage early stage investigators (ESIs) to initiate short-term, complementary pilot studies that enrich the team's program objectives.

### Scope of Research

Successful Collaborative Program Grant applications will bring together scientists to apply complementary approaches to work on an important and well-defined problem. Applications may address any area of science within the NIGMS mission, which is to support basic research that increases understanding of biological processes at a range of levels, from molecules and cells to tissues, whole organisms and populations. NIGMS also supports research in a limited number of clinical areas that affect multiple organ systems (see [here](#) (<https://www.nigms.nih.gov/about/overview/pages/default.aspx>) for scientific areas supported by NIGMS). Truly new interdisciplinary ideas for approaching significant biological problems are encouraged. Applications that bridge the research interests of more than one NIGMS division are also encouraged, but must remain within the scope of the NIGMS mission. Consultation with NIGMS staff (see below) prior to preparing an application is strongly encouraged.

Applications for smaller projects with one or two PD/PIs should consider submitting a multi-PD/PI application to the "NIH Research Project Grant (Parent R01)" FOA (see the [Parent Announcement website](#) ([https://grants.nih.gov/grants/guide/parent\\_announcements.htm](https://grants.nih.gov/grants/guide/parent_announcements.htm)) for the current issuance of this FOA). Applications that are mainly focused on the creation, expansion, and/or maintenance of community resources, or on infrastructure development are not appropriate for this FOA. Although Collaborative Program Grants may include some technology development, applications with a central focus on the creation of new technologies would not be considered for funding as a Collaborative Program Grant and are more appropriate for other NIGMS mechanisms for funding technology [research](#)

(<https://www.nigms.nih.gov/about/overview/BBCB/biomedicaltechnology/Pages/technologydevelopment.aspx>) and resources (<https://grants.nih.gov/grants/guide/pa-files/PAR-17-316.html>).

Applications that employ specific cells or tissues to address a fundamental biomedical question are appropriate. However, applications that focus solely on a specific organ or disease state and that are within the mission areas of other NIH Institutes and Centers would not be appropriate for this FOA. All clinical research must be completely within the context of NIGMS clinical areas (anesthesiology and peri-operative pain; clinical pharmacology; sepsis; trauma, burn injury and wound healing). Finally, NIH-defined clinical trials are not allowed.

## Program Organization

Applications submitted to this FOA are expected to propose a single, well-integrated research plan of sufficient scope, complexity, and impact to justify the investment of significant resources. Applicants are expected to describe a cohesive program with a single set of specific aims sufficient to accomplish program objectives that can be achieved within a maximum of ten years (one five-year program with one competitive five-year renewal). Program objectives that are unlikely to be achieved within ten years are not appropriate for this FOA.

Applications should be sufficiently challenging, ambitious, and innovative that the proposed research cannot be achieved by a single investigator or small group of investigators. Therefore, a multiple PD/PI application is required and applications must include a minimum of three and a maximum of six PD/PIs who are all necessary to provide sufficient research capacity and the relevant expertise to address the proposed scientific problem. Applications that propose extrapolations of a single line of research or propose parallel but independent advancement of different areas are not appropriate for this FOA.

Applicant teams should be sufficiently nimble to provide new knowledge and techniques mid-stream that might be required to tackle unsolved challenges and achieve program objectives. Therefore, proposed approaches can be complemented by adding new pilot studies led by ESIs.

## Team Management and Optional Activities

Studies of team science have highlighted the need for effective management structures to achieve program goals. These structures grow in importance as the team size increases. Many resources exist to aid in developing effective team-based programs (see e.g., the [NCI Team Science Toolkit](https://www.teamsciencetoolkit.cancer.gov/public/Home.aspx) (<https://www.teamsciencetoolkit.cancer.gov/public/Home.aspx>)). In addition to the required multiple PD/PI leadership plan, applications are expected to develop a comprehensive team management plan that addresses the following points:

- Appropriate organizational structure and team composition
- Shared leadership, contributions and distributed responsibility for decision making
- Resource allocation
- Plans for professional development
- Conflict resolution

If teams include individuals from widely divergent scientific backgrounds, applicants may wish to address how they will develop trust and a shared vision, as well as how shared responsibilities, interpersonal interactions and professional credit will be managed. Additionally, applicants may want to consider a scientific project manager or program coordinator as part of the management plan.

Collaborative Program Grant applications may propose optional activities to support ESIs through a program of exploratory pilot study projects. If applicable, the exploratory pilots must start after the first year of the award and propose new approaches that are within the original scope of the grant. For an NIH definition of ESI please refer to the [New Investigator Policy](https://grants.nih.gov/grants/new_investigators/investigator_policies_faqs.htm#2650) ([https://grants.nih.gov/grants/new\\_investigators/investigator\\_policies\\_faqs.htm#2650](https://grants.nih.gov/grants/new_investigators/investigator_policies_faqs.htm#2650)). If the application includes pilot studies directed by ESIs, plans must be included for selecting the projects and for leveraging existing resources for appropriate mentoring, including the effective conduct of multidisciplinary team science, as described in [Part 2. Section IV.2](#). An expectation for any successful pilot projects program would be that it would lead to funding independence for the participating ESIs. This will be a criterion in a subsequent Renewal

application to evaluate the effectiveness of the pilot program in meeting this goal. Note that pilot studies are an optional activity, are not required, and, if requested, must be extremely well justified.

### **Prior Consultation with IC staff**

NIGMS intends to fund a limited number of applications. Therefore, consultation with relevant staff at least 10 weeks prior to the application due date is strongly encouraged. Once applicants have identified overall program objectives and PD/PI participants, NIGMS staff may be able to advise applicants whether the proposed research strategy meets the goals and mission of the Institute, whether it addresses one or more high priority research areas, and whether it is appropriate for a collaborative team program. A collaborative program that is closely related to the goal of a PD/PIs' existing NIGMS-funded research might require that funding be relinquished to avoid overlap. Institute staff will not evaluate the technical and scientific merit of the proposed program in advance; technical and scientific merit will be determined during peer review using the review criteria indicated in this FOA. During the consultation phase, if the proposed research strategy does not meet NIGMS' programmatic needs or is not appropriate as a Collaborative Program Grant, applicants will be encouraged to consider other funding opportunities.

See [Section VIII. Other Information](#) for award authorities and regulations.

## **Section II. Award Information**

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### **Funding Instrument**

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

### **Application Types Allowed**

New  
Resubmission

The [OER Glossary \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11116\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types.

### **Clinical Trial?**

Clinical Trials Not Allowed for due dates on or after January 25, 2018: Only accepting applications that do not propose clinical trials

[Need help determining whether you are doing a clinical trial? \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82370\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)

### **Clinical Trial?**

Not Allowed: Only accepting applications that do not propose clinical trials

[Need help determining whether you are doing a clinical trial? \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82370\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)

### **Funds Available and Anticipated Number of Awards**

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications

NIGMS anticipates supporting no more than 4-6 awards, corresponding to a total of \$10,000,000 (total costs), for fiscal year 2019. Future year amounts will depend on annual appropriations and Institute priorities.

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## Award Budget

While applications may request research program budgets of up to \$1.5 million direct costs per year, it is anticipated that most awards will be between \$700,000-\$900,000 direct costs. Inflationary adjustments are not allowed. The requested budget should be consistent with the number of PDs/PIs and the complexity and needs of the proposed program. In addition to the research program budget, an additional \$250,000 direct costs per year may be requested for optional exploratory pilot studies for ESIs.

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## Award Project Period

Applications may request up to five years of support.

NIH grants policies as described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) will apply to the applications submitted and awards made in response to this FOA.

# Section III. Eligibility Information

## 1. Eligible Applicants

### Eligible Organizations

#### Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

#### Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

#### For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

#### 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)
- Eligible Agencies of the Federal Government

- U.S. Territory or Possession

#### Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

## Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components, as [defined in the NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11118\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are** allowed.

## Required Registrations

### Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The [NIH Policy on Late Submission of Grant Applications \(//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html\)](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- [Dun and Bradstreet Universal Numbering System \(DUNS\) \(http://fedgov.dnb.com/webform\)](http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- [System for Award Management \(SAM\) \(https://www.sam.gov/portal/public/SAM/\)](https://www.sam.gov/portal/public/SAM/) (formerly CCR) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
  - [NATO Commercial and Government Entity \(NCAGE\) Code \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11176\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- [eRA Commons \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11123\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. 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.
- [Grants.gov \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=82300\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82300) – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

### Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

### Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

The application is required to be submitted as a multiple PD/PI application, with a minimum of 3 and a maximum of 6 PD/PIs. Visit the multiple PD/PI Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide, and the Grant Policy Statement on [Multiple Principal Investigators \(https://grants.nih.gov/grants/multi\\_pi/\)](https://grants.nih.gov/grants/multi_pi/). Minimum allowed efforts by the PD/PIs are described in the [R&R Budget instructions](#) in Part 2. Section IV.2.

Any scientists with the interest and ability to develop a team science program to address an important research question is welcome to apply. NIGMS encourages the participation of junior, early, and mid-career investigators as part of the multiple PD/PI team, with advising as appropriate. ESIs and new investigators who participate as PD/PIs will lose their early stage status for future NIH applications, but ESI leads of pilot studies will not lose ESI status. PD/PIs who have an active [NIGMS R35 award \(https://www.nigms.nih.gov/Research/mechanisms/MIRA/Pages/default.aspx\)](https://www.nigms.nih.gov/Research/mechanisms/MIRA/Pages/default.aspx) can participate as PD/PIs as part of the 51% effort on their current R35 award but may not receive additional funds from this award. Applicants with [substantial unrestricted research support \(https://www.nigms.nih.gov/Research/Pages/unrestricted-support.aspx\)](https://www.nigms.nih.gov/Research/Pages/unrestricted-support.aspx) may receive funding from this award as their one NIGMS grant award, or may participate in an unfunded advisory or consulting role without loss of their ability to receive one funded NIGMS grant, consistent with [NIGMS policies \(https://www.nigms.nih.gov/Research/Pages/unrestricted-support.aspx\)](https://www.nigms.nih.gov/Research/Pages/unrestricted-support.aspx).

## 2. Cost Sharing

This FOA does not require cost sharing as defined in the [NIH Grants Policy Statement \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11126\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11126).

## 3. Additional Information on Eligibility

### Number of Applications

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see [NOT-OD-11-101 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html)).

Only one application per institution (normally identified by having a unique DUNS number or NIH IPF number) is allowed for the Collaborative Research Program Grant (RM1) per review cycle. See [Scientific/Merit Review](#) in the Key Dates section.

## Section IV. Application and Submission Information

### 1. Requesting an Application Package

Buttons to access the online ASSIST system or to download application forms are available in [Part 1](#) of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

## 2. Content and Form of Application Submission

It is critical that applicants follow the Research (R) Instructions in the [SF424 \(R&R\) Application Guide \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=12000\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit [Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=41137\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=41137).

### Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in [Part 1. Overview Information](#), prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

Paul Sammak, Ph.D.

Telephone: 301-594-8494

Email: [paul.sammak@nih.gov](mailto:paul.sammak@nih.gov) (<mailto:paul.sammak@nih.gov>)

### Page Limitations

All page limitations described in the SF424 Application Guide and the [Table of Page Limits \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11133\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11133) must be followed along with the following page limitations for the Research Strategy:

- A. The Research Program section is limited to 30 pages.
- B. The Team Management and Optional Activities section is limited to 6 pages.

### Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

#### SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

#### SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

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

All instructions in the SF424 (R&R) Application Guide must be followed.

**Facilities and Other Resources:** Describe aspects of the institutional environment that support team science. Describe the institutional and regional research resources that will be utilized to accomplish the goals of the program, and how access to these resources will be ensured for team members.

Since proposed ESI exploratory pilot studies cannot provide funds for mentoring and training, guidance for these investigators is expected from existing resources. Consistent with the NIGMS policy of training and mentoring the next generation of investigators, applicants need to describe how existing institutional resources will be leveraged to invest in the success of the ESI including:

- Resources for classes, travel, or training;
- Collegial support, such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the ESI's project, and availability of organized peer groups;
- Logistical support, such as administrative management and oversight and best practices training;
- Financial support, such as protected time for research with salary support

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

All instructions in the SF424 (R&R) Application Guide must be followed.

If a scientific project manager or program coordinator is included, it is strongly recommended that the individual be appointed as a Senior/Key Person with adequate authority to administer operational aspects of the program.

### **Budget**

All instructions in the SF424 (R&R) Application Guide must be followed.

To be successful, programs of this level of complexity are expected to require significant effort from all PD/Pis involved. The contact PD/PI is required to devote at least 30% of his/her time available for research to this award, while other PD/Pis are required to devote at least 25% of his/her time available for research to this award. The time available for research should be expressed in person-months and should not include time expended toward teaching, administration, and/or clinical duties.

A single integrated application research budget must cover all aims, personnel, equipment, resource assignments, and other costs of the program, with subcontracts as necessary. Certain supporting functions such as equipment, animal research costs, and clinical research costs may be requested if well justified and unique to the institution(s) involved. Within the research budget, equipment, including data sharing and management systems, can be included if well justified. These costs must be included within the \$1.5 million research budget cap for direct costs. Equipment that duplicates existing institutional or regional shared facilities that are available to investigators must be identified and the proposed duplication should be well justified. Applicants should consider the need to ramp-up programs of this complexity, and propose annual budgets accordingly. Do not request cost of living increases in the overall budget or any of the budget categories. Changes in budget should reflect changes in activities required by the science.

Optionally, in addition to the application research budget, applicants may request additional funds of up to \$250,000 in direct costs, to support exploratory pilot studies for ESIs. Funds for exploratory pilot studies cannot be requested in the first year of the program and cannot overlap with ongoing funded projects. Pilot study leads must be independent ESIs, and pilot study support is limited to three years, non-renewable, for each individual ESI. Multiple pilot studies in parallel are allowed within the annual direct cost optional budget of \$250,000. Pilot studies cannot provide direct funds for training or mentoring or for alterations and renovations. A unified application budget should be prepared that includes both the research budget and the optional activities budget.

### **R&R Subaward Budget**

All instructions in the SF424 (R&R) Application Guide must be followed.

### **PHS 398 Cover Page Supplement**

All instructions in the SF424 (R&R) Application Guide must be followed.

### **PHS 398 Research Plan**

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

**Specific Aims:** A single specific aims attachment must be provided that addresses both the Research Program and the Team Management and Optional Activities sections.

**Research Strategy:** The Research Strategy must consist of the following two subsections, uploaded as a single pdf attachment:

A. Research Program

B. Team Management Plan and Optional Activities

A. Research Program:

The proposed research should be presented as an integrated scientific program with a single set of specific aims organized to address the overall objectives rather than individual PD/PI contributions. The applicant should fully describe the biomedical problem being addressed, its significance within the relevant scientific field(s) and how successful accomplishment of the goals would provide substantial scientific advances.

The research strategy should describe how the Collaborative Program Grant will enable the applicants to challenge existing paradigms, overcome long-standing bottlenecks to substantial progress, and/or develop new synergies between different scientific fields. Applications should justify the need for a larger-scale collaborative approach and explain why the goals of the program could not be accomplished by other means. Innovative solutions by any means can be proposed. The Collaborative Program presupposes that high-impact science could be produced by unanticipated combinations of well-established science.

The long-term goals of the research proposed should be achievable within a ten-year timeframe. The objectives for the first five years should be clearly defined. If a renewal application is anticipated for a second, five-year period, longer-term, ten-year objectives should be included, and should clearly be identified as goals that extend beyond the current work plan. A process for deciding whether or not to submit a renewal application should be included. The criteria for the decision to resubmit should include achievement of milestones or objectives, and the significance of the work proposed in the renewal. Note that significant accomplishments are expected within the first five years of funding whether or not applicants plan to renew. Renewals beyond 10 years of support will not be allowed.

The Research Program section should thoroughly describe the underlying premise and scientific foundation of the project, experimental rationale, approaches, and steps taken to assure scientific rigor, with attention to the reasons a team science approach is required. Applications should describe critical research milestones and any innovative aspects of the approach, including those arising from collaborative interactions. Applications should justify any plans for technology development or new data sharing and archiving resources that are necessary to achieve program goals. Shared resources that are needed to achieve project objectives should be integrated in the research plan. The rationale and use of shared resources should be described within the research plan. Applications requesting resources should include evaluations of the existing resources that are available to the PDs/PIs, but considered inadequate. Technology development should not be the primary goal of the Collaborative Grant Program.

Two tables are required and must be included within the page limit for the Research Program:

1) A table, organized by specific aims, that identifies the contributions expected from each PD/PI toward accomplishing that aim. For a truly integrated collaborative project, it is expected that most or all of the scientific aims will require substantial contributions from more than one PD/PI. This table will aid reviewers in assessing the degree of integration and collaboration and the availability of appropriate intellectual and technical expertise for each aim.

2) A table that identifies critical milestones and performance criteria, a timeline for completion, and whether critical milestones depend on the completion of antecedent milestones. Metrics for identifying successful completion of program aims and goals, and criteria for acceptable outcomes should be defined. It is useful to identify interdependent steps with critical risks. Risk management and alternative approaches can be addressed elsewhere in the Research Strategy and can reference the table. This table will aid reviewers in assessing the feasibility and likelihood that the work plan is adequate for achieving project objectives within the funding period.

B. Team Management and Optional Activities:

A "Multiple PD/PI Leadership Plan" is required as a separate attachment, and the information in that plan should not be duplicated here. Rather, this section should contain an overall team management plan that addresses how the entire group will function to accomplish program objectives and vision. Inclusion of a scientific project manager or coordinator as a Senior/Key Person with adequate authority is recommended. A key characteristic that distinguishes productive teams is the degree that all member contributions are valued. Strategies for building and maintaining group participation to develop collective intelligence are encouraged. A plan for how credit will be shared should also be included.

The program management structure should avoid giving any single individual undue authority that prevents contributions from the wider team for setting program priorities, resource distribution and reward. Strong leadership is expected for complex teams to be successful, but effective team leadership makes decisions based on the amalgam of competing interests, guided by recognized project objectives.

Applicants should develop a management structure based on project objectives that effectively promote the proposed research. The structure should account for team composition, institutional resources, and policies; NIGMS does not specify an organizational structure. Practical aspects should be described, including real time communication, intra-team data sharing, data archiving and long-term preservation for team use.

Applications should describe management and decision-making processes that promote collective input for the overall project objectives and for oversight and reallocation of program resources, recognizing that resources may need to be dynamically reallocated to achieve programmatic goals. Methods for attributing contributions to publications should be described to enable individual professional assessment in joint projects. The overall management plan should include all key personnel, consultants, and other significant contributors regardless of effort level. It is recommended that the Team Management Plan include procedures for evaluating scientific progress and overall support for program objectives of each of the PD/PIs and key personnel, the changing need for PD/PI expertise to achieve program objectives, and the replacement of key personnel and PD/PIs as needed, [with the required prior approval for PD/PI changes. \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-118.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-118.html)

The Team Management Plan should include a description of how the PD/PIs will establish and sustain a diverse team of researchers with an optimal range of backgrounds, expertise and skills to successfully accomplish the goals of the program. There is evidence that teams employing complementary approaches and having diverse areas of intellectual and technical expertise are more productive if the process for making decisions incorporates different points of view. The Team Management Plan should describe how major decisions will be resolved.

Programs may wish to appoint an external advisory committee (EAC) to provide advice and perspectives on progress and any major changes in project direction. If an EAC is to be appointed, its functions and operation should be described in this section. *However, applicants should not identify any members in the application or contact potential candidates before the application has been reviewed.*

If exploratory pilot studies are proposed, the process for evaluation must include:

- A plan for the solicitation of proposals, the review of their methodology and research performance, and prioritization and selection of the projects.
- The plans for defining the scope of the projects, eligibility requirements, the limit on the dollars available, and the number of years of support per project. The eligibility must indicate that investigators of pilot studies are ESIs and hold a faculty appointment or equivalent position at the time the pilot award commences. For the purposes of this FOA, these are individuals who can independently apply for Federal or non-Federal investigator-initiated peer-reviewed Research Project Grants (RPGs). Individuals holding postdoctoral fellowships or other positions that lack independent status are not eligible to lead pilot studies. Pilot study ESIs must not be concurrently appointed as PD/PIs and will retain their ESI status.
- The available pool of eligible ESIs at participating institutions should be identified at the time of application to assess resources that will be drawn upon for new expertise that supports program objectives.
- Governance, oversight, and evaluation procedures that include an EAC, if proposed.

- Expectations of ESIs submitting pilot studies should be clearly described before proposal submission. Evaluation of ESI mentoring, career development interdisciplinary science training, overall productivity and attainment of independent funding should be provided upon completion of pilot studies.

Research plans for individual pilot studies should not be included in the application and must begin in years 2-5 of the program. All pilot studies individually and in aggregate must adhere to the limits of budget per year and the number of years per project. The evaluation of ESI productivity, career development and attainment of independent funding should be documented. Success of the pilot studies in the first five-year funding period will be assessed if the pilot program is requested in a renewal application.

NIGMS approval of the pilot study must be obtained before initiating a new pilot study or releasing funds for the pilot study.

**Resource Sharing Plan:** Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide, with the following modification:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.
- **Appendix:**

Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

## Human Subjects and Clinical Trials Information

When involving NIH-defined human subjects research, clinical research, and/or clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with 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 a **Delayed Onset Study** record.

### Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed

### Delayed Onset Study

All instructions in the SF424 (R&R) Application Guide must be followed.

## PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

## 3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

## 4. Submission Dates and Times

[Part I. Overview Information](#) contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or [Federal holiday](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82380](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82380)), the application deadline is automatically extended to the next business day.

Organizations must submit applications to [Grants.gov \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11128\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

**Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.**

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

## 5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to [intergovernmental review. \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11142\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11142)

## 6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11120\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11143\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11143).

Funds for pilot projects may only be used for that purpose, with NIGMS prior approval, and cannot be rebudgeted.

## 7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

**Applicants must complete all required registrations before the application due date.** [Section III. Eligibility Information](#) contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit [Applying Electronically \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11144\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11144). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the [Guidelines for Applicants Experiencing System Issues \(//grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines\)](https://grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines). For assistance with application submission, contact the Application Submission Contacts in [Section VII](#).

### Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See [Section III](#) of this FOA for information on registration requirements.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See [more tips \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11146\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH. Applications that are incomplete or non-compliant will not be reviewed.

## Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=82299\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82299).

# Section V. Application Review Information

## 1. Criteria

Only the review criteria described below will be considered in the review process. As part of the [NIH mission \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11149\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11149), all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

### Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

### Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

#### Significance

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

#### For this FOA:

Is the program of sufficient scope and complexity, and of sufficient potential impact, to warrant a team approach? Do the specific aims form a single cohesive program, and if accomplished will these aims advance the stated goals of the program? Is the problem such that definitive outcomes can be accomplished during the funding period? If successful, will the proposed program's coordinated research effort uniquely advance a scientific field/community that increases basic research for understanding biological processes?

#### Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

#### For this FOA:

Is the planned effort by the PD/PIs appropriate and sufficient for the work proposed? Are the critical mass and diversity of investigator backgrounds and expertise sufficient to address the proposed scientific problem? Is it clear that each investigator is necessary and will contribute to achieving the goals of the program? Is there evidence for synergistic interactions among PD/PIs beyond the additive benefits of additional investigators? If the application includes collaborating investigators who will not receive direct support, is it clear how these

investigators will participate in the program? If foreign investigators are involved are they uniquely qualified to participate in the team?

## **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?

### **For this FOA:**

Does the program involve innovative ideas or approaches that would be very difficult to pursue through independently funded individual or multiple PD/PI research project grants? Does the program involve innovative combinations of scientific fields and/or intellectual viewpoints to address its goals? Is innovation evident in the method that established areas of science are combined?

## **Approach**

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators 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 project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

### **For this FOA:**

#### *Research Program:*

Is the program presented as a coherent and fully integrated set of specific aims or objectives? Are the approaches and personnel appropriate for the specific aims proposed? Are the timeline and milestones proposed appropriate for accomplishing the specific aims? Are the resources and infrastructure adequate for accomplishing the specific aims and supporting team science? Are any plans for technology development necessary to address the scientific problems and specifically focused on these problems as opposed to being more general technology development goals? If new databases or resource collections will be developed, are they well justified and clearly ancillary to the research goals? Does the work plan make adequate use of existing institutional and regional resources? If new resources or equipment are requested, are they well justified and not redundant with resources available elsewhere in the institution or region? If a second five-year period is anticipated, are long-term, ten-year objectives clearly described? Do plans include criteria for making the go/no-go decision for a renewal application?

#### *Team Management Plan:*

Does the team management plan describe adequately the governance and processes that will be used for decision making? Does the plan allow for flexibility in pursuing the aims and allocation of resources? Does the plan assure that all investigators are encouraged to have a voice in decision making so that no single PD/PI will become overly dominant? Is the team management plan complementary to the multiple PD/PI plan? Does it provide for effective team leadership and management with distributed responsibility and decision-making processes? Is the team plan sufficiently detailed to create a sustainable environment for maintaining trust and shared vision? Does the management plan include adequate plans for shared professional credit? Is there evidence of institutional buy-in for shared professional credit for team activities that is sufficient for professional

advancement? If shared research resources will be utilized, are plans adequate to ensure that all team members will have the access they require? If an external advisory committee is proposed, is the plan for this appropriate? If a scientific program manager or coordinator is proposed, are the qualifications and role of this individual appropriate? Are adequate plans presented to establish and sustain a team of researchers with an optimal range of backgrounds, expertise and skills and plans to arrive at major decisions, accounting for diverse points of view?

#### *Optional Activities:*

If proposed, are plans for a pilot studies program appropriate? Are plans for the solicitation, review, and monitoring of exploratory pilot studies appropriate? Does the management plan describe how these investigators will be integrated into the program and learn best practices in team science? Are clear pathways for developing the research programs of the ESIs described that will likely lead to independent funding? Is team diversity considered in plans for recruiting ESIs for pilot projects?

### **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 unique features of the scientific environment, subject populations, or collaborative arrangements?

#### **For this FOA:**

Is there synergy to be gained from the involvement of multiple departments and institutions? Will the range of departments and/or institutions involved enhance the diversity of the team in terms of the backgrounds, expertise and skills of the researchers? If foreign organizations are involved do they provide unique resources that are not otherwise available?

### **Additional Review Criteria**

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

#### **Protections for Human Subjects**

For research that involves human subjects but does not involve one of the six categories of research that are exempt 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: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the [Guidelines for the Review of Human Subjects \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11175\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

#### **Inclusion of Women, Minorities, and Children**

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the [Guidelines for the Review of Inclusion in Clinical Research \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11174\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11174).

#### **Vertebrate Animals**

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animal Section \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11150\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

### **Biohazards**

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

### **Resubmissions**

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

### **Renewals**

Not Applicable

### **Revisions**

Not Applicable

## **Additional Review Considerations**

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

### **Applications from Foreign Organizations**

Not Applicable

### **Select Agent Research**

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

### **Resource Sharing Plans**

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) [Data Sharing Plan \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11151\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11151); (2) [Sharing Model Organisms \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11152\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and (3) [Genomic Data Sharing Plan \(GDS\) \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11153\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11153).

### **Authentication of Key Biological and/or Chemical Resources:**

For projects involving key biological and/or chemical resources, reviewers will comment on the brief 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. Additionally, reviewers should address the following criteria: Are the administrative personnel and activities, resources, and equipment, and foreign investigators appropriate and well justified? If exploratory pilot studies and personnel are requested for Optional Activities, are they appropriate and well justified?.

## 2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by CSR, in accordance with [NIH peer review policy and procedures \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11154\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated [review criteria](#). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- Will receive a written critique.

Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Portfolio balance.

## 3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the [eRA Commons \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11156\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11156).

## Section VI. Award Administration Information

### 1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11157\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11157).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in [Section IV.5. Funding Restrictions](#). Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the [Award Conditions and Information for NIH Grants \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11158\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

#### Prior Approval of Exploratory Pilot Studies

Awardee-selected pilot studies will require prior approval by NIH prior to initiation of those studies (see the [NIH Grants Policy Statement 8.1.3 Requests for Prior Approval \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_8/8.1\\_changes\\_in\\_project\\_and\\_budget.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.1_changes_in_project_and_budget.htm) for instructions on submitting a request). While a change in scope is not permitted without re-review, additional

approaches and expertise that take advantage of new opportunities and support the Collaborative Program are encouraged. ESI pilot studies should support the overall project goals, rather than the specific research plans of individual PD/PIs.

Prior to the commencement of any exploratory pilot studies, the following documentation must be submitted to NIGMS staff for administrative review six weeks before the requested start date, using PHS398 forms and instructions:

- Face page (signed by institutional signing official)
- Project Summary (page 2)
- Research Strategy section
- Research proposal (6 pages)
- Rigor and transparency: As appropriate, include a description of the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of project, and a description of the experimental design and methods proposed and how the investigator will achieve robust and unbiased results. If applicable, also include a brief description of the methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed project. See Notice [NOT-OD-16-011 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-011.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-011.html) for details.
- Biographical sketch of lead investigator of pilot study and other key personnel.
- Pilot study PIs must not be added to the multi-PD/PI Leadership Plan for the overall collaborative program, and therefore, will retain their ESI status.
- External Advisory Committee (EAC) approval – EACs are optional unless clinical research is proposed. If proposed, the EAC is required and communication from the EAC chair (at a minimum) indicating that the EAC concurs with supporting the pilot studies must be included.
- If the proposed study involves human subjects, the following documents must be submitted to NIH:
- Plan addressing the risks and protections for human subjects, in accordance with [NIH's Instructions for Preparing the Human Subjects Section of the Research Plan \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=12000\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000).
- Institutional Review Board (IRB) approval.
- Human Subjects education certification.
- Create Inclusion Data Record (IDR) and enter inclusion data in Inclusion Management System (IMS).
- If the study involves Vertebrate Animal, Institutional Animal Care and Use Committee (IACUC) approval and the Vertebrate Animal Section must be submitted.

Mentoring and training cannot be funded by the pilot study, but a description should be provided that explains how institutional or other resources can be leveraged for appropriate ESI mentoring, including the effective conduct of interdisciplinary team science, with a goal of achieving independent funding.

## 2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11120\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) as part of the NoA. For these terms of award, see the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11157\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11159\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at [Award Conditions and Information for NIH Grants \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11158\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11158).

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research

protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.

For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA. HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see <http://www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html>. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see <http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html>); and <http://www.hhs.gov/ocr/civilrights/understanding/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/index.html>). Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>). Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at <http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html> (<http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html>) or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at <http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53> (<http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>).

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

### **Cooperative Agreement Terms and Conditions of Award**

Not Applicable

## **3. Reporting**

When multiple years are involved, awardees will be required to submit the [Research Performance Progress Report \(RPPR\)](http://grants.nih.gov/grants/rppr/index.htm) (<http://grants.nih.gov/grants/rppr/index.htm>) annually and financial statements as required in the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161). ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11161](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161))

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161) ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11161](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161)).

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under

Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at [www.fsrs.gov](http://www.fsrs.gov) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11170](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11170)) on all subawards over \$25,000. See the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11171) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11171](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11171)) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than \$10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

## Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

### Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)

Finding Help Online: <http://grants.nih.gov/support/> ([//grants.nih.gov/support/](http://grants.nih.gov/support/)) (preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

[Grants.gov Customer Support](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82301) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=82301](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82301)) (Questions regarding Grants.gov registration and submission, downloading forms and application packages)

Contact Center Telephone: 800-518-4726

Email: [support@grants.gov](mailto:support@grants.gov) (<mailto:support@grants.gov>)

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)

Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov) (<mailto:GrantsInfo@nih.gov>) (preferred method of contact)

Telephone: 301-945-7573

### Scientific/Research Contact(s)

Paul Sammak, Ph.D.

National Institute of General Medical Sciences (NIGMS)

Telephone: 301-594-8494

Email: [paul.sammak@nih.gov](mailto:paul.sammak@nih.gov) (<mailto:paul.sammak@nih.gov>)

### Peer Review Contact(s)

Raymond Jacobson, Ph.D.

Center for Scientific Review (CSR)

Telephone: 301-996-7702

Email: [jacobsonrh@csr.nih.gov](mailto:jacobsonrh@csr.nih.gov) (<mailto:jacobsonrh@csr.nih.gov>)

## Financial/Grants Management Contact(s)

E. C. Melvin

National Institute of General Medical Sciences (NIGMS)

Telephone: 301-594-3912

Email: [melvine@nigms.nih.gov](mailto:melvine@nigms.nih.gov) (<mailto:melvine@nigms.nih.gov>)

## Section VIII. Other Information

Recently issued trans-NIH [policy notices](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11163](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11163)) may affect your application submission. A full list of policy notices published by NIH is provided in the [NIH Guide for Grants and Contracts](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11164](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164)). All awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11120](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120)).

## Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

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[Weekly TOC for this Announcement](http://grants/guide/WeeklyIndex.cfm?09-22-17) ([/grants/guide/WeeklyIndex.cfm?09-22-17](http://grants/guide/WeeklyIndex.cfm?09-22-17))

[NIH Funding Opportunities and Notices](http://grants/guide/index.html) ([/grants/guide/index.html](http://grants/guide/index.html))

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National Institutes of Health ([/grants/oer.htm](http://grants/oer.htm))  
Office of Extramural Research



(<http://www.hhs.gov/>)

Department of Health  
and Human Services (HHS)



(<http://www.usa.gov/>)

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**Note:** For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see [Help Downloading Files](http://grants/edocs.htm) ([/grants/edocs.htm](http://grants/edocs.htm)).