

# 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 Allergy and Infectious Diseases ([NIAID \(https://www.niaid.nih.gov/\)](https://www.niaid.nih.gov/))

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**Funding Opportunity Title**

NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed)

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**Activity Code**

[P01 \(http://grants.nih.gov/grants/funding/ac\\_search\\_results.htm?text\\_curr=p01&Search.x=0&Search.y=0&Search\\_Type=Activity\)](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=p01&Search.x=0&Search.y=0&Search_Type=Activity) Research Program Projects

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**Announcement Type**

Reissue of PAR-22-225

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**Related Notices**

- Check for any recent [Notices of NIH Policy Changes \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11163\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11163) that may impact application requirements.

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**Funding Opportunity Number (FON)**

PAR-27-082

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**Companion Notice of Funding Opportunity**

None

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**Number of Applications**

See [Section III. 3. Additional Information on Eligibility](#).

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**Assistance Listing Number(s)**

93.855

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**Notice of Funding Opportunity Purpose**

This notice of funding opportunity (NOFO) invites submission of investigator-initiated Program Project (P01) applications. The proposed Programs should address scientific areas relevant to the NIAID mission including: biology and pathogenesis of infectious microbes, including HIV; host-microbe interactions; mechanisms regulating immune system development and function across the lifespan, and in response to infectious pathogens; immune dysfunction resulting in allergy, asthma, autoimmunity, immunodeficiency, or transplant rejection; and translational research to develop vaccines, therapeutics, and diagnostics to prevent and treat infectious and immune-mediated diseases. Each application submitted to this NOFO must include at least two related, synergistic Research Projects that share a common central theme, focus, and/or overall objective; and an Administrative Core. An application may include Scientific Core(s), if needed for the proposed research.

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**Funding Opportunity Goal(s)**

To assist public and private nonprofit institutions and individuals to establish, expand and improve biomedical research and research training in infectious diseases and related areas; to conduct developmental research, to produce and test research materials. To assist public, private and commercial institutions to conduct developmental research, to produce and test research materials, to provide research services as required by the agency for programs in infectious diseases, and controlling disease caused by infectious or parasitic agents, allergic and immunologic diseases and related areas. Projects range from studies of microbial physiology and antigenic structure to collaborative trials of experimental drugs and vaccines, mechanisms of resistance to antibiotics as well as research dealing with epidemiological observations in hospitalized patients or community populations and progress in allergic and immunologic diseases. Because of this dual focus, the program encompasses both basic research and clinical research.

## Key Dates

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**Posted Date**

May 07, 2026

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**Open Date (Earliest Submission Date)**

August 25, 2026

The following table includes NIH [standard due dates \(https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm\)](https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm), marked with an asterisk.

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
September 25, 2026 *	September 25, 2026 *	Not Applicable	March 2027	May 2027	July 2027
January 25, 2027 *	January 25, 2027 *	Not Applicable	July 2027	October 2027	February 2028
May 25, 2027 *	May 25, 2027 *	Not Applicable	November 2027	January 2028	March 2028
September 25, 2027 *	September 25, 2027 *	Not Applicable	March 2028	May 2028	July 2028
January 25, 2028 *	January 25, 2028 *	Not Applicable	July 2028	October 2028	February 2029
May 25, 2028 *	May 25, 2028 *	Not Applicable	November 2028	January 2029	March 2029
September 25, 2028 *	September 25, 2028 *	Not Applicable	March 2029	May 2029	July 2029
January 25, 2029 *	January 25, 2029 *	Not Applicable	July 2029	October 2029	February 2030
May 25, 2029 *	May 25, 2029 *	Not Applicable	November 2029	January 2030	March 2030

All applications are due by 5:00 PM local time of applicant organization.

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.

#### Expiration Date

May 26, 2029

#### Due Dates for E.O. 12372

Not Applicable

#### Required Application Instructions

It is critical that applicants follow the Multi-Project (M) Instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), except where instructed to do otherwise (in this NOFO or in a Notice from the [NIH Guide for Grants and Contracts \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11164\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164)). Conformance to all requirements (both in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the [NIH ASSIST system \(https://public.era.nih.gov/assist/landing\\_era?tabId=0819b5fc-46b7-4f02-b6b7-127e5a4e19fa\)](https://public.era.nih.gov/assist/landing_era?tabId=0819b5fc-46b7-4f02-b6b7-127e5a4e19fa) to prepare, submit and track your application online.
2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and [eRA Commons \(https://public.era.nih.gov/commons/\)](https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.

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## Part 2. Full Text of Announcement

### Section I. Notice of Funding Opportunity Description

#### Background

The mission of the National Institute of Allergy and Infectious Diseases (NIAID) is to conduct and support basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. To accomplish its mission, NIAID conducts and supports a comprehensive portfolio of research on the biology and pathogenesis of microbes; host-microbe interactions; the mechanisms of normal immune system development and function across the lifespan, and/or in response to infectious pathogens; immune dysfunction resulting in allergy, asthma, autoimmunity, immunodeficiency, and transplant rejection; and translational research to develop vaccines, therapeutics, and diagnostics to prevent and treat infectious, immune-mediated, and allergic diseases that afflict people throughout the world.

#### Purpose

This notice of funding opportunity (NOFO) invites Program Project applications (P01) that address the mission of NIAID as outlined in the Background section above. Investigators are encouraged to visit the [NIAID website \(https://www.niaid.nih.gov/about/mission-planning-overview\)](https://www.niaid.nih.gov/about/mission-planning-overview) for additional information about the research mission.

The purpose of Program Project (P01) grants is to support integrated, multi-project research Programs that have a well-defined, central research focus or objective. The P01 application must include a minimum of two individual Research Projects that contribute to the Program objective. Each individual Research Project should reflect a distinct, separate, scientifically meritorious research effort led by an independent investigator, the Project Leader. In addition, the individual Research Projects should be clearly interrelated and synergistic so that the research ideas, efforts, and outcomes of the Program as a whole will offer a distinct advantage over pursuing the individual Projects separately.

In addition to individual Research Projects, an Administrative Core is required. The Administrative Core is responsible for the general organization and administrative management of the overall Program, which includes ensuring lines of communication are effectively established and maintained, monitoring progress, and establishing the necessary infrastructure to support collaborative research and encourage optimal interactions and leveraging of resources.

Applications may propose one or more Scientific Core(s) if needed for the proposed research. Scientific Core(s) perform services and tasks, not research activities. Each Scientific Core must be utilized by two or more Research Projects within the Program. For renewals and resubmissions, new Scientific Core(s) may be proposed and/or existing Scientific Core(s) may be augmented or dropped to support the proposed research.

Clinical trials are NOT allowed and will not be reviewed or funded. However, Research Projects and/or Scientific Core(s) may include analyses of samples collected from independently funded clinical trials.

Applicants are encouraged to review NIAID's [Preparing Multiproject Research Applications \(https://www.niaid.nih.gov/grants-contracts/multi-project-research-p-u-applications\)](https://www.niaid.nih.gov/grants-contracts/multi-project-research-p-u-applications) tutorial for additional guidance on NIAID P01s, including the option to submit each Research Project simultaneously as an R01 application.

### Synergy in Multi-Project Applications

This NOFO supports multi-project applications. In the context of a multi-project application, synergy entails enhancement of scientific knowledge, ideas, and outcomes obtained through the cooperative interactions of the individual Projects and Core(s). The proposed merger of complementary skills, perspectives, and resources has the potential to produce outcomes greater than would otherwise be achieved. The outcomes resulting from conducting the proposed research as a Program will exceed the outcomes from conducting separate research activities as a single Project application. Synergy is defined as the sharing of data generated by the individual Projects and Core(s) that will inform the other Project(s) such that the research is enhanced through this additional knowledge and/or the direction of science and research outcomes are transformed. Resources and tools that can help facilitate synergy include, but are not limited to sharing research data, samples, reagents, pathogens, human subject cohort(s), technologies, new approach methodologies, research approaches, data management/analytical tools, and model organisms.

For more information, see [here \(https://www.niaid.nih.gov/grants-contracts/questions-answers-niaid-investigator-initiated-program-project-p01\)](https://www.niaid.nih.gov/grants-contracts/questions-answers-niaid-investigator-initiated-program-project-p01). Potential applicants are highly encouraged to contact the Scientific/Research Contacts in Section VII.

See Section VIII. Other Information for award authorities and regulations.

## Section II. Award Information

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### Funding Instrument

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

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### Application Types Allowed

New  
Renewal  
Resubmission  
Revision

The [OER Glossary \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11116\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) provides details on these application types. Only those application types listed here are allowed for this NOFO.

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### Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials. Note: Applications may propose activities involving human subjects that are not deemed 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)

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### 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.

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### Award Budget

Application budgets are not limited but need to reflect the actual needs of the proposed project.

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### Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is five years.

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

## Section III. Eligibility Information

### 1. Eligible Applicants

#### Eligible Organizations

Higher Education Institutions - Includes all types

- 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 (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)

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

## Foreign Organizations/International Collaborations

Non-domestic (non-U.S.) Entities (Foreign Organization) **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 \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11118\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are** allowed.

NIH will no longer issue awards (i.e., new, renewal, or non-competing continuation) to domestic or foreign entities that involve foreign subawards/subcontracts. All NIH-funded research involving foreign subawards/subcontracts must be submitted in response to a NOFO that is specifically designated for funded international collaborations. See [NIH Grants Policy Statement 16.8 Collaborative International Research Awards \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_16/16.8\\_collab\\_int\\_res\\_awards.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_16/16.8_collab_int_res_awards.htm).

Applications involving foreign subawards/subcontracts submitted in response to this NOFO will be deemed noncompliant and will not be considered for funding. This policy applies to all monetary international collaborations resulting in foreign subawards/subcontracts, however, it does not preclude unfunded international collaborations or [foreign components \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_1/1.2\\_definition\\_of\\_terms.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_1/1.2_definition_of_terms.htm), funding for foreign consultants, or procurement of unique equipment or supplies from foreign vendors.

## Required Registrations

### Applicant organizations

Applicant organizations must complete and maintain the following registrations as described in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) 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. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference [NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82423\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423) for additional information.

- [System for Award Management \(SAM\) \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82390\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82390) – 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. Foreign organizations must obtain a [NATO Commercial and Government Entity \(NCAGE\) Code \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11176\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) (in lieu of a CAGE code) in order to register in SAM.
  - Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- [eRA Commons \(https://era.nih.gov/\)](https://era.nih.gov/) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registration; all registrations must be in place by 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.
- [Grants.gov \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82300\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82300) – Applicants must have an active 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.

All PD(s)/PI(s) must be registered with [ORCID \(https://orcid.org/\)](https://orcid.org/). The personal profile associated with the PD(s)/PI(s) eRA Commons account must be linked to a valid ORCID ID. For more information on linking an ORCID ID to an eRA Commons personal profile see the ORCID topic in our eRA Commons online help.

### 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.

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 [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

Note that the multiple PDs/PIs option may only be used for the overall Program Leader. NIAID does not support multiple Project/Core Leaders for individual Research Projects and Scientific Core(s) within a multi-project application.

## 2. Cost Sharing

This NOFO does not require cost sharing as defined in the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11126\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11126) Section 1.2- Definitions of Terms. ([https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_1/1.2\\_definition\\_of\\_terms.htm](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_1/1.2_definition_of_terms.htm))

## 3. Additional Information on Eligibility

### Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time per [NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82415\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82415). 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 [NIH Grants Policy Statement 2.3.9.4 Similar, Essentially Identical, or Identical Applications \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82423\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423)).

## Section IV. Application and Submission Information

### 1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST or an institutional system-to-system solution. A button to apply using ASSIST is available in Part 1 of this NOFO. See the administrative office for instructions if planning to use an institutional system-to-system solution.

### 2. Content and Form of Application Submission

It is critical that applicants follow the Multi-Project (M) Instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), except where instructed in this notice of funding opportunity to do otherwise (in this NOFO, in a [policy notice \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11163\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11163), or other notice from [NIH Guide for Grants and Contracts \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11164\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11164)) and where instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) are directly related to the Grants.gov downloadable forms currently used with most NIH opportunities. Conformance to the requirements in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

### Page Limitations

All page limitations described in the [How to Apply-Application Guide \(https://grants.nih.gov/grants/how-to-apply-application-guide.html\)](https://grants.nih.gov/grants/how-to-apply-application-guide.html) and the [Table of Page Limits \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=61134\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=61134) must be followed.

Component	Component Type for Submission	Page Limit	Required/Optional	Minimum	Maximum
Overall	Overall	12	Required	1	1
Admin Core	Admin Core	6	Required	1	1
Scientific Core(s)	Core	6	Optional	0	NA
Research Projects	Project	12	Required	2	NA

### Instructions for the Submission of Multi-Component Applications

The following section supplements the instructions found in [How to Apply-Application Guide \(https://grants.nih.gov/grants/how-to-apply-application-guide.html\)](https://grants.nih.gov/grants/how-to-apply-application-guide.html) and should be used for preparing a multi-component application.

Revision applications must include an Overall component and the components that are affected by the revision. Therefore, the component requirements listed below may not apply to the revision application.

The application should consist of the following components:

- Overall: required, 1
- Administrative Core: required, 1
- Scientific Core(s): optional, each Core must support at least two Research Projects
- Research Projects: required, minimum 2

### Overall Component

When preparing the application, use Component Type 'Overall'.

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed, with the following additional instructions, as noted.

#### SF424(R&R) Cover (Overall)

Complete entire form.

#### PHS 398 Cover Page Supplement (Overall)

Note: Human Embryonic Stem Cell lines from other components should be repeated in cell line table in Overall component.

#### Research & Related Other Project Information (Overall)

Follow standard instructions.

### Project/Performance Site Locations (Overall)

Enter primary site only.

*A summary of Project/Performance Sites in the Overall section of the assembled application image in eRA Commons compiled from data collected in the other components will be generated upon submission.*

### Research and Related Senior/Key Person Profile (Overall)

Include only the Project Director/Principal Investigator (PD/PI) and any multi-PDs/PIs (if applicable to this NOFO) for the entire application.

*A summary of Senior/Key Persons followed by their Biographical Sketches in the Overall section of the assembled application image in eRA Commons will be generated upon submission.*

### Budget (Overall)

The only budget information included in the Overall component is the Estimated Project Funding section of the SF424 (R&R) Cover.

*A budget summary in the Overall section of the assembled application image in eRA Commons compiled from detailed budget data collected in the other components will be generated upon submission.*

### PHS 398 Research Plan (Overall)

**Introduction to Application:** For Resubmission and Revision applications, an Introduction to Application is required in the Overall component.

**Specific Aims:** List the goals of the research and summarize expected outcomes.

**Research Strategy:** Describe the significance and approach of the Program Project and highlight the Program's conceptual unity, innovation, and synergy. Include a description of the major research objectives and strategic plan. Detail how the proposed Research Projects and shared Scientific Core(s) (if proposed) will be integrated and coordinated and how their collective efforts will work together to address the overall goals and aims of the Program and enhance the output(s) more effectively than if the Projects were conducted independently. Describe the synergistic nature of the proposed Research Projects and shared Scientific Core(s) (if proposed) at the overall Program level and include the placement/contribution of each Project and Core in the overall scheme. The Program Project may include study design and methods that are not by themselves innovative but address innovative hypotheses or important questions and unmet needs, thus making the proposed study conceptually innovative. Describe how the Program as a whole will benefit from any unique cohorts and samples, collaborations, or resources and summarize any special features in the environment and/or resources that make the overall Program strong or unique.

If appointing an External Advisory Committee (EAC) (optional), describe the expertise and responsibilities of the potential EAC members. New applications that include an optional EAC should not name potential members in the application or solicit potential members prior to award. For a renewal application, provide the names of current and former members, but do not name new members in the application or recruit new members until completion of peer review activities.

#### Resource Sharing Plan:

Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the [How to Apply - Application Guide](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400) ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=82400](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400)).

#### Other Plan(s):

All instructions in the [How to Apply- Application Guide](https://grants.nih.gov/grants/how-to-apply-application-guide.html) (<https://grants.nih.gov/grants/how-to-apply-application-guide.html>) must be followed, with the following additional instructions:

- A Data Management and Sharing Plan (DMS Plan) is required for any NIH-funded or conducted research that will generate scientific data. Applicants must submit the DMS Plan at the time of application using the [NIH DMS Plan Format Page](https://grants.nih.gov/grants-process/write-application/forms-directory/data-management-and-sharing-plan-format-page) (<https://grants.nih.gov/grants-process/write-application/forms-directory/data-management-and-sharing-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. The Data Management and Sharing (DMS) Plan must be provided in the Overall component.
- Investigators funded under this NOFO may be expected to share their data publicly through [ImmPort](https://import.niaid.nih.gov/home) (<https://import.niaid.nih.gov/home>) or other public portals approved by NIAID.

#### Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in [How to Apply- Application Guide](https://grants.nih.gov/grants/how-to-apply-application-guide.html) (<https://grants.nih.gov/grants/how-to-apply-application-guide.html>); any instructions provided here are in addition to the [How to Apply - Application Guide](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400) ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=82400](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400)) instructions.

### PHS Human Subjects and Clinical Trials Information (Overall)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the [How to Apply - Application Guide](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400) ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=82400](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400)), with the following additional instructions:

If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, there must be 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 within the application. The study record(s) must be included in the component(s) where the work is being done, unless the same study spans multiple components. To avoid the creation of duplicate study records, a single study record with sufficient information for all involved components must be included in the Overall component when the same study spans multiple components.

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

All instructions in the [How to Apply - Application Guide](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400) ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=82400](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400)) must be followed.

#### Delayed Onset Study

Note: [Delayed onset](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy) (<https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy>) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the [How to Apply- Application Guide](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400) ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=82400](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400)) must be followed.

### PHS Assignment Request Form (Overall)

All instructions in the [How to Apply- Application Guide](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400) ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=82400](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400)) must be followed.

### Administrative Core

When preparing your application, use Component Type 'Admin Core.'

All instructions in the [How to Apply- Application Guide](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400) ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=82400](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400)) must be followed, with the following additional instructions, as noted.

#### SF424 (R&R) Cover (Administrative Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

### PHS 398 Cover Page Supplement (Administrative Core)

Enter Human Embryonic Stem Cells in each relevant component.

### Research & Related Other Project Information (Administrative Core)

**Human Subjects:** Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

**Vertebrate Animals:** Answer only the 'Are Vertebrate Animals Used?' question.

**Project Narrative:** Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

### Project/Performance Site Location(s) (Administrative Core)

List all performance sites that apply to the specific component.

*Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.*

### Research & Related Senior/Key Person Profile (Administrative Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

### Budget (Administrative Core)

Budget forms appropriate for the specific component will be included in the application package.

*Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.*

### PHS 398 Research Plan (Administrative Core)

**Introduction to Application:** For Resubmission and Revision applications, an Introduction to Application is allowed for each component.

**Specific Aims:** List in priority order, the broad, long-range objectives, tasks and goals of the proposed Administrative Core. In addition, state the Administrative Core's relationship to the proposed Program's goals and how it is related to the individual Research Projects and Scientific Core(s) (if proposed) in the application.

**Research Strategy:** The institution and the Core Lead are responsible for the application and collaborative research activities. Describe the operational plan for organizational and administrative management of the overall Program, and for coordination and communication within the Program. Detail the methods that will be used for monitoring progress in the Projects and effective use of the shared Scientific Core(s) (if proposed). Explain the plans for internal quality control of on-going research, management of day-to-day program activities, management of contractual agreements (if applicable), and a plan for resolution of disputes. Describe how the Core Lead's administrative, management, and leadership capabilities adequately provide for: internal quality control of on-going research, management of day-to-day program activities, and management of contractual agreements (if applicable). Describe communication and cooperation among Program leaders and/or Program investigators, plans for resolution of disputes, development of scientific meetings and allocation of funds as applicable.

**Resource Sharing Plan:** Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

### Other Plan(s):

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed, with the following additional instructions:

- Do not include a Data Management and Sharing (DMS) Plan within this Component. If a DMS Plan is required for this NOFO, it must be included within the Overall Component.

### Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400); any instructions provided here are in addition to those in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) instructions.

### PHS Human Subjects and Clinical Trials Information (Administrative Core)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), 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 [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

### Delayed Onset Study

Note: [Delayed onset \(https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy\)](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

### Scientific Core(s)

When preparing your application, use Component Type 'Core.'

All instructions in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed, with the following additional instructions, as noted.

### SF424 (R&R) Cover (Scientific Core(s))

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

### PHS 398 Cover Page Supplement (Scientific Core(s))

Enter Human Embryonic Stem Cells in each relevant component.

### Research & Related Other Project Information (Scientific Core(s))

**Human Subjects:** Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

**Vertebrate Animals:** Answer only the 'Are Vertebrate Animals Used?' question.

**Project Narrative:** Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

### Project/Performance Site Location(s) (Scientific Core(s))

List all performance sites that apply to the specific component.

*Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.*

### Research & Related Senior/Key Person Profile (Scientific Core(s))

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

### Budget (Scientific Core(s))

Budget forms appropriate for the specific component will be included in the application package.

*Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.*

### PHS 398 Research Plan (Scientific Core(s))

**Introduction to Application:** For Resubmission and Revision applications, an Introduction to Application is allowed for each component.

**Specific Aims:** State the Scientific Core's relationship to the proposed Program's goals and how it is related to the individual Research Projects and other Scientific Core(s) in the application. List in priority order, the tasks of the proposed Scientific Core.

**Research Strategy:** A Scientific Core is a resource for the entire Program. Each shared Scientific Core must be utilized by two or more Research Projects within the Program. List the Research Projects the Scientific Core will serve, services it will provide, and the applicable tasks. Describe the facilities, techniques, and skills the Scientific Core will provide and the role of the Core Lead and each key participant.

**Resource Sharing Plan:** Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

### Other Plan(s):

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed, with the following additional instructions:

- Do not include a Data Management and Sharing (DMS) Plan within this Component. If a DMS Plan is required for this NOFO, it must be included within the Overall Component.

### Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400); any instructions provided here are in addition to those in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) instructions.

### PHS Human Subjects and Clinical Trials Information (Scientific Core(s))

When involving human subjects research, clinical research, and/or NIH-defined clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), 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 [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

### Delayed Onset Study

Note: [Delayed onset \(https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy\)](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

### Research Projects

When preparing your application, use Component Type 'Project.'

All instructions in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed, with the following additional instructions, as noted.

### SF424 (R&R) Cover (Research Projects)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

### PHS 398 Cover Page Supplement (Research Projects)

Enter Human Embryonic Stem Cells in each relevant component.

### Research & Related Other Project Information (Research Projects)

**Human Subjects:** Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

**Vertebrate Animals:** Answer only the 'Are Vertebrate Animals Used?' question.

**Project Narrative:** Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

### Project/Performance Site Location(s) (Research Projects)

List all performance sites that apply to the specific component.

*Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.*

### Research & Related Senior/Key Person Profile (Research Projects)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Project Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

### Budget (Research Projects)

Budget forms appropriate for the specific component will be included in the application package.

*Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.*

### PHS 398 Research Plan (Research Projects)

**Introduction to Application:** For Resubmission and Revision applications, an Introduction to Application is allowed for each component.

**Specific Aims:** List the broad long-range objectives and goals of the proposed Research Project. Describe the hypothesis or hypotheses to be tested. In addition, state the individual Project's relationship to the Program's goals and how it is synergistic to other Project(s) and relevant Core(s).

**Research Strategy:** Describe the proposed research and how it will contribute to meeting the Program's goals and objectives and explain the rationale for selecting the methods to accomplish the specific aims. State the biological significance of the research, indicating the Project's relevance to the primary theme of the application. Describe how the proposed study is innovative, which may include innovative hypotheses(sis) and/or a study design and methods that are not by themselves innovative but address important questions or unmet needs. In addition, provide a description of the interactions among Projects and Core(s) (if proposed).

**Resource Sharing Plan:** Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

### Other Plan(s):

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed, with the following additional instructions:

- Do not include a Data Management and Sharing (DMS) Plan within this Component. If a DMS Plan is required for this NOFO, it must be included within the Overall Component.

### Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400); any instructions provided here are in addition to those in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) instructions.

### PHS Human Subjects and Clinical Trials Information (Research Projects)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) 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 [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

### Delayed Onset Study

Note: [Delayed onset \(https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy\)](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

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

See Part 2. 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. 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 \(https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=82380\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to [Grants.gov \(http://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11128\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies) using ASSIST or other electronic submission systems. Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons \(http://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11123\)](http://grants.nih.gov/grants/guide/uri_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 Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications \(http://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=82423\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82423).

**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 [How to Apply - Application Guide. \(https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400).

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

This initiative is not subject to [intergovernmental review \(https://grants.nih.gov/grants/policy/nihgps/html5/section\\_10/10.10.1\\_executive\\_orders.htm\)](https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm).

#### 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 \(http://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11120).

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11143\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11143) Section 7.9.1 Selected Items of Cost. ([https://grants.nih.gov/grants/policy/nihgps/html5/section\\_7/7.9\\_allowability\\_of\\_costs\\_activities.htm#Selected](https://grants.nih.gov/grants/policy/nihgps/html5/section_7/7.9_allowability_of_costs_activities.htm#Selected)).

#### 7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400). Paper applications will not be accepted.

For information on how applications will be automatically assembled for review and funding consideration after submission, refer to:

[http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic\\_Multi-project\\_Application\\_Image\\_Assembly.pdf](http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf) ([http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic\\_Multi-project\\_Application\\_Image\\_Assembly.pdf](http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf)).

**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 [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the [Dealing with System Issues \(https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm\)](https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

##### Important reminders:

All PD(s)/PI(s) and component Project Leads must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form. 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.

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. Additional information may be found in [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400).

See [more tips \(http://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11146\)](http://grants.nih.gov/grants/guide/uri_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.

##### Prior Consultation with NIAID

Consultation with NIAID staff at least 15 weeks prior to the application due date is strongly encouraged for submission of any NIAID Program Project (P01) application, including new, renewal and resubmission applications so that NIAID staff can consider whether the proposed Program Project meets the goals and mission of the Institute, and whether it addresses one or more high priority research areas. NIAID staff will not evaluate the technical and scientific merit of the proposed application/Program; technical and scientific merit will be determined during peer review using the review criteria indicated in this NOFO.

##### Mandatory Disclosure

Recipients or subrecipients must submit any information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. See Mandatory Disclosures, [2 CFR 200.113 \(https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113\)](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113) and [NIH Grants Policy Statement Section 4.1.35 \(http://grants.nih.gov/grants/policy/nihgps/html5/section\\_4/4.1.35\\_mandatory\\_disclosures.htm\)](http://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.35_mandatory_disclosures.htm).

Send written disclosures to the NIH Chief Grants Management Officer listed on the Notice of Award for the IC that funded the award and to the [HHS Office of Inspector Grant Self Disclosure Program \(https://oig.hhs.gov/compliance/self-disclosure-info/hhs-oig-grant-self-disclosure-program/\)](https://oig.hhs.gov/compliance/self-disclosure-info/hhs-oig-grant-self-disclosure-program/) at [grantdisclosures@oig.hhs.gov](mailto:grantdisclosures@oig.hhs.gov) (<mailto:grantdisclosures@oig.hhs.gov>).

##### Post Submission Materials

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

## Section V. Application Review Information

### 1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to NIH in support of the [NIH mission \(http://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11149\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

### Overall Impact - Overall

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 - Overall

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 the prior research that serves as the key support for the proposed project rigorous? 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?

#### Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those 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?

#### 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?

#### Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed 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, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

*Specific to this NOFO:*

To what extent does the application adequately convey coordination and synergy of the individual Research Projects and Scientific Core(s) towards the achievement of the central objectives of the Program? To what extent does the Program benefit from integrating individual Research Projects into a single Program rather than pursuing each project independently?

#### 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?

### Overall Impact - Individual Research Projects

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 five review criteria, and additional review criteria (as applicable for the project proposed).

#### Significance

Does the program project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the program 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?

#### Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the program project? If Early-Stage Investigators or those 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?

#### 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?

#### Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the program project? Have investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed 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 program 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, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

#### 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?

### Overall Impact - Cores

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

#### Administrative Core

To what extent are the Administrative Core operational plan and organizational structure adequately described and justified? Is the proposed Administrative Core adequate to accomplish the objectives of the overall Program? How appropriate are the Core Lead's administrative, management, and leadership capabilities? How appropriate are the time commitments of the Core Lead and key personnel associated with the Administrative Core?

#### Scientific Core(s) (if applicable)

To what extent is the Scientific Core sufficiently justified and how well does it support at least two Research Projects? To what extent is the Scientific Core adequately connected to the central focus of the overall Program? How appropriate and of what quality are the facilities or services provided by the Scientific Core (including procedures and techniques)? How appropriate are the qualifications and time commitments of the Core Lead and key personnel associated with the Scientific Core?

### Additional Review Criteria - Overall, Research Projects, and Cores

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 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 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 \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11175\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

This NOFO only accepts applications that do not propose clinical trials. Note: Applications may propose activities involving human subjects that are not deemed clinical trials.

#### 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 \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11174\)](http://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 three points: (1) a complete description of all proposed procedures including the species, strains, ages, sex, and total numbers of animals to be used; (2) justifications that the species is appropriate for the proposed research and why the research goals cannot be accomplished using an alternative non-animal model; and (3) interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints that will be used to limit any unavoidable discomfort, distress, pain and injury in the conduct of scientifically valuable research. Methods of euthanasia and justification for selected methods, if NOT consistent with the American Veterinary Medicine Association (AVMA) Guidelines for the Euthanasia of Animals, is also required but is found in a separate section of the application. For additional information on review of the Vertebrate Animals Section, please refer to the [Worksheet for Review of the Vertebrate Animals Section \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11150\)](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 (as applicable), 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

For Renewals (as applicable), the committee will consider the progress made in the last funding period.

#### Revisions

For Revisions (as applicable), the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

### Additional Review Considerations - Overall, Research Projects, and Cores

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 Resource Sharing Plan(s) (e.g., [Sharing Model Organisms \(https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy#policy-overview\)](https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy#policy-overview)) or the rationale for not sharing the 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 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.

## 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 policies and practices \(http://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11154\)](http://grants.nih.gov/grants/guide/uri_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 will receive a written critique.

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.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the National Advisory Allergy and Infectious Diseases Council. 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.

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 Section 2.5.1. Just-in-Time Procedures \(http://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=82418\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82418). This request is not a Notice of Award nor should it be construed to be an indicator of possible funding.

Prior to making an award, NIH reviews an applicant's federal award history in SAM.gov to ensure sound business practices. An applicant can review and comment on any information in the Responsibility/Qualification records available in SAM.gov. NIH will consider any comments by the applicant in the Responsibility/Qualification records in SAM.gov to ascertain the applicant's integrity, business ethics, and performance record of managing Federal awards per 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

## 3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access their Summary Statement (written critique) via the [eRA Commons \(http://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11123\)](http://grants.nih.gov/grants/guide/uri_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 Section 2.4.4 Disposition of Applications \(http://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=82416\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82416).

# Section VI. Award Administration Information

## 1. Award Notices

A Notice of Award (NoA) is the official authorizing document notifying the applicant that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is signed by the Grants Management Officer and emailed to the recipient's business official.

In accepting the award, the recipient agrees that any activities under the award are subject to 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, and applicable statutory provisions.

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Any pre-award costs incurred before receipt of the NoA are at the applicant's own risk. For more information on the Notice of Award, please refer to the [NIH Grants Policy Statement Section 5. The Notice of Award \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_5/5\\_the\\_notice\\_of\\_award.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_5/5_the_notice_of_award.htm) and NIH Grants & Funding website, see [Award Process. \(https://grants.nih.gov/grants/pre-award-process.htm#award\)](https://grants.nih.gov/grants/pre-award-process.htm#award)

Institutional Review Board or Independent Ethics Committee Approval: Recipient organizations must ensure that protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the recipient must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

## 2. Administrative and National Policy Requirements

The following Federal wide and HHS-specific policy requirements apply to awards funded through NIH:

- The rules listed at [2 CFR Part 200 \(https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200\)](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200), Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11120) as part of the terms and conditions in the Notice of Award (NoA). The NoA includes the requirements of this NOFO. For these terms of award, see the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General \(http://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11120) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities \(http://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11159\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11159).

All federal statutes and regulations relevant to federal financial assistance, including those highlighted in [NIH Grants Policy Statement Section 4 Public Policy Requirements, Objectives and Other Appropriation Mandates. \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_4/4\\_public\\_policy\\_requirements\\_objectives\\_and\\_other\\_appropriation\\_mandates.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements_objectives_and_other_appropriation_mandates.htm)

By applying for or accepting federal funds from HHS, recipients certify compliance with all federal antidiscrimination laws and these requirements and that complying with those laws is a material condition of receiving federal funding streams. Recipients are responsible for ensuring subrecipients, contractors, and partners also comply.

Applicants and recipients are strongly encouraged to refer to the [NIH Director's Statement of Priorities \(https://www.nih.gov/about-nih/nih-director/statements/advancing-nih-mission-through-unified-strategy\)](https://www.nih.gov/about-nih/nih-director/statements/advancing-nih-mission-through-unified-strategy), entitled "Advancing NIH's Mission Through a Unified Strategy."

Recipients are responsible for ensuring that their 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).

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 \(https://www.nist.gov/cyberframework\)](https://www.nist.gov/cyberframework), 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 \(hhs.gov\) \(https://405d.hhs.gov/kod/five-threats\)](https://405d.hhs.gov/kod/five-threats) 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 \(cisa.gov\) \(https://www.cisa.gov/sites/default/files/publications/Incident-Response-Plan-Basics\\_508c.pdf\)](https://www.cisa.gov/sites/default/files/publications/Incident-Response-Plan-Basics_508c.pdf) 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.

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.

### Cooperative Agreement Terms and Conditions of Award

Not Applicable

### 3. Data Management and Sharing

A Data Management and Sharing Plan (DMS Plan) is required for any NIH-funded or conducted research that will generate scientific data. Applicants must submit the DMS Plan at the time of application using the [NIH DMS Plan Format Page \(https://grants.nih.gov/grants-process/write-application/forms-directory/data-management-and-sharing-plan-format-page\)](https://grants.nih.gov/grants-process/write-application/forms-directory/data-management-and-sharing-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. The Data Management and Sharing (DMS) Plan must be provided in the Overall component.

### 4. Reporting

- When multiple years are involved, recipients 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 Section 8.4.1 Reporting \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82419\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82419). To learn more about post-award monitoring and reporting, see the NIH Grants & Funding website, see [Post-Award Monitoring and Reporting \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82428\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82428).

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 Section 8.6 Closeout \(https://grants.nih.gov/grants/policy/nihgps/html5/section\\_8/8.6\\_closeout.htm\)](https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.6_closeout.htm). NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 2 CFR Part 200.301.

## 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 \(https://www.era.nih.gov/need-help\)](https://www.era.nih.gov/need-help) - Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues.

[Grants.gov Support Center \(https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fgrants.gov%2Fsupport&data=05%7C02%7Cantoinette.caliman%40nih.gov%7Caf6dde64d644478d4e8b08dde6700581%7C14b77578977342d58507251ca2dc2b\)](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fgrants.gov%2Fsupport&data=05%7C02%7Cantoinette.caliman%40nih.gov%7Caf6dde64d644478d4e8b08dde6700581%7C14b77578977342d58507251ca2dc2b)

- Questions regarding Grants.gov registration and services (e.g., Workspace, subscriptions).

### Scientific/Research Contact(s)

National Institute of Allergy and Infectious Diseases (NIAID)

Email: [NIAID\\_P01\\_NOFO@mail.nih.gov \(mailto:NIAID\\_P01\\_NOFO@mail.nih.gov\)](mailto:NIAID_P01_NOFO@mail.nih.gov)

### Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

### Financial/Grants Management Contact(s)

National Institute of Allergy and Infectious Diseases (NIAID)

Email: [NIAIDFinancial-GrantsContact@mail.nih.gov](mailto:NIAIDFinancial-GrantsContact@mail.nih.gov) (<mailto:NIAIDFinancial-GrantsContact@mail.nih.gov>)

## Section VIII. Other Information

Recently issued trans-NIH [policy notices](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) ([http://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) ([http://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) ([http://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 2 CFR Part 200.